08/27/07
NYS Department of Health Monitoring of Early Intervention and Other Programs and to Review Provider Applications for the Early Intervention Program
RFP (#0509300249)

New York State Department of Health
Division of Family Health

REQUEST FOR PROPOSALS, RFP No. 0509300249: To Conduct Monitoring Activities for Early Intervention and Other Programs and to Review Early Intervention Provider Applications

IMPORTANT DATES:

A. RFP Issued	August 27, 2007
B. Written Question Deadline	September 12, 2007
C. Letter of Intent to Bid Deadline	September 19, 2007
D. Registration for Bidders' Conference Due	September 19, 2007
E. Bidders' Conference	September 24, 2007
F. Responses to Questions	October 10, 2007
G. Proposal Submission Deadline	October 24, 2007
H. Contractor Selection	December 5, 2007
I. Begin Project	February 1, 2008

Designated Contacts:

Pursuant to State Finance Law §§ 139-j and 139-k,the Department of Health identifies the following designated contacts to whom all communications attempting to influence this procurement must be made:

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Wendy Shaw, New York State Department of Health, Bureau of Women's Health, Room 1805, Corning Tower, Empire State Plaza, Albany, New York

PERMISSIBLE SUBJECT MATTER CONTACTS:

Pursuant to State Finance Law § 139-j(3)(a), the Department of Health also identifies the following allowable contacts for communications related to the following subjects:

Submission of written proposals or bids: Margaret Dennin, New York State Department of Health, Bureau of Early Intervention, Room 287, Corning Tower, Empire State Plaza, Albany, New York, 12237-0660.

Submission of Written Questions: Margaret Dennin, New York State Department of Health, Bureau of Early Intervention, Room 287, Corning Tower, Empire State Plaza, Albany, New York, 12237-0660.

Participation in the Pre-Bid Conference: Margaret Dennin, New York State Department of Health, Bureau of Early Intervention, Room 287, Corning Tower, Empire State Plaza, Albany, New York, 12237-0660.

Debriefings: Wendy Shaw, Bureau of Women's Health, New York State Department of Health, Bureau of Women's Health, Room 1805, Corning Tower, Empire State Plaza, Albany, NY 12237-0621, or Terry Ayers, New York State Department of Health, Bureau of Early Intervention, Room 287, Corning Tower, Empire State Plaza, Albany New York 12237-0660.

Negotiation of Contract Terms after Award: Wendy Shaw, Bureau of Women's Health, New York State Department of Health, Bureau of Women's Health, Room 1805, Corning Tower, Empire State Plaza, Albany, NY 12237-0621, or Terry Ayers, New York State Department of Health, Bureau of Early Intervention, Room 287, Corning Tower, Empire State Plaza, Albany New York 12237-0660.

For further information regarding these statutory provisions, see the Lobbying Statute summary in Section V, T of this solicitation.

REQUEST FOR PROPOSALS (RFP)

To Conduct Monitoring Activities of Early Intervention and other Programs and Review Provider Applications For the NYS Early Intervention Program

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REQUEST FOR PROPOSALS (RFP)

Monitoring and Quality Improvement: To Conduct Monitoring Activities and Review Provider Applications, Essential Components of the NYS Early Intervention Program Quality Improvement Initiative and Other Programs

I. INTRODUCTION

Monitoring of programs is an integral part of improving the efficacy of activities and services performed. Monitoring helps not only to ensure that required services are being delivered and delivered appropriately, but that the quality of services is maximized. Further, monitoring enables improvement in the quality of services by identifying opportunities for improvement. This RFP has two basic components: the first and largest component of this RFP is for monitoring, quality improvement, and review of provider applications for the Early Intervention Program (EIP). **All proposals in response to this RFP must address both components, the EIP component and Optional Component.** The "Optional" component expands the monitoring component to other Department of Health funded programs that have a strong clinical focus and requests a per diem rate for monitoring of such programs. All proposals in response to this second component must conduct monitoring activities for clinical programs identified by the Department such as School-Based Health Centers, the Prenatal Care Assistance Program and Family Planning Program. "Optional" means that the Department will have the option of rejecting bids, reducing the number of programs to be reviewed or the number of site visits per program or negotiating the start up of monitoring activities if projected costs exceed available funds**. No proposals will be accepted from bidders who do not submit a proposal for both components.**

The Department will award one contract for both components. It is the Department's intent to implement the EIP component at the time of award, subject to availability of funds; however, the Optional component will be implemented at the discretion of the Department anytime during the life of the contract period. The Optional component shall not commence until the contractor has been instructed to do so by the Department.

A. Quality Improvement Requirement

A federal requirement for state early intervention programs is the supervision and monitoring of local early intervention programs. One way the New York State Early Intervention Program (EIP) meets this requirement is through a statewide quality improvement initiative that includes monitoring providers that deliver early intervention services and municipalities, which are responsible for local implementation of the EIP, to ensure infants, toddlers and their families have access to timely, consistent and appropriate services and administrative processes while participating in the EIP.

A second way the EIP meets this requirement is through the early intervention provider approval process. Evaluators, service coordinators, and early intervention service providers must be approved by the Department of Health or other designated state agencies prior to contracting with municipalities or approved EI agencies to provide early intervention services.

The Optional component of this RFP will involve programs with a clinical focus that also require monitoring for quality improvement which has been handled up to now by regional program nurses and central office oversight. Due to a proliferation of programs without a concomitant increase in regional and central office resources, alternative arrangements to meeting the monitoring workload are being explored, and bids are being sought for handling a portion of the on-site monitoring via contractual arrangements with an organization that has the resources to conduct clinical and administrative reviews of a variety of clinically-focused programs.

B. Purpose of this Request For Proposals

The purpose of this document is to solicit proposals from organizations interested in bidding to monitor early intervention providers and approve early intervention provider applications for the New York State Department of Health's Early Intervention Program. The second component solicits proposals from organizations to bid to monitor, on a per diem basis, other Department of Health programs. One contract covering both components will be awarded for a five (5) year period.

The Optional component will be funded separately from the EI component. The initiation of monitoring activities related to this component will be negotiated with the contractor once the selection has been made and the contract is in place. The initiation and scope of the Optional component is dependent on the availability of funding. For the purposes of this RFP, bidders should submit bids using the information contained in the RFP.

The bidder will be requested to submit a bid for a set number of days of monitoring activities for the Optional component of this RFP. The Department will have the option of rejecting bids, reducing the number of programs to be reviewed or the number of site visits per program, or negotiating the start up of monitoring activities if projected costs exceed available funds. The Department reserves the right to seek a "best and final offer" from the selected bidder.

This document solicits proposals for the following three areas:

<u>Conduct Monitoring Activities for EI Agencies, Individuals and Municipalities</u> **-** Comprehensive monitoring of agencies and individuals who have delivered early intervention services, and municipalities, which are responsible for the local administration of the EIP. Monitoring activities will include:

- provider and municipal self assessments;

- provider and municipal input via mail surveys;
- site visit scheduling;
- onsite reviews (visits) following a standard protocol;
  - comprehensive routine reviews
  - focused reviews
- parent input via interviews and/or surveys;
- generation and distribution of reports of monitoring results;
- tracking of corrective action plans due, extensions, and resubmissions;
- corrective action plan review;
- development of draft corrective action plan responses to send to the Department;
- collection of monitoring data regarding reviews, corrective action plans, and compliance;
- development of computer generated management reports;
- clinical review of records of children with certain diagnosed conditions or certain service packages; and,
- ongoing communication with the Department relative to these activities.

Review Early Intervention Provider Applications **-** Review of applications for approval or reapproval submitted by agencies that intend to provide evaluations, service coordination and early intervention services under the Early Intervention Program and, at the Department's option if funding is available, review of applications for approval or reapproval submitted by individuals. Provider approval activities will include:

- assistance to applicants with obtaining and completing provider applications;
- provider application review;
- applicant character and competence review;
- data entry into database maintained by the Department ; and,
- completion of recommendation of approval.

Information gathered under this contract for the above two areas will be utilized to target and improve the Bureau of Early Intervention's future technical assistance, training, and other quality improvement activities.

Optional Monitoring Component for Selected Clinical Programs:

Activities will include the following:

- pre-site visit mailing and review of surveys to gather initial information;
- review of workplans, quarterly reports and other workplan deliverables, as appropriate;
- review of previous Statements of Deficiencies or site visit findings, plans of correction, and survey findings prior to the on-site visit;
- scheduling of visits at times acceptable to the contractor;
- on-site visits for review of administration (including fiscal component) and services provided;
- report write-up;
- review of plan of correction; and,
- follow-up as needed to ensure changes have been implemented (may require on-site visit).

This request for proposals contains specific eligibility criteria, project activities, and outlines anticipated awards. This RFP also provides guidance on specific elements that must be included for a proposal to be considered for funding. Instructions and provider application forms are contained herein.

C. Who Can Bid

1. For the Early Intervention Program Monitoring and Application Review Component:

Eligible organizations are existing public or private organizations, companies, partnerships, or corporations, which are legally authorized to perform the contracted services. Eligible organizations should have substantial expertise in quality improvement and utilization review and meet the following requirements:

- have experience with the coordination and support of a statewide quality improvement program (it is preferred that this experience includes assessment and evaluation of programs delivering developmental services to young children); and experience with review of credentials of professional individuals and agencies;

- demonstrate they can directly hire or subcontract, on a statewide basis, with qualified personnel as defined in Public Health Law, Section 2541, and individuals with expertise in quality improvement and utilization review in order to establish an administrative structure that will result in the achievement of the deliverables specified in the RFP;

- have knowledge of and/or experience related to the credentials and qualifications of early intervention providers;

- demonstrate they have the ability to develop, modify, and manage an electronic data system to capture, analyze and report on monitoring data;

- have knowledge of and/or experience related to New York State contracting and funding procedures; and,

- not be directly or indirectly involved in the provision of early intervention services in New York State and have no conflict of interest with respect to conducting the duties and responsibilities outlined in this RFP.

2. For the Optional Department of Health Program Monitoring Component:

- the bidder must be submitting a bid for the EI Program Monitoring Component;

- the bidder must demonstrate they can directly hire or subcontract with, on a statewide basis, individuals with expertise in the program areas being monitored [e.g., individuals with clinical expertise (MD, RN, PA, NP) in the provision of services under Title X for family planning, the provision of services under Section 85.40 of the 10NYCRR for Prenatal Care Assistance Program and in the provision of School Based Health services];

- the bidder must demonstrate they have the ability to develop, modify and manage a simple electronic data system developed specifically for the Optional programs to track the status of monitoring visits, reports and corrective action plans and other significant information as requested by the Department of Health; and,

- the bidder must not be a current contractor of the department for delivery of any of the monitored services (School Based Health, Prenatal Care Assistance Program, or Family Planning);

- not be directly or indirectly involved in the provision of the programs to be addressed through the Optional Component in New York State and have no conflict of interest with respect to conducting the duties and responsibilities outlined in this RFP.

II. BACKGROUND

The Early Intervention Program is New York State's implementation of Part C of the federal Individuals with Disabilities Education Act. The program provides a range of therapeutic and supportive services for eligible children with disabilities, ages birth through two years, and their families. The mission of the Early Intervention Program is "to identify and evaluate as early as possible those infants and toddlers whose healthy development is compromised and provide for appropriate intervention to improve child and family development."

Title II-A of Article 25 of the Public Health Law and Early Intervention Program regulations (http://www.health.state.ny.us/nysdoh/eip/index.htm) require the Department of Health to approve individuals and agencies as providers of evaluations, service coordination, and/or early intervention services. Providers complete an application for approval that is reviewed for character and competence of individual providers and the principals of agencies, for capacity to provide services in the catchment area requested and for compliance with laws and regulations.

In addition to approval of agency and individual provider initial proposals, the Department also requires that currently approved providers be reapproved on a periodic basis. The reapproval process also requires individual and agency providers to submit proposals for review. The Department has approved approximately 1,800 agency providers and 18,400 individual providers who applied to deliver early intervention services.

Additionally, Title II-A of Article 25 and regulations require that providers of early intervention services be monitored by their approving state early intervention service agencies. The Department currently has the responsibility for monitoring 57 local municipalities and New York City as local administrators of the Early Intervention Program. Of currently approved providers, approximately 700 agency and 1350 individual providers are or have recently been in contract with municipalities to deliver early intervention services. These contracted providers are the providers that will be monitored under this contract.

The monitoring of municipalities and contracted early intervention providers for regulatory compliance has been underway since June 2002 through a contract that is scheduled to end January 31, 2008. Approximately 1,300 individual providers, 600 agencies, and all 58 municipalities have received at least an initial comprehensive monitoring review. Approximately 550 individual providers and 250 agencies have received a second comprehensive monitoring review,; and 90 individual providers and 170 agencies have received focused reviews. As a result of these reviews, system generated monitoring reports with consistent findings language and customized statements of findings have been issued to municipalities and providers.

The other Optional program monitoring component of this RFP will involve conducting supplemental monitoring for several of the clinically-focused programs contracted by the Department of Health, such as the Family Planning Program, the School-Based Health Program, and the Prenatal Care Assistance Program. These programs provide key services to

low income individuals, primarily women of reproductive age, and children. Each program has established standards and monitoring practices.

III. DETAILED SPECIFICATIONS

A. Work Plan Activities For Early Intervention

For purposes of this RFP, the Department has established a target number of early intervention monitoring encounters, corrective action plan reviews, record reviews, and provider application reviews. The Department reserves the right to modify the mix of monitoring activities and/or provider application reviews using the pricing provided by the Bidder.

1. Deliverables for Early Intervention

The following section delineates the deliverables for the Early Intervention Program to be completed under this RFP. *The Department reserves the right to modify the schedule and mix of types of monitoring encounters and/or provider application reviews throughout the contract period using the pricing provided by the Bidder.*

a. Early Intervention Monitoring Reviews

i. Types

Comprehensive Early Intervention Monitoring Encounters - A completed comprehensive monitoring encounter is defined as a systematic review of a service provider site or municipality in accordance with NYS regulations and applicable state and federal laws. To complete comprehensive encounters the successful Contractor is expected to follow the attached protocols (Attachment D) and tools (Attachment F), and:

- in conjunction with the Department, develop a proposed monitoring schedule each quarter;
- conduct the pre-review, onsite, and post-review activities; and,
- release a system-generated monitoring report that allows for the insertion of customized findings language and comments.

Pre-review activities will include:

- developing a monthly monitoring schedule from the Department approved list of providers and list of municipalities;
- inviting municipalities in contract with providers scheduled to be monitored to attend the onsite monitoring review;

- confirming the visit with the municipalities and scheduled provider and sending pre-review materials to the scheduled provider and municipality, which include Self Assessment Tools, Onsite Visit Agenda, list of items to be available during the monitoring review process; distributing Parent and/or Provider and Municipal Surveys; and,

- determining, in collaboration with the Department, which and how many child records will be reviewed. The Department reserves the right to determine the final number of child records the contractor must examine during a comprehensive review. The Department will consider factors such as the size of the provider, number and type of children served, state and local monitoring, and fiscal audit history of the provider, etc. when determining the number of child records the contractor will be directed to review on site. Additional details about pre-review activities can be found in Attachment D.

The Contractor will use protocols and tools developed by the Department, which are included in Attachments D and F to conduct the onsite activities associated with comprehensive reviews of individual and agency providers delivering early intervention services, and of municipalities administering the program on the local level. The protocols and tools used during the onsite review allow for a review of child records, written policies and procedures, and interviews with staff and program managers to ascertain policies and practices. A team comprised of individuals with administrative expertise, and at least one individual meeting the definition of "qualified personnel" per Public Health Law, Section 2541, must conduct each monitoring encounter. When invited municipalities attend the onsite review, reviewers will coordinate onsite review activities with municipal representative(s). It is projected that completion of onsite activities, relative to a comprehensive monitoring visit, will take the monitoring team an <u>average</u> of:

- 3 days for a municipality
- 2 days for an agency provider, and
- .5 days for an individual provider.

Comprehensive agency monitoring encounters will occur at various provider sites where records and staff are accessible. Individual provider comprehensive monitoring encounters may occur at the provider's place of business (which may be his/her home) or an appropriate community location, as agreed to by the Department and the Contractor.

The Department reserves the right to request that certain comprehensive monitoring encounters of a provider or municipality will be performed within thirty (30) calendar days of the Department's request. These "priority" monitoring encounters must follow the same protocol as other comprehensive monitoring encounters and will not take more time, effort or resources than other comprehensive monitoring encounters of an agency or individual provider or a municipality. The Contractor will be paid the same rate for a priority monitoring encounter as for other comprehensive monitoring encounters. A priority monitoring encounter will count toward the agreed-upon target number of comprehensive monitoring encounters to be completed each operational year of the contract. Results of comprehensive monitoring

encounters will be shared with municipalities in contract with the monitored provider, per the protocols included in Attachment D.

Focused Early Intervention Monitoring Encounters – A focused monitoring encounter is defined as a systematic review of a provider or municipality that focuses on particular programmatic and/or administrative practices as identified by the Department. A focused monitoring encounter may utilize sections of the comprehensive monitoring tools (Attachment F) and may utilize additional or alternative questions determined by the Department, depending on the issues involved.

Focused encounters may be conducted to determine:

- the appropriateness and quality of the physical environment of a provider's facility that is currently used, or is proposed to be used, to deliver early intervention services;
- whether a provider/municipality has complied with the terms of a Corrective Action Plan;
- whether the provider/municipality has remediated previously identified health and safety and unqualified personnel issues;
- whether the provider/municipality has fiscal issues that warrant further review;
- the consistency and/or quality of provider practices when delivering services to children with certain diagnoses, or when delivering certain types of early intervention services; and
- other issues identified by the Department.

Direct observation of provider practices will be included during focused reviews conducted to determine the consistency and/or quality of provider practices when delivering services to children with certain diagnoses, or when delivering certain types of early intervention services. Therefore, the Bidder will have to demonstrate it will have the capacity to subcontract for specialist clinical consultant(s) to conduct these reviews (see Section III (A)(1)(a)(ii) of this RFP for information regarding the anticipated number of focused reviews that will include observations, and Section III (A)(2)(c)(vii) regarding qualifications of the specialist clinical consultants who will conduct these reviews).

The Contractor will be expected to:

- in conjunction with the Department, develop a monthly schedule for focused reviews;
- conduct required pre-review, onsite, and post-review activities; and,
- release a draft monitoring report to the Department.

To complete the focused monitoring encounters the Contractor is expected to follow a protocol developed and approved by the Department, which may be similar to the protocol found in Attachment E of this RFP. However, for certain focused reviews, the Department reserves the right to modify/enhance that protocol and tool and/or develop a new protocol and tool and/or format for reporting focused review findings to the Department.

ii. Early Intervention Monitoring Review Deliverables

In order to ensure there is no substantial lapse in current monitoring efforts, comprehensive and focused monitoring encounters must begin by month three of the first year of the contract. *Penalties may be imposed if monitoring encounters begin after this time and/or the agreed upon target number is not reached due to non-performance of the Contractor (see Section V (G)(1.) of this RFP).*

Monitoring Reports – For comprehensive and focused monitoring reviews, the Contractor will be responsible to produce standardized computer generated monitoring reports that utilize data gathered from the review, using formats approved by the Department. The reports sent to providers and municipalities will use standard and customized language approved by the Department to: describe the monitoring process; identify the indicators that met the standard; identify regulatory violations; and identify areas that need improvement. It is anticipated that most of the text of the reports will be generated from the electronic monitoring system, with the ability to insert customized language into each finding to describe the specifics of the problems identified by the reviewers or the Department. The system must calculate the numbers of records that were examined and associate the number of records with the appropriate findings statements. There may be instances where the monitoring report will contain wholly customized language as determined by the Department.

Monitoring reports for comprehensive reviews must be available for release to municipalities and providers that were reviewed, and municipalities in contract with the providers that were reviewed, within 45 days of the completion of the onsite review. There may be instances where reports are released after the 45-day timeframe due to additional research required by the Department. Monitoring reports for focused reviews must be available for release to the same entities within 30 days of the completion of the onsite review. Sample report templates for comprehensive and focused reviews are included in Attachment G of this RFP.

Target Number of Monitoring Reviews – The Contractor is expected to complete the following number of monitoring reviews:

- Each municipality would receive a comprehensive monitoring review approximately once every three (3) years. The target number of municipalities to be reviewed statewide every quarter is **5**;

- Each provider that has delivered services sometime during the past three (3) years would receive a comprehensive monitoring review approximately once every five (5) years. The

target number of agency providers statewide to receive a comprehensive routine review every quarter is **32**; the target number of individual providers statewide to receive a comprehensive routine review every quarter is **64**;

The purpose of focused reviews will be to monitor for CAP compliance, health and safety and unqualified personnel remediation, or for other reasons identified by the Department. The target number of providers to receive focused reviews each quarter is **44**. (Note: it is anticipated that 10 of the 44 focused reviews that will be conducted each quarter (approximately 40 per year) will involve direct observation of provider practices as described in Section III (A)(1)(a)(i) of this RFP). These must be conducted using specialist clinical consultants (see Section III (A)(2)(vi of this RFP).

The Department may determine which providers will be given priority and advise the Contractor of this information for scheduling purposes.

For the purposes of bid development, the Bid Detail Sheet (Attachment C-1) contains target numbers for each type of review. The Department cannot guarantee the number of monitoring encounters that will be available to the Contractor resulting from this RFP. The Department reserves the right to limit the number of encounters during any contract year.

b. Early Intervention Corrective Action Plan Reviews

The Contractor will be responsible for accepting and systematically tracking and screening all Corrective Action Plans (CAPs) received from municipalities and providers resulting from comprehensive and focused monitoring reviews. The Contractor will review and develop draft responses to all provider CAPs, as described in the protocols in Attachments D and E, and is responsible to send draft provider CAP responses to the Department. Finalized CAP responses will be issued by the Department.

When a provider or municipal report requires a CAP, the Contractor will be required to:

- receive and track all CAPs;
- grant extensions under circumstances defined by the Department;
- screen all CAPs to ensure essential components are included;
- follow-up all CAPs when not received or essential components are missing;
- within 7 days of the screen, send all municipal CAPs which were screened and determined to be complete, with relevant correspondence, to the Department to review;
- within 45 days after provider CAPs are screened and determined to be complete, the Contractor will follow the protocol in Attachments D and E and review all provider CAPs

(with enclosures and materials submitted), develop appropriate draft CAP responses (in a format determined by the Department), and send to the Department.

The Contractor will provide technical assistance to providers to assist with development of CAPs. When provider CAPs involve serious health and safety practice issues, unqualified personnel findings or other unusual circumstances that the Department identifies, the Department will work closely with the Contractor so the Contractor will develop appropriate CAP responses to the unique situations. It is anticipated that no more than 15% of all CAPs will fall into this category.

For bidding purposes, it should be assumed that approximately 70% of comprehensive provider reviews will result in submission of a CAP and approximately 55% of focused reviews will result in submission of a CAP. See Attachment C-1, Bid Detail Sheet, for bidding numbers. The Department cannot guarantee the number of CAPs that will be available to the Contractor resulting from this RFP. The Department reserves the right to limit the number of CAPs processed during any contract year.

c. Early Intervention Clinical Record Reviews

The Contractor will be required to have the capacity to subcontract for specialist consultant(s) to conduct periodic clinical record reviews of clinical practices utilized in evaluation and service delivery for young children with certain diagnosed conditions and/or for young children receiving certain service packages as identified by the Department. The Department will provide clinical record review protocols based on the type of record review to be conducted. A sample protocol used for the clinical record review of autism and pervasive developmental disorder (PDD) is included in Attachment H. Protocols will identify the objective of the review; prescribe the sampling methodology to be used; delineate the discrete activities to occur pre-review and onsite during the review; identify the required educational and/or experiential qualifications reviewers must have; and, prescribe the format for compilation and submission of findings to the Department. The Contractor will be responsible for developing appropriate tools based on the Department's Clinical Practice Guidelines. A sample data collection tool, used for the clinical record review of autism/PPD records, is included in Attachment I. The Department will approve final tools the Contractor will use to capture data and report results for the clinical record reviews. Timelines for the reviews and data submissions will be defined by the Department.

Clinical record reviews of children with certain diagnoses or service packages will consist of a target number of records and begin at a time agreed to between the successful contractor and the Department. It is anticipated that at least one condition or service package per contract year will be reviewed and the protocol will be of comparable size and scope of the autism/PDD reviews completed under the current monitoring contract, which was approximately 200 per year. Protocols, tools, sampling methodology and report formats to be used during clinical record reviews may be developed by the Contractor in collaboration with the Department; however, the Department will approve all materials used in the clinical record review process.

d. Maintain Early Intervention Monitoring Application and Store Early Intervention Monitoring Data

The Department will make available its existing monitoring data application and associated database to the successful contractor. The Contractor will be responsible for providing all hardware and equipment to support and maintain the monitoring data application and to collect and maintain monitoring data.

The existing data application performs the following functions:

- allows for the collection of data during monitoring encounters using laptops provided by the Contractor;
- calculates the number of records examined and findings (as defined by the Department) associated with those records for each monitoring encounter;
- electronically captures notes made by monitoring team members on laptop computers while conducting reviews;
- prints provider and municipal computer generated monitoring reports (see Attachment G) that contain:
    - a standardized narrative explaining the monitoring process;
    - instructions about how to submit a Corrective Action Plan, if appropriate;
    - standardized phrases, based on system calculations, that explain how many indicators in each cluster area met all Early Intervention Program requirements;
    - standardized phrases, based on system calculations and type of findings, that explain which indicators/findings in each cluster area did not meet Early Intervention Program requirements and are considered regulatory citations or areas needing improvement, according to Department-defined standards;
    - standardized phrases that can be customized, describing specific issues and problems identified during the monitoring review, or by the Department, that resulted in a finding; and,
    - customized comments relating to provider practices as identified by the Contractor during the review or by the Department.
- captures and tracks data so the Contractor can periodically report to the Department the status of various monitoring events, documents and products, on a schedule determined by the Department;

- assists with monitoring encounter scheduling for the Contractor;

- allows Department staff to directly access, view and print monitoring reports from Contractor's system; and,

- maintains confidentiality of information and security of the data exchanged among the various Contractor sites and the Department, according to Department standards.

The successful Contractor will assume the current monitoring application and associated database. The Contractor will be responsible for establishing a Virtual Private Network (VPN) to access the Department's Provider database. The VPN must be developed in accordance with the Department's standards. The Contractor will be responsible for supplying the hardware to collect and manage the monitoring data.

i. Modifications to the Early Intervention Data Application

During the first three years of the current monitoring contract, the Department made necessary adjustments to monitoring tools and criteria based on clarifications or new or revised program requirements. The Department requires that the Contractor complete modifications to the current application. These modifications will include, but not be limited to:

- improving the capability for Department staff to directly access monitoring data "on demand" by developing the capability to produce ad hoc management reports in a secure environment. Department staff will determine the content and format of these ad hoc reports by selecting chosen data fields. It is anticipated most reports will be in Microsoft Excel formats;

- ensuring that the monitoring data application and associated database can be linked to the NYS Early Intervention System data system (NYEIS);

- adding or deleting tool indicators with corresponding report statements, and changing the corresponding calculations, as approved by the Department;

- using parameters defined by the Department, adjusting the calculation function to distinguish between "met," "needs improvement" and "regulatory finding" and to print out appropriate corresponding text for additional or revised report statements;

- developing the capability to maintain old data when indicators are no longer used and/or new indicators are added;

- maintaining the capability to link old data, as appropriate, to related new data for purposes of trend analysis;

- developing the capability to search text for selected phrases and key words in selected individual or groups of monitoring reports;

- developing the capability for the application to produce monitoring reports, in a format defined by the Department, for focused monitoring and clinical reviews;

- creating the ability to add/delete data captured during clinical record reviews; and,

- developing the capability for the application to produce reports, in a format defined by the Department, for clinical record reviews.

Due to the limitations of the current electronic monitoring application, the following significant modifications must be completed by the Contractor.

- addition of new key indicators and subindicators with corresponding criteria, identified by the Department;

- on demand report capability for the Department;

- deletion of indicators identified by the Department;

- creation of the ability to add/delete data captured during clinical record reviews; and,

- creation of reports for clinical record reviews.

The Contractor must guarantee that the remaining significant modifications to the system will be completed to the Department's satisfaction.

ii. Maintenance of the Early Intervention Data Application

The Contractor will be expected to work with the Department, throughout the life of the contract, to adjust and improve the data application based on clarifications and new or revised program requirements. Programming for these adjustments, as well as programming that will allow the application to continue to operate in an effective and timely manner, will be considered "ongoing maintenance." "Ongoing maintenance" of the electronic monitoring data application is defined as all activities involved in programming or adjusting for ongoing changes/clarifications of EIP requirements and keeping the application in good working order, including any routine adjustments required to correct faults, improve performance or other attributes (e.g. new functions, faster, or more compatible with other systems), or to otherwise adapt the application to meet the Department's needs. Routine adjustments will include, but not be limited to:

- continued addition and/or deletion of new key and/or subindicators with corresponding criteria as determined by the Department;

- production of management reports, the content and format determined by the Department, which are directly accessible to Department staff "on demand" (it is anticipated most of these reports will be weekly, monthly and quarterly statistics and lists of providers or municipalities with associated data reporting on completed contractual activities); and

- revision of the text, content and criteria of tool indicators and corresponding monitoring report statements as approved by the Department.

The above stated routine adjustments must be completed within ten business days upon written request (including email) of the Department.

- production of ad-hoc management reports, using data from the monitoring data application and associated database, the content and format determined by the Department, which may be needed for special projects, presentations and the like.

The above stated reports must be completed within two business days upon written request (including email) of the Department.

e. Conduct Early Intervention Provider Application Reviews

A completed review of an application for which payment is rendered is a systematic review of an application for approval as an early intervention evaluator, service provider and/or service coordinator in accordance with NYS regulations and applicable state and federal laws. The Contractor will conduct a comprehensive review of individual and agency applications for approval or reapproval to participate in the Early Intervention Program (Attachments J and K) using protocols developed by the Department (Attachment L). The Contractor will be responsible for processing applications, reviewing completed applications, and providing the Department with recommendations regarding approval of individual and agency providers.

The Contractor will be responsible for ensuring that individuals and agencies seeking approval and reapproval as early intervention providers will have access to and assistance in completing applications for approval or reapproval as early intervention providers. This will include establishing a telephone number for applicants to call to request application forms, maintaining an adequate supply of application forms for both individual and agency providers, and mailing application forms as requested. The Contractor will be responsible for the cost of printing a sufficient number of application forms to meet all requests, all costs associated with maintaining the telephone application request line and all costs for mailing requested application forms.

The Contractor will be responsible for notifying currently approved providers of the requirement for submitting applications for reapproval. Notification will occur on a schedule that is developed in conjunction with the Department. The Contractor will be responsible for mailing application forms and providing technical assistance to all providers required to submit applications for reapproval.

The Contractor must provide a mailing address to which completed applications will be sent. The Contractor will be responsible for receiving all paper applications. When on-line applications are available, the Contractor must have the capability to receive both electronic submissions and hard copy submissions.

The Contractor will provide technical assistance by telephone, e-mail or written correspondence to applicants to ensure that applications are completed appropriately and that all supporting documentation is submitted. This will include initial review of provider applications and returning incomplete or incorrect forms to the applicant with deficiencies noted (Attachment M).

The Department maintains a database of individual and agency providers. The database is under revision and will reside in an Oracle software application. The information on each application will be entered by the Contractor into the Provider database upon receipt of the application. After completion of the review, the database will be updated by the Contractor to reflect approval or denial.

The Contractor will be responsible for review of all applications for approval or reapproval that are deemed to be complete. For individuals, this review will include verification of the applicant's credentials through a review of databases maintained by licensing or certifying agencies. A review of the applicant's character is conducted through database checks for criminal history, civil actions or actions against professional license or certification and, verification of the applicant's experience through telephone contact and correspondence with employers. For agency applications, in addition to the overall review of the agency's qualifications, the Contractor will conduct credential and character reviews of the Program Director and officers of the agency. The list of databases to be checked is found in Attachment L.

Upon completion of the review of a provider's application documents, the Contractor will be responsible for submitting to the Department a completed Recommendation of Approval or Disapproval form (Attachment N) and a letter of approval or denial form. If the applicant is denied approval, all documentation supporting the grounds for denial must be submitted with the recommendation.

The Contractor will be responsible for mailing all letters of approval or denial to applicants and notifying, in writing, each municipality of providers approved or denied to provide services in the municipality. The Contractor will update the approval status of the provider in the Provider database.

Should the Department find it necessary to revise the application forms during the contract period; the Contractor will be expected to perform all application approval functions as described in this RFP utilizing the revised form(s).
It is projected that review of a completed agency application will take an average of three hours and the review of a completed individual provider application will take the reviewer approximately one hour. For the purposes of bid development, the bidder may assume that

325 agency applications will be reviewed each year. During the course of the contract period, the Department may require the Contractor to conduct reviews of individual providers. These applications will be reimbursed at one-third the bid price of agency provider applications. The Contractor should demonstrate in its proposal that, if requested by the Department, it has the ability to minimally process up to 1,500 individual application reviews annually. The Department reserves the right to require the Contractor to complete agency application reviews only at any time during the contract period. The Department cannot guarantee the number of provider applications that will be available to the Contractor resulting from this RFP. The Department reserves the right to limit the number of application reviews during any contract year.

f. Turnover

The successful Contractor will be expected to provide for an orderly and controlled turnover to either the Department or a successor Contractor at the end of the contract period, with minimum disruption of report generation, provision of monitoring reviews, or any other contract activity. At the end of the contract, the Contractor will turn over complete electronic monitoring data application and associated database, with title, leasing, or license rights to the Department, or at the Department's option, a successor Contractor. The Contractor shall similarly transfer to the Department or the successor Contractor all nonproprietary system software, data files, application programs and documentation. Additionally, the Contractor must turn over all written policies and procedures, training materials, validation tools, and any resources utilized in conducting monitoring reviews (e.g. checklists).

The bidder must include a plan in the proposal which specifies what will be turned over, how the successor Contractor will be trained in protocols and practices, and how delivery of the system specifics will be made to the successor Contractor.

2. Early Intervention Administrative Services & Supports

a. Reporting Serious Problems to the Department

Following procedures defined by the Department, the Contractor must immediately communicate to the Department any provider or municipal situations identified during monitoring that have potential for imminent danger for children and/or their families receiving services, or that may indicate inappropriate fiscal practices. These situations include, but are not limited to: poor, inadequate or dangerous health and safety practices, unsafe physical plant, unqualified personnel providing services, failure to screen appropriate staff through the State Central Register of Child Abuse and Maltreatment, duplicate billing, services billed but not delivered, services not delivered as described in the IFSP, etc. Any findings of this nature should be communicated by the Contractor to the Department in writing to include significant details of the findings within two business days of the monitoring review. The Contractor must also report findings of this nature immediately to the provider during the exit interview.

Also, the Contractor must immediately communicate to the Department certain provider or municipal situations identified during early intervention provider application review that have the potential to compromise the provider approval process. These situations include, but are not limited to: identification of unqualified personnel providing services, possible fraudulent documentation of credentials, providers operating out of compliance with federal, state or local laws or regulations, etc.

b. Required Meetings

The Project Manager must be available to meet with Department staff at least two days each month in the first year of the contract, and a minimum of one day each month thereafter, to coordinate and evaluate the progress of contract work products and resolve outstanding problems as identified by the Department. Other Contractor staff (direct or contracted) may be asked by the Department to attend these meetings when appropriate. At the Department's discretion, these meetings may occur by phone or in person in either Albany or another location as agreed to by the Department and Contractor.

The Contractor must convene at least four 1-day meetings in Albany, of the individuals conducting monitoring activities during the first year of the contract (at least quarterly), for the purpose of meeting with Department staff to review various aspects of contract monitoring or other activities. The Contractor must convene at least four 1-day meetings in Albany of the individuals conducting early intervention application reviews during the first year of the contract (at least quarterly), for the purpose of meeting with Department staff to review various aspects of application reviews or other activities. During the remaining term of the contract, the Contractor will convene at least two 1-day meetings each year in Albany of the staff conducting monitoring activities and early intervention application reviews.

The Contractor must be prepared to convene, at the Department's discretion, any relevant staff to answer questions and provide additional training to attend at least two meetings each year in Albany or another location is agreed to by the Department and contractor.

The Contractor is responsible for all costs associated with the meetings described above and the costs for attendees working on behalf of the Contractor.

In addition to the meetings described above, the Project Manager, the Monitoring and Application Coordinators, the Quality Assurance Specialist(s) and the Systems Manager must be available to participate in weekly conference calls with Department staff to report on and discuss work progress, clarify issues, respond to questions, request guidance, and discuss other pertinent related issues related to monitoring activities. The Project Manager must be available to participate in weekly conference calls with Department staff to report on and discuss work progress, resolve problems or clarify issues, respond to questions, request guidance, and discuss other pertinent contract-related issues.

c. Contractor Early Intervention Personnel

The key positions of Early Intervention Project Manager, Monitoring Coordinator, Application Coordinator, Systems Manager and Quality Assurance Specialists cannot be subcontracted out, nor may they be employed on a consultant basis. These positions must be filled by employees of the Contractor. See additional information regarding subcontracting in Section IV (B) (1) (a)(ii).

i. Project Manager

The successful contractor must designate a "Project Manager" who will be responsible for overall implementation and delivery of contract work products for the duration of the contract period. Preference will be given to those organizations with a Project Manager who has qualifications that include demonstrated knowledge of the Early Intervention Program and expertise in the areas of quality improvement, utilization review, and performance based monitoring, and familiarity with EIP provider qualifications, expertise in credential review, and training, and technical assistance. This person will ensure that all work conducted under the contract is performed according to Early Intervention Program policies and standards of performance. The Project Manager will be responsible for the overall quality, accuracy, and timeliness of contract work products and deliverables. In addition, the Project Manager will have responsibility for resolution of problems related to application reviews, oversight of data system development and maintenance conducted by direct or contracted staff. The Project Manager will also provide oversight of data report generation functions conducted by direct or contracted staff, to ensure the accuracy and quality of data reports produced, and to ensure the reports meet the needs of the State.

ii. Monitoring Coordinator

The Contractor must designate one FTE individual to serve as "Monitoring Coordinator." The Monitoring Coordinator will be located in the Capital District and will coordinate all (NYC metropolitan area and upstate) monitoring team activities.

The Monitoring Coordinator will be responsible for day-to-day implementation of contract deliverables and resolution of problems relating to monitoring encounter activities. S/he will coordinate scheduling, training, and other monitoring encounter activities that require a statewide approach.

The Monitoring Coordinator will be responsible for supervising the review teams that complete monitoring encounters of municipalities and agency and individual early intervention providers and ensuring that individuals conducting monitoring encounters:

- use approved monitoring tools and follow approved monitoring protocols;

- receive up-to-date information regarding revisions to the monitoring protocol and changes to the early intervention law, regulations, or Department policy and procedure;
- receive initial and ongoing training, including orientation and promotion of consistent implementation of the monitoring protocol, tools, and regulations;
- are observed while performing onsite activities;
- receive ongoing technical assistance when they have questions;
- are formally evaluated regarding the quality and quantity of their work on a regularly scheduled basis, including direct observation;
- produce high quality, accurate reports and documents;
- provide accurate and timely technical assistance;
- appropriately screen, review and recommend approval for corrective action plans; and,
- conduct themselves in a professional manner.

The Monitoring Coordinator will be the primary contact with the Department regarding day-to-day monitoring activities. S/he will work closely with the Department to successfully address any concerns about team member conduct, technical assistance, monitoring protocols, content of computer generated monitoring reports and recommendations regarding corrective action plans. The Monitoring Coordinator must have qualifications that include demonstrated knowledge of the Early Intervention Program and expertise in the areas of quality improvement, utilization review, and performance-based monitoring, training, and technical assistance.

iii. Early Intervention Provider Application Coordinator

The Contractor must designate one full-time employee as the Application Coordinator. The Application Coordinator must be located in the Capital District and will coordinate all application review activities. The Application Coordinator must have early intervention program experience. This experience may be as a provider of service or in the administration of the early intervention program in a local or state capacity. This individual will be responsible for day-to-day implementation of contract deliverables, including coordinating initial approval and reapproval application review activities, reapproval notification, and technical assistance. The Application Coordinator will train and supervise the Provider Application Reviewers; ensure that provider reapproval notification adheres to the schedule; ensure that reviewers comply with established procedures for application review and ensure that technical assistance provided to applicants is accurate and consistent with Department standards.

iv. Monitoring Quality Assurance Specialists

The Contractor must designate two FTE individuals to serve as "Quality Assurance Specialists." One Quality Assurance Specialist will be located in the New York City metropolitan area, and the other in the Capital District.

The Quality Assurance Specialists will assume primary responsibility for all validation and editing of the computer generated monitoring reports and corrective action plan-related correspondence. These individuals will work under the supervision of the Monitoring Coordinator and will work closely with the monitoring review teams, data system personnel, and Department staff to:

- clarify and resolve discrepancies and inconsistencies;
- correct errors prior to the issuance of monitoring reports and/or corrective action plan responses to providers and municipalities;
- review data reports generated by the Contractor for accuracy and ensure that the data reports are responsive to the questions raised by the Department;
- provide formal feedback to review teams regarding errors and problematic products needing corrections; and,
- meet with and provide periodic training to review teams to improve the quality of work products.

In addition, the Quality Assurance Specialists may assist with conducting comprehensive or focused monitoring encounters. The Quality Assurance Specialists must have demonstrated knowledge and/or experience with the Early Intervention Program and with administration and/or fiscal management; demonstrated knowledge and experience in quality improvement; and have excellent writing and editing skills.

v. Monitoring Assistants

The Contractor must arrange for two FTE Monitoring Assistants to work under the direction of the Monitoring Coordinator. These individuals will assist the Project Manager and Monitoring Coordinator and Quality Assurance Specialists with all activities involved in the scheduling and implementation of monitoring reviews and subsequent issuance of reports, screening and recommending approvals for CAPs, and CAP-related correspondence, and quality assurance activities.

vi. Teams to Conduct Statewide Early Intervention Monitoring Reviews

The Contractor must provide a sufficient number of individuals to comprise teams that will conduct simultaneous monitoring reviews throughout the state as described in this RFP. Each comprehensive review, and most focused monitoring reviews, will be conducted using a team of at least two individuals who meet the following qualifications:

- individuals must have had some training and/or experience in the administration and/or fiscal management of organizations providing health and human services, preferably to young children with developmental delays and their families (the Contractor may provide such training, after Departmental approval, and should be prepared to have that training prior to implementation);

- individuals must have demonstrated expertise in the area of quality improvement (e.g., utilization review, performance based monitoring, technical assistance); and,

- one of the team members must be recognized as qualified personnel by the Early Intervention Program, as defined in 10NYCRR Section 69-4.1(a-j), preferably with experience in the provision of developmental services/therapies to children ages birth to five years and their families. The Contractor will be responsible for verifying the currency of certification, registration and licensure of each team member at least every six months during the term of employment.

As indicated in Section III (A)(1)(a) of this RFP, certain focused reviews will include direct observation of provider practices when delivering services to children with certain diagnoses, or when delivering certain types of early intervention services. These particular focused reviews must be conducted by specialist clinical consultant(s). Therefore, the Bidder must demonstrate that, in addition to the statewide teams described above, it will have the capacity to subcontract for specialist clinical consultant(s) to conduct approximately 40 focused reviews annually that include direct observation of provider practices. The Department reserves the right to identify the required educational and/or experiential qualifications for these specialist clinical consultants; those qualifications will be consistent with the early intervention qualified personnel standards recognized by the Department.

Individuals conducting the monitoring encounters must demonstrate that there is not a conflict of interest with respect to the relationship with the provider(s) or municipalities being monitored. They cannot review any provider or municipality where they were contracted or employed, and they cannot review any municipality where they previously provided services.

vii. Clinicians to Complete Early Intervention Record Reviews

As indicated in Section III (A)(1)(c) of this RFP, the Contractor will be required to have the capacity to subcontract for specialist consultant(s) to conduct periodic clinical record reviews of clinical practices utilized in evaluation and service delivery for young children with certain

diagnosed conditions and/or for young children receiving certain service packages as identified by the Department. The successful contractor must ensure that consultants hired to work on this project have appropriate clinical credentials, demonstrated competence and expertise in evaluating and delivering services to very young children with diagnoses or services the Department identifies to examine, as well as, knowledge and background on the content of any of the Department's published Clinical Practice Guidelines.

viii. Early Intervention Data Manager

The Contractor must directly employ one "Data Manager" at least .3 FTE. This individual must be a high-level person within the organization who will be responsible to oversee the following data-related functions as they pertain to the monitoring application and database and the VPN:

- data management;
- application programming; and,
- data analysis.

The Data Manager must have qualifications that include demonstrated knowledge of the field of computer programming and systems analysis and expertise including, but not limited to, the design and implementation of data applications, the conduct of feasibility studies, development of program and application specifications, flowcharting, coding, development of test data, program and parallel testing, and post implementation follow-up.

The successful contractor may subcontract staff to perform application programming and/or report development and data analysis. The Data Manager will work closely with the Project Manager and Department staff to identify and resolve problems and deficiencies with respect to the electronic monitoring system and VPN. This individual will direct and coordinate the work of any Contractor staff or subcontractors, who improve, enhance and maintain the monitoring application or database.

Data Management functions include:

- ensuring the accuracy and timeliness of changes to the monitoring application;
- ensuring the quality of products produced by the monitoring application;
- providing the State with timely, understandable documentation regarding the monitoring application and database, contract products, and the VPN;
- collaborating directly with Department Early Intervention Program and/or Information Technology staff to ensure the monitoring application, database and VPN are meeting the needs of the Department; and,

- working directly with the Project Manager, Quality Assurance Specialists, and Monitoring Coordinator to ensure the monitoring application meets the needs of both the Contractor and the Department with respect to monitoring activities, reporting, data analysis activities, and with the Application Coordinator to ensure the VPN meets the needs of both the Contractor and the Department with respect to monitoring and application review activities.

Programming functions include:

- ensuring the VPN is completed in a timely manner and meets the needs of the Department and the Contractor;

- ensuring requested improvements, modifications, and changes to the existing monitoring application are completed in a timely manner and meet the needs of the Department and the Contractor; and,

- overseeing development of the capability for the Department to directly access monitoring and provider application data.

Data Analysis and reporting functions include:

- ensuring tracking systems for monitoring and application review events and products for the Department and Contractor are developed and implemented;

- providing routine and ad hoc reports that meet Department and Contractor's needs; and,

- working with the Project Manager, Monitoring Coordinator, Application Coordinator, Quality Assurance Specialists, and the Department to ensure data are appropriately and correctly collected and recorded; methodologies used to analyze data are accurate and correct; and, reports generated are accurate and timely.

ix. Early Intervention Provider Application Reviewers

The Contractor must provide for a sufficient number of individuals to complete initial reviews of all applications within three business days of date of receipt of the application and to provide telephone technical assistance to individuals requesting assistance with completion of applications for approval or reapproval. Technical assistance must be provided at the time of the request or no later than two business days from the time of the request.

The Contractor must provide for a sufficient number of individuals to complete reviews of fully completed provider applications within five business days of date of receipt of the completed application. It is assumed that individuals conducting application reviews do not have to be qualified personnel as recognized by the Early Intervention Program, although monitoring reviewers may also conduct application reviews.

x. Administrative Support

The selected contractor must provide other administrative support that will allow the Project Manager, Systems Manager, Monitoring Coordinator, Quality Assurance Specialists, and monitoring teams to complete monitoring project activities and application reviews in an efficient and timely manner. In addition, the Contractor must provide other administrative support that will allow the Application Coordinator and application reviewers to complete provider approval project activities in an efficient and timely manner. This support includes:

- secretarial services;
- data entry services;
- mass mailing capability;
- access to and use of overnight mail;
- access to and use of courier services;
- appropriate equipment, including cellular phones and laptop computers;
- local supervision and oversight; and
- adequate, secure storage.

The selected contractor is invited to add, at their own expense, professional support as necessary to complete the project requirements in a timely and accurate manner.

The Contractor must designate the location and hours of administrative services and provide a description of the facility and resources to be dedicated to this contract. If multiple sites will be used, a description of each site must be provided.

If the bidder has identified individuals to fill the following project management positions at the time the proposal is submitted, the Proposal Narrative should include the names of the individuals and their resumes should be appended to the proposal:

- Project Manager;
- Monitoring Coordinator;
- Application Coordinator;
- 2 Quality Assurance Specialists; and
- Data Manager.

d. Early Intervention Progress Reports

i. Weekly Reports

Monitoring: During each year of the contract, the Contractor will submit weekly reports on the numbers and status of completed monitoring reviews, reports, Corrective Action Plans, backlogs or other problems, and newly identified health and safety issues, unqualified personnel or fiscal issues or other issues as identified by the Department. The formats for these weekly statistical reports will be determined by the Department (most statistical reports will be an exchange of data in Excel spreadsheet formats).

Application Reviews: During each year of the contract, the Contractor will submit weekly reports containing the number of provider applications received, the number of technical assistance calls or letters responded to, the number and types of approvals and reapprovals processed, and any other information requested by the Department. The formats for these weekly statistical reports will be determined by the Department (most statistical reports will be an exchange of data in Excel spreadsheet formats).

ii. Monthly Reports

Monitoring: During the contract period, the Contractor will submit monthly statistical reports summarizing the numbers and types of activities related to monitoring completed during the previous month. The Contractor will also report any changes made to the monitoring data system and any other data or information requested by the Department in these reports. The Department reserves the right to determine the format and content of monthly statistical reports.

Application Reviews: During the contract period, the Contractor will submit monthly statistical reports summarizing the number and types of recommendations of provider approval and other activities completed during the previous month. The Contractor will also report progress made in achievement of deliverables, completed activities, status of incomplete activities and issues or problems that were encountered and resolved or are outstanding. The Department reserves the right to determine the format and content of monthly statistical reports.

iii. Quarterly Reports

Monitoring: During each contract period, the Contractor will submit three quarterly reports, each describing contract activities for the previous three-month period that includes quarterly statistical reports summarizing the numbers and types of activities related to monitoring completed during the previous quarter, changes made to the monitoring data system, progress made in achievement of deliverables, completed activities, status of incomplete activities, issues or problems that were encountered and resolved or are outstanding, and any other data or information requested by the Department. The Department reserves the right to determine the format and content of quarterly reports.

Application Reviews: During each contract period, the Contractor will submit three quarterly reports, each describing contract activities for the previous three-month period that includes quarterly statistical reports summarizing the number and types of recommendations of provider approval, progress made in achievement of deliverables, completed activities, status of incomplete activities and issues or problems that were encountered and resolved or are outstanding. The Department reserves the right to determine the format and content of monthly reports.

iv. Annual Reports

Monitoring: The Contractor will submit an annual report describing monitoring activities for the previous three-month period per the Quarterly Report requirements stated above, and which also summarizes monitoring-related activities completed during the previous twelve months.

Application Reviews: The Contractor will submit an annual report describing application review activities for the previous three-month period per the Quarterly Report requirements stated above, and which also summarizes application review-related activities completed during the previous twelve months.

v. Ad Hoc Reports

The Contractor will also report on any other data or information requested by the Department. All reports must be submitted in a format as determined by the Department.

3. Early Intervention Performance Standards

a. Monitoring Reviews

Reports released must be timely, free from errors in calculation, contain no typographical or grammatical errors, and be easily understood, with respect to findings and additional comments, by the reader. Payment may be withheld for reports not meeting Department standards, and such reports may have to be corrected and/or re-released before payment is issued, as determined by the Department.

b. Corrective Action Plan (CAP)

CAP responses must contain no typographical or grammatical errors, and be easily understood by the reader. Payment may be withheld for CAP responses not meeting Department standards, and such CAP responses may have to be corrected and/or re-released before payment is issued, as determined by the Department.

c. Clinical Record Review

Clinical record review findings must follow Department requirements and format, be free from data errors; contain no typographical errors, and be easily understood, with respect to findings, by the reader.

d. Monitoring Data Application

"Significant Modifications" of the monitoring application is defined as all activities involved in necessary programming to accommodate the changes and timelines described in Section III (A)(4)(a) of this RFP and the Bidder's proposal, which will be included as Appendix C of the contract. "Ongoing maintenance" of the monitoring application is defined as all programming to adjust and improve the application based on clarifications to and new revised program requirements and activities involved in keeping the application in good working order, including any modifications required to correct faults, improve performance or other attributes (e.g. new functions, faster, or more compatible with other systems), or to otherwise adapt the application to meet the Department's needs as described in Section III (A)(4)(b) of this RFP and the Bidder's proposal which will be included as Appendix C of the contract.

e. Early Intervention Provider Application Review

Recommendations for Approval submitted must document that all required review steps were completed, must be timely, accurate and free from typographical errors and must identify and contain the signature of the reviewer.

f. Administrative Services

Administrative services must be completed in a timely manner as described in Section III (A) (2) of this RFP and the Bidder's proposal which will be included as Appendix C of the contract.

Failure of the Contractor to meet the deliverables and performance standards of the contract may result in the Department withholding payment as specified in this RFP and/or may result in termination of the contract.

4. Early Intervention Schedule of Deliverables

a. Early Intervention Monitoring Products

Comprehensive and focused monitoring reports must be available for release within 45 days of the completion of the onsite review unless otherwise determined by the Department;

- corrective action plans (CAPs) must be screened, determined to be complete or requiring additional information, and a letter sent to the provider/municipality explaining problems, within 7 days of receipt;

- all monitoring-related activities must be entered into a tracking database within five business days;
- provider CAP responses must be mailed to the provider within 45 days of receipt of a CAP passing the initial screen;
- related monitoring correspondence and materials must be provided to the Department;
- clinical record review reports for all records subject to a particular record review project must be compiled and made available to the Department within 60 days of the completion of the review.

b. Early Intervention Provider Application Reviews

- Notification of reapproval to currently approved providers must begin within 90 days of the contract start date.
- Reapproval materials are mailed to currently approved providers not less than ninety days prior to the scheduled date for notification of reapproval.
- Application materials are mailed to new applicants within five days of date of request for application.
- Data entry of applications is completed within two days of receipt of application.
- Incomplete applications are returned to the applicant within three days of receipt of application.
- Responses to requests for technical assistance in completing applications are provided within two days of the date of the request.
- Recommendations of approval or disapproval are submitted within five days of receipt of fully completed applications.
- Notification of approval or disapproval to applicants and municipalities is provided within five days of Department approval.

c. Early Intervention Monitoring Application and Data

- the existing monitoring application and associated database obtained as a result of this contract must be fully operational within 60 days of the contract start date. It is expected that the Data Manager will demonstrate the necessary proficiency to implement the existing application and maintain the database within this time frame;

- the existing monitoring application and associated database must be modified during the first year of the contract per the timeframes described in Section III(A)(1)(d)(i)) of this RFP;

- ad hoc management reports must be available within 2 business days of the written request from the Department;

- addition of a new indicator identified by the Department must be completed within 10 business days of the written request from the Department;

- disabling an old indicator identified by the Department must be completed within 5 business days of the written request from the Department;

- revisions to the existing text and content of tools and corresponding report statements requested by the Department must be available within 10 business days of the written request from the Department;

- written requests may be sent via electronic mail; and

- the Virtual Private Network (VPN) established to access the provider database must be fully operational within 60 calendar days of the contract start date.

d. Early Intervention Progress Reports

- the weekly reports specified earlier in this RFP must be submitted no later than Wednesday of the following week;

- the monthly statistical reports specified earlier in this RFP must be submitted within 5 calendar days of the end of each month during each year of the contract;

- the three quarterly progress reports specified earlier in this RFP must be submitted within 30 calendar days of the end of the last month of each quarter during each year of the contract; and

- the annual report specified earlier in this RFP must be submitted within 30 calendar days of the end of each contract year.

5. What the New York State Early Intervention Program Will Provide

The Department will automatically provide the current monitoring application documentation, copies of the Department's "Report of the Recommendations" for all published clinical practice guidelines, and standards and specifications for the VPN to anyone who participates in the Bidders' Conference. This information will also be provided to any other potential bidders upon request.

B. Work Plan Activities for Optional Monitoring Component for Other Department of Health Programs

The Department is requesting monitoring for selected other programs. Monitoring visits could vary in length, dependent on a number of factors, such as complexity of the program, number of sites of service for a given contractor, number of sites visited, provider's level of compliance with program standards, etc. Due to the variability of these factors, bids are requested on a per diem basis, inclusive of all activities outlined in section I.B. above. In addition, one-time preparation time for monitoring tool revisions to meet contractor specifications and reduce subjectivity of reviews will be allowed. The bid should include the contractor's preparation time costs for the reviews, on a per program basis, as well as all post site visit follow up . The Department will have the option of reducing the number of programs to be reviewed if projected costs exceed available funds.

1. Deliverables for Optional Monitoring Component

The following section delineates the deliverables to be completed under this RFP. The Department reserves the right to modify the schedule and mix of types of monitoring encounters throughout the contract period using the pricing provided by the bidder.

a. Planning to Conduct Monitoring Reviews

All reviews conducted under this Optional section of the RFP will be program-specific monitoring reviews of Department programs with a significant clinical component. Three types of programs are envisioned as eligible for monitoring visits:

- Family Planning Program Reviews
- Prenatal Care Assistance Program (PCAP) Reviews
- School-Based Health Center Reviews

The protocols and monitoring tools currently used for program monitoring are program specific, and are tailored to the specific needs and requirements of each of these programs. Each monitoring tool contains a fiscal and administrative component as well as a clinical services component. It is expected that the monitoring contractor will work closely with the Department of Health and provider representatives to review and revise each of these current tools in order to make the reviews as objective as possible. The amount of funding required by the monitoring contractor to complete these revisions to the current program monitoring tools should be provided as a one-time flat fee in year one based on initial review of the tools provided in Attachments S-U and the total price must be included in the "Monitoring Tool Review" price in Attachment C-1 – Monitoring Bid Sheet.

b. Conduct Monitoring Reviews

Monitoring reviews are comprised of four components:

1. **Pre-review activities** – These include review of previous monitoring reports, workplans, quarterly reports and other program deliverables, mailing and review of pre-survey tools (if any), and scheduling of visits (in conformance with priorities assigned by the Department, and any other criteria the Department applies) at times acceptable to the facilities to be reviewed.

2. **On-site review** – This will include sending appropriately qualified and trained staff to the facility to assess the program's operation using the pre-approved review tool.

3. **Post-review activities** – After the on-site portion of the review is completed, the monitoring report is completed and sent to the facility reviewed within 30 days of the completion of the on-site visit, with a copy to the Department. The reports sent to providers will use standard and customized language approved by the Department to: describe the monitoring process; identify the indicators that met the standards; and identify indicators that did not meet the standards and areas in need for improvement. The Department should be consulted if there are any questions about the content of the report, or any major issues identified that may impact the ability of the facility to continue providing services in a safe and effective manner It is anticipated that initial reviews will require much more extensive collaboration with the Department than later reviews, as the reviewers' confidence in assessing provider responses grows.

4. **Follow-up site visit** – The contractor will receive and track all Corrective Action Plans (CAPs); grant extensions as agreed to by the Department; follow-up on all CAPs when not received or essential components are missing; and, within seven days of the contractor's receipt of the CAP, forward those CAPs to the Department after the CAP's preliminary review by the contractor that are determined to be complete. Follow-up related to the review and approval of a provider's CAP and ongoing technical assistance pursuant to the receipt of a monitoring report will be the responsibility of the Department's Regional Office staff. Where provider performance is assessed as being potentially problematic to continuation of the program, and/or there is a question of patient endangerment or non-implementation of a plan of correction, a return site visit to assess changes implemented may be scheduled and conducted by the contractor to assess compliance with the standards.

Conducting monitoring reviews is expected to comprise the bulk of costs. Site visits are estimated to take between 1-5 days on site. For ease of calculation, we are estimating an average of 3 on-site days per site visit, and 100 site visits required, for a total of 300 on-site

days annually. For the purpose of costs, approximately 60% of the on-site visits will occur downstate in the Hudson Valley, Long Island and New York City area of the state.

Bidders will be asked to supply a cost per on-site day, a cost of pre-site visit activities per provider (100 days) and a cost of post-review activities per provider (100 days), on average. These costs are expected to represent a reasonable average for such activities. Potential bidders should take into consideration the fact that these activities will become easier and less time consuming over the course of the contract, and provide an average cost that reflects these later savings.

The Department also reserves the right to change the number of visits reimbursable under the contract, depending on the availability of funds.

2. Administrative Services and Supports for Optional Monitoring Component

a. Reporting Serious Problems to the Department

Following procedures defined by the Department, the Contractor must immediately communicate to the Department any provider situations identified during monitoring that have potential for imminent health and safety issues including a potentially unsafe physical plant, or that may indicate inappropriate fiscal practices such as duplicate billing practices.

b. Required Meetings

The Project Manager must be available to meet with Department staff in Albany up to six days annually to coordinate and evaluate the progress of contract work products and resolve outstanding problems as identified by the Department. Other Contractor staff (direct or contracted) may be asked to attend these meetings when appropriate. At the Department's discretion, these meetings may occur by phone or in person.

The Contractor must convene up to four meetings in Albany annually of the individuals conducting monitoring activities during the first year of the contract for the purpose of meeting with Department staff to review various aspects of contract monitoring or other activities.

The Contractor must be prepared to convene, at the Department's discretion, any relevant staff to attend at least two meetings each year in Albany or the metropolitan New York City area as agreed to by the Department for the purpose of program planning, updates or training needs and technical assistance.

The Contractor is responsible for all costs associated with the meetings described above and the costs for attendees working on behalf of the Contractor.

In addition to the meetings described above, the Project Manager must be available to participate in periodic conference calls with Department staff to report on and discuss work

progress, clarify issues, respond to questions, request guidance, and discuss other pertinent related issues related to monitoring activities.

c. Contractor Personnel

The key position of Project Manager and Monitoring Coordinator cannot be subcontracted out, nor may they be employed on a consultant basis. This position must be filled by an employee of the Contractor. See additional information regarding subcontracting in Section IV (B)(1)(a)(ii).

i. Project Manager/Monitoring Coordinator

The successful contractor must designate a "Project Manager/Monitoring Coordinator" who will be responsible for overall implementation and delivery of contract work products for the duration of the contract period. Preference will be given to those organizations with a Project Manager/Monitoring Coordinator who has qualifications that include demonstrated knowledge of the Family Planning, Prenatal Care Assistance or School Based Health Center Programs and expertise in the areas of quality improvement, utilization review, and performance based monitoring and technical assistance.

This person will ensure that all work conducted under the contract is performed according to all monitored programs' policies, requirements and standards of performance. The Project Manager/Monitoring Coordinator will be responsible for the overall quality, accuracy, and timeliness of contract work products and deliverables. In addition, the Project Manager/Monitoring Coordinator will have responsibility for periodic quality assurance review of monitoring activities, report development and CAP reviews and responses and the simplified data tracking system.

The Project Manager/Monitoring Coordinator will be responsible for day-to-day implementation of contract deliverables and resolution of problems relating to monitoring encounter activities. S/he will coordinate scheduling, training, and other monitoring encounter activities that require a statewide approach.

The Project Manager/Monitoring Coordinator will also be responsible for supervising the review teams that complete monitoring of providers and ensuring that individuals conducting monitoring activities:

- use approved monitoring tools and follow approved monitoring protocols;
- receive up-to-date information regarding revisions to the monitoring protocol and changes to program policies, procedures or standards, or Department policy and procedure;
- receive initial and ongoing training, including orientation and promotion of consistent implementation of the monitoring protocol, tools, and standards;

- are observed while performing onsite activities;
- receive ongoing technical assistance when they have questions;
- are formally evaluated regarding the quality and quantity of their work on a regularly scheduled basis, including direct observation;
- produce high quality, accurate reports and documents;
- provide accurate and timely technical assistance;
- appropriately screen, review and recommend approval for corrective action plans; and,
- conduct themselves in a professional manner.

The Project Manager/Monitoring Coordinator will be the primary contact with the Department regarding day-to-day monitoring activities. S/he will work closely with the Department to successfully address any concerns about team member conduct, technical assistance, monitoring protocols, content of computer generated monitoring reports and recommendations regarding corrective action plans.

ii. Teams to Conduct Statewide Monitoring Reviews

The Contractor must provide a sufficient number of individuals to comprise teams that will conduct simultaneous monitoring reviews throughout the state as described in this RFP. Each on-site visit will be conducted using a team of at least two individuals who meet the following qualifications:

- individuals must have had some training and/or experience in the administration and/or fiscal management of organizations providing health and human services, preferably in Family Planning, Prenatal Care Assistance Program, and/or School Based Health Centers (the Contractor may provide such training, after Departmental approval, and should be prepared to have that training prior to implementation);
- individuals must have demonstrated expertise in the area of quality improvement (e.g. utilization review, performance based monitoring, technical assistance); and,
- one of the team members must possess work experience in the program area being monitored (e.g., individuals monitoring a Family Planning Program must have been either previously employed in a clinical capacity (RN, NP, MD, PA) in a Family Planning clinic and/or be thoroughly familiar with Title X requirements and have demonstrated ability to conduct chart reviews and bring a clinical perspective to these review; Prenatal Care Assistance Program, and School Based Health Centers must have analogous qualifications for those settings.

Individuals conducting the monitoring activities must demonstrate that there is not a conflict of interest with respect to the relationship with the provider(s) being monitored. They cannot review any provider where they were contracted or employed.

d. Optional Monitoring Component Progress Reports

i. Monthly Reports

Monitoring: During the contract period, the Contractor will submit the data tracking sheet to provide the status of monitoring activities.

ii. Quarterly Reports

Monitoring: During each contract period, the Contractor will submit three quarterly reports, each describing contract activities for the previous three-month period summarizing the numbers and types of activities related to monitoring completed during the previous quarter, progress made in achievement of deliverables, completed activities, status of incomplete activities, issues or problems that were encountered and resolved or are outstanding, and any other data or information requested by the Department. The Department reserves the right to determine the format and content of quarterly reports.

iii. Annual Reports

Monitoring: The Contractor will submit an annual report describing monitoring activities for the previous three-month period per the Quarterly Report requirements stated above, and which also summarizes monitoring-related activities completed during the previous twelve months.

iv. Ad Hoc Reports

The Contractor will also report on any other data or information requested by the Department. All reports must be submitted in a format as determined by the Department.

IV. PROPOSAL REQUIREMENTS

A. Review

The requirements established by this RFP for proposal content and format will be enforced in evaluating proposals. The bidder's compliance to the format prescribed herein, as well as the bidder's response to each specific requirement and question stated in the RFP will be considered during the evaluation process.

B. Part 1 - Technical Proposal

1. Proposal Narrative

a. For Early Intervention (Monitoring and Provider Applications) - use no more than 20 pages

In a clear and concise manner, the Bidder should provide a complete description of what activities are to be accomplished and under what circumstances. The Bidder must specify how the contract deliverables presented in the proposal will be delivered by direct staff and/or subcontractors.

The proposal should be typewritten on 8.5 x 11 inch paper, using 12 point font or larger, and double spaced not to exceed 20 pages.

i. Project Activities to Meet Deliverables

Activities must be responsive to the Department's monitoring and application approval initiatives stated in this RFP. Bidders should describe:

- what activities are to be accomplished and under what conditions;
- the nature and scope of the activities that lead to the successful completion of each deliverable; and,
- how the contract activities presented in the proposal will be delivered.

ii. Persons Responsible and Completion Dates

The Bidder must identify for both the Monitoring and Application review, by title (and name, if known), the individual(s) responsible to ensure work activities as described in the RFP are carried out. The responsible individual(s) must have appropriate authority to ensure successful completion of each major work activity. The Bidder must include a detailed timeline for the implementation of the work activities which includes beginning dates for each activity and the completion of major interim steps leading to the completion of each deliverable. Bidders should provide:

- a detailed timeline to meet the prescribed schedule of completing required activities in accordance with the deliverables outlined in Section III.A. of this RFP;
- personnel descriptions with the position/title for the person(s) responsible for each work plan activity. Bidders should identify individuals who will be responsible for certain project management positions, if known, as directed in Section III.(A) (2) (c). of this RFP; and

- fully describe any subcontracts the vendor intends to enter into for the performance of contract obligations. The key positions of Project Manager, Monitoring Coordinator, Application Coordinator, Data Manager and Quality Assurance Specialists, cannot be subcontracted. Prior written approval by the State shall be required for all subcontracts. All subcontracts shall be in writing and shall contain provisions which are functionally identical to, and consistent with, the provisions of this Agreement.

iii. Bidder Qualifications and References

The successful contractor(s) and/or its subcontractor(s) are required to have certain experience as described in Section I.C. of this RFP. Any vitae/resumes of proposed project management staff should be included as attachments to the proposal. With the Department's prior written approval, Contractors may make substitutions to key project personnel provided that the substitutes/replacements possess equal or greater qualifications. The Bidder should:

- describe how the bidder is an existing public or private organization, company, partnership or corporation which is legally authorized to perform the contracted services;

- describe how the bidder is qualified to bid by meeting all requirements of Section I.C. of this RFP; and

- include organization chart(s) describing where the project staff will be located and the reporting structure of key project staff as attachment(s) to the proposal.

b. For Optional Monitoring Component – Use no more than 20 pages

In a clear and concise manner, the Bidder must explain the manner in which it will approach this project, and the projected skills of staff to conduct the monitoring, in sufficient detail to ensure reviewers that there has been a significant commitment of thought to how this Optional program monitoring component would be conducted, if awarded. The Bidder must describe an organizational structure that will fully support statewide monitoring and describe a process and staff support to develop and implement a quality assurance component to ensure all monitoring activities are conducted, reports are written and CAPs reviewed in conformance with established program standards and procedures. The Bidder must specify how the contract deliverables presented in the proposal will be delivered by direct staff and/or subcontractors. The Bidder should also build into the cost up to six meetings annually in Albany with Department staff.

The proposal should be typewritten on 8.5 x 11 inch paper, using 12 point font or larger and double spaced not to exceed 20 pages.

i. Project Activities to Meet Deliverables

Activities must be responsive to the Department's monitoring and application approval initiatives stated in this RFP. Bidders should describe how the contract activities presented in the proposal will be delivered.

ii. Persons Responsible and Completion Dates

The Bidder must identify by title (and name, if known), the individual(s) responsible to ensure work activities as described in the RFP are carried out. Resumes should be included if staff are identified. The responsible individual(s) must have appropriate authority to ensure successful completion of each major work activity. The Bidder must include a detailed timeline for the implementation of the work activities which includes beginning dates for each activity and the completion of major interim steps leading to the completion of each deliverable. For the purposes of the development of this proposal, on-site monitoring activities must begin no later than the beginning of the second quarter of the contract year. (Once the award is made, the Department will negotiate the start date for monitoring activities related to the Optional component.) Bidders should provide:

- a detailed timeline to meet the prescribed schedule of completing required activities in accordance with the deliverables outlined in Section III.A. of this RFP;

- Personnel descriptions with the position/title for the person(s) responsible for each work plan activity. Bidders should identify individuals who will be responsible for certain project management positions, if known, as directed in Section III.(A)(2)(c). of this RFP; and

- Fully describe any subcontracts the vendor intends to enter into for the performance of contract obligations. Prior written approval by the State shall be required for all subcontracts. All subcontracts shall be in writing and shall contain provisions which are functionally identical to, and consistent with, the provisions of this Agreement.

iii. Bidder Qualifications and References

In order to be eligible to receive funding, bidders must submit proposals for both the Early Intervention component and the Optional component. For the Optional component, the Department will have the option of rejecting bids, reducing the number of programs to be reviewed or the number of site visits per program or negotiating the start up of monitoring activities if projected costs exceed available funds.

2. Bidder Information: Requirements and References

a. Vendor Responsibility Questionnaire

New York State Procurement Law requires that state agencies award contracts only to responsible vendors.

Attachment Q contains the "Vendor Responsibility Questionnaire" that all bidders must complete and submit with their proposal.

In addition to the questionnaire, bidders are required to provide the following with their proposal:

- Proof of financial stability in the form of audited financial statements, Dunn & Bradstreet Reports, etc.
- Department of State Registration.
- Certificate of Incorporation, together with any and all amendments thereto; Partnership Agreement; or other relevant business organizational documents, as applicable.
- N.Y.S. Dept of Taxation and Finance's Contractor Certification Form ST-220-CA.

b. References (required)

The bidder must provide a list of all direct federal, state or local governmental contracts for quality assurance-related activities it currently has or had during the past seven (7) years, as well as any indirect or sub-contractual contract work it performed where federal, state or local public funding was used. In each case, the governmental agency that provided oversight of the contract or funding should be listed, along with a brief description of the contracted work, the contract number, term of contract or dates of work, contract value, and the name of the contract manager and telephone number.

c. Assurances

By submitting a proposal in response to this RFP, the bidder assures that the following is true:

- the organization is able to fulfill all statewide requirements and has or will have adequate space and capacity to fulfill contract deliverables;
- the organization and its employees, subcontractors, consultants and volunteers will not be directly or indirectly involved in the provision of early intervention or optional component services while conducting the activities described in the proposal, and have no conflict of interest with respect to conducting the duties and responsibilities outlined in this RFP. The Department reserves the right to make a final determination regarding conflict of interest with respect to the Contractor's relationship with other providers or parties and the Contractor agrees to abide by this decision;
- the organization and its employees, subcontractors, consultants and volunteers will collaborate with the Department and its designees; and,
- the organization and its employees, subcontractors, consultants and volunteers will implement and maintain policies and procedures to assure the confidentiality of personally

identifiable data, information or records pertaining to children and families participating in the Early Intervention Program according to Section 69-4.17 of Early Intervention Program regulations and other applicable State and federal laws and regulations.

C. Part 2 - Cost Proposal

1. For Early Intervention

Complete the Bid Detail Sheet in Attachment C-1. The numbers used in the Bid Detail Sheets are provided for comparison and rating purposes and for setting targets and contract pricing. Payment will be based on the actual number of satisfactorily completed deliverables. The Department cannot guarantee the number of monitoring encounters, CAPs, clinical records or agency provider applications that will be processed by the Contractor resulting from this RFP. The Department reserves the right to limit the number of encounters and record and application reviews during any contract year.

Costs should be inclusive of all activities necessary to implement a successful contract based on the information included in this RFP.

2. For Optional Monitoring Component for Other Department of Health Programs

A separate Bid Detail Sheet (see Attachment C-2) must be completed for funding to conduct the Optional program monitoring component. The sheet should include the following:

- Preparation to monitor costs – based on review of the current monitoring forms in Attachments S, U, and W, a one-time flat rate for preparation to monitor should be provided, inclusive of all three programs.

- Daily cost of an on-site monitoring visit, inclusive of average travel costs. This should be multiplied by 300.

- Average cost of pre-site visit preparation. This should be multiplied by 100.

- Average cost of post-site visit activities (multiplied by 100), including compilation of report, preparation of correspondence, review of plan of correction, subsequent activities and/or correspondence to achieve an acceptable plan of correction, and potential need in rare instances to re-visit the site to ensure changes have been implemented.

- The best time costs for revisions to the monitoring review tools.

- Any administrative costs related to administrative staff overseeing monitoring activities, quality assurance staff and costs for travel to Albany for Department

meetings as required, up to six meetings in Albany annually. Administrative Services price may not exceed 10% of the grand total five year bid price.

The Department of Health reserves the right to change the anticipated number of sites to be monitored (increase or decrease) depending on availability of funding, or to remove components from the monitoring if too costly, such as pre-site visit preparations or post-visit activities.

D. Method of Award

1. For Early Intervention

At the discretion of the Department, all bids may be rejected. The evaluation of the bids will include, but not be limited to, the considerations described in this subsection.

The Department will accept proposals from a single organization or agency that will provide for the statewide administration (coordination, supervision, fiscal oversight, recruitment, training, information dissemination, and similar administrative duties) and delivery of the contract deliverables described in Section III.A. of this RFP. The entire state must be covered in each proposal.

During the evaluation process, the Department may require clarifying information from a Bidder for the purpose of assuring the Department's full understanding of the Bidder's responsiveness to the RFP requirements. This clarifying information must be submitted in writing in accordance with formats set forth in this RFP, and, if received by the due date set forth in the Department's request for clarification, will be included as a formal part of the Bidder's proposal.

Proposals deemed by the Department to be responsive to the Submission Requirements set forth in the RFP will be evaluated by the Department and may be assisted by other persons, as the Department deems appropriate. In order to award a contract, the Department will select the Bidder that submits the proposal that offers the best value. The best value basis means awarding the contract for services to the Bidder that optimizes quality, cost, and efficiency among all responsive and responsible Bidders.

The Department will use a combination of pass/fail and scored evaluation methods to rate Bidder's proposals on a best value basis. The Department will evaluate proposals using the following factors and weights:

Initial Screening	Pass/Fail
Technical Proposal	75 points
Cost Proposal	25 points
Total Possible Score	100 points

The Bidder's technical and cost proposal will be separately evaluated and scored as described below.

a. Initial Screening

The Bidder's proposal will receive an initial screening and evaluation to determine if RFP Administrative Requirements were met. The screening may result in either a passing or failing evaluation by the Department. The Department maintains sole discretion to determine whether the Bidder's proposal:

- Appears complete (by addressing all mandatory RFP requirements);
- Conforms to the format for proposals as prescribed by the RFP; and,
- Contains all required forms.

b. Technical Score

A Technical Evaluation Committee will evaluate and score each bidder's Technical Proposal (Part 1 of the bid) based on each bidder's ability to deliver the services described in this RFP. Up to 75 points will be awarded for the evaluation of the bidder's Technical Proposal. The highest scoring bidder will receive the full points available. The evaluation of the bidder's technical approach will be based on the proposal, responses to any clarifying questions, and corporate and personnel reference checks. Information from the Cost Proposal (Part 2 of the bid) or the evaluation of the Cost Proposal will not be available to the Technical Evaluation Committee during their evaluation.

*Detailed evaluation criteria will not be disclosed to bidders***.** The technical proposal will be evaluated based upon the following categories and point allocations:

Deliverables	30
Persons Responsible and Completion Dates	15
Bidder Qualifications and References	30
Total Points Available	75

The evaluation will be scored on a scale of zero (0) through and including five (5) by each evaluator. Scores are categorized as follows:

0	=	Non-responsive	3	=	Good
1	=	Poor	4	=	Very Good
2	=	Fair	5	=	Excellent

This score (0 through 5) is a Raw Score. Each evaluator's Raw Score will be added to all other evaluators' Raw Scores. The sum of evaluators' Raw Scores will be divided by the number of

evaluators, resulting in an Average Raw Score. The Average Raw Score will be multiplied by the corresponding Weight set by the Department. This will result in a Weighted Raw Score for each criterion. Weighted Raw Scores for each criterion will be added together and will result in a Total Weighted Raw Score for each proposal.

Up to 5 points may be deducted from the technical score if the proposal is not complete (e.g., sections are missing) and/or does not conform to the prescribed format described in section V. E. 1. of this RFP. Proposals will be normalized in descending order.

The technical raw scores will be normalized as follows: (X/Y)*Z [(X divided by Y)] times Z) where:

- X is Total Weighted Raw Score of proposal being scored;
- Y is Total Weighted Raw Score of highest scoring Technical proposal; and
- Z is Technical points available.

c. Cost Score

Each Bidder's Cost Proposal will be scored using the scale described below. Up to 25 points will be awarded for the evaluation of the Bidder's Cost Proposal. The lowest Bidder will receive the full points available.

Cost will be calculated as (A/B)*C [(A divided by B)] times C) where:

- A is Total Price of lowest price Cost proposal;
- B is Total Price of Cost proposal being scored; and,
- C is Cost points available.

2. For Optional Program Monitoring Component for Other Department of Health Programs

Proposals submitted in response to this component of the RFP will be scored in a fashion similar to the EI component, i.e., for responsiveness to the requirements set forth in the RFP.

E. Total Combined Score

To arrive at the Total Combined Score, the Department will combine the Bidder's Technical Score and Cost Score. The maximum score a Bidder can receive is 100 points.

Early Intervention=		Optional Component=	
Technical Score	up to 75 points	Technical Score	up to 75 points
Plus: Cost Score	up to 25 points	Plus: Cost Score	up to 25 points
Total Combined Score	up to 100 points	Total Combined Score	up to 100 points

Final Combined Score:

Early Intervention Total Combined Score X 0.75
Plus: Optional Component Total Combined Score X0.25

V. ADMINISTRATIVE REQUIREMENTS

A. Issuing Agency

This Request for Proposal (RFP) is a solicitation issued by the NYS Department of Health. The Department is responsible for the requirements specified herein and for the evaluation of all proposals.

B. Timeline of Relevant Events and Dates

A. RFP Issued	August 27, 2007
B. Written Question Deadline	September 12, 2007
C. Letter of Intent to Bid Deadline	September 19, 2007
D. Registration for Bidders' Conference Due	September 19, 2007
E. Bidders' Conference	September 24, 2007
F. Responses to Questions	October 10, 2007
G. Proposal Submission Deadline	October 24, 2007
H. Contractor Selection	December 5, 2007
I. Begin Project	February 1, 2008

C. Inquiries/RFP Questions and Answers

All requests for information pertinent to the preparation and submission of a proposal and to the procurement process shall be made through electronic mail (e-mail) to (**mmd03@health.state.ny.us**) with a cc to (**slj03@health.state.ny.us**) or through written correspondence to:

New York State Department of Health
Bureau of Early Intervention, Room 287
Corning Tower, Empire State Plaza
Albany, New York 12237-0657
Attn: Margaret Dennin

Such requests shall be received no later than the Written Question Deadline, which is 5:00 PM on September 12, 2007. No other Department employee is to be contacted regarding the RFP # 0509300249 procurement and/or process.

Except during the Bidders' Conference, no oral questions will be accepted. All questions concerning this RFP shall reference the pertinent RFP page number, section number, and paragraph. Questions shall be concisely stated and be numbered in sequential order. Responses to written questions and any updates/modifications to this RFP will be automatically provided to all Bidders who submit a Letter of Intent to Bid or who participate in the Bidders' Conference. Questions and answers, as well as any updates and/or modifications, will be

posted on the Department of Health's website at http://www.health.state.ny.us/funding/ by October 10, 2007

Prospective bidders should note that all clarifications and exceptions, including those relating to the terms and conditions of the contract, are to be raised by the date indicated above.

D. Letter of Intent to Bid and Non-Mandatory Bidders' Conference

1. Letter of Intent to Bid

The Letter of Intent to Bid should be received no later than September 19, 2007, at the address below or by fax to (518) 486-1090. The Department will acknowledge receipt of the letter. Changes to the Official Representative shall be made by mail only. Failure to submit a Letter of Intent to Bid will not preclude the submission of a proposal. A sample Letter of Intent to Bid is included as Attachment O.

2. Non-Mandatory Bidders' Conference

A non-mandatory Bidders' Conference will be held via conference call on September 24, 2007 from 1:00 p.m. to 4:00 p.m. In order to participate in the conference call, potential Bidders must register by completing and mailing the Intent to Attend Bidders' Conference form (Attachment O). Registered bidders will be contacted and receive instructions and the codes necessary to participate in the Bidders' Conference.

To ensure that adequate accommodations can be made for the number of participants, a maximum number of two (2) representatives from each prospective bidder will be permitted to participate in the conference call. Registration for the Bidders' Conference must be received by September 19, 2007, to the address below:

New York State Department of Health
Bureau of Early Intervention, Room 287
Corning Tower, Empire State Plaza
Albany, New York 12237-0657
Attn: Margaret Dennin

Specific questions relating to this RFP must be submitted in writing. Although oral questions will be permitted at the Bidders' Conference, answers may be deferred and included in the official answers and/or minutes of the Bidders' Conference. Only written answers distributed by the Department will be official. Questions and answers will be posted on the Department's website.

Although participation in the Bidders' Conference and/or submission of a Letter of Intent to Bid is not mandatory, only those prospective Bidders submitting a Letter of Intent to Bid or participating in the Bidders' Conference will automatically receive the written answers to questions and any/all addenda to this RFP.

E. Submission of Bid Proposal

1. Proposal Format

Proposals should be prepared simply and economically, providing a concise description of the Bidder's ability to meet the requirements of the RFP. The technical and cost proposals must be in separate, clearly marked envelopes (*no cost or pricing information should be submitted in a Bidder's technical proposal*) and identified as follows:

> **RFP#0509300249** Technical Proposal (includes both Early Intervention and Optional Program Monitoring as 2 distinct documents, up to 20 pages each).
> Name of Bidder
>
> **RFP#0509300249** Cost Proposal (includes both Early Intervention and Optional Program Monitoring as 2 distinct documents up to 20 pages each).
> Name of Bidder

To promote uniformity of preparation and to facilitate the review, the Technical Proposal(s) should be submitted on white paper and the pages should be consecutively numbered from 1 to the end for each proposal. The Department requires that the Technical Proposals adhere to the following criteria:

- proposal and appendices should be typewritten
- proposal and appendices should be on 8.5 by 11-inch paper;
- proposal and appendices should use 12-point font or larger;
- proposal narrative should be double-spaced; and,
- each proposal narrative should **not** exceed 20 pages in length. Illustrations, resumes, letters of support and any other required attachments are not considered part of the proposal narrative.

These requirements are made for the purpose of enabling the evaluators to adequately review the Technical Proposals. Proposals must be self-contained; no models, videotapes or Web site postings will be accepted. Illustrations that support the text should be simple and direct and should be reproducible in black and white; photographs (if appropriate) should be black and white.

The Bidder's technical and cost proposals must not be conditioned and/or contingent. This will result in disqualification of the proposal.

Proposals failing to provide all response requirements or failing to follow the prescribed format may be removed from consideration or points may be deducted when the proposal is rated.

2. Proposal Submission

Interested bidders should submit one original and four signed copies of both their Early Intervention and Optional Program Monitoring Bid Proposal not later than **4:00 PM, October 24, 2007** at which time they will be opened. No proposals will be accepted after that time. All proposals must have the detailed bid sheet(s) filled out in their entirety and the responsible individual for contract negotiation listed and signed by this individual. All evidence and documentation requested under Proposal Requirements should be provided at the time the proposal is submitted.

No proposal will be accepted by fax, electronic mail (e-mail) or telephone. Responses should be clearly marked RFP # 0509300249 and each must be in two distinct parts (technical and cost proposals) separately sealed and identified. The "Optional Program Monitoring" technical proposal should be submitted with the Early Intervention technical proposal. The "Optional Program Monitoring" cost proposal should be submitted with the Early Intervention cost proposal. For both categories, see Section V.E.1. of this RFP.

All proposals should be directed to:

New York State Department of Health
Bureau of Early Intervention
Corning Tower, Room 287
Albany, New York 12237-0657
Attn: Margaret Dennin

It is the bidder's responsibility to see that the Bid Proposal is delivered to Room 287 prior to the date and time of the bid due date. Late bids due to delay by postal or other carrier or not received in the Department's mail room in time for transmission to Room 287 by 4:00 PM, October 24, 2007 will not be considered. The bids will be opened at 4:00 PM October 24, 2007 in Room 287 Corning Tower, Albany, New York.

- the Bid Form must be filled out in its entirety;
- the responsible corporate officer for contract negotiation must be listed. This document must be signed by the responsible corporate officer;
- all evidence and documentation requested under Section IV, Proposal Requirements must be provided at the time the proposal is submitted.

Department staff may request to meet with some or all bidders in Albany, prior to Contractor selection, to provide an oral presentation. The purpose of the oral presentation would be to

clarify the bidder's proposal. The oral presentation will not be permitted as a means to change the content of the bidder's proposal. The Department is not responsible for any costs incurred by bidders prior to the issuance of a contract.

The Bidder's proposal shall remain in effect for 270 days from the last day to submit a proposal. However, a non-successful contractor may withdraw its proposal upon notice any time after the selection of the successful contractor, upon written notice to the Department. Bidders whose proposals have been rejected by the Department will be notified of such rejection.
If a Bidder's proposal includes another provider's product(s) and/or services, the Bidder shall be required to assume responsibility for those products and/or services as prime Contractor to the Department.

The successful contractor shall not assign, transfer, or convey the award, nor shall it assign, transfer, or convey the agreement entered into or any part thereof or any interest therein without the prior consent of the Department in writing.

F. Reserved Rights

The Department of Health reserves the right to:

- reject any or all proposals received in response to this RFP;
- waive or modify minor irregularities in proposal received after prior notification to the Bidder;
- adjust or correct cost or cost figures with the concurrence of Bidder if errors exist and can be documented to the satisfaction of the Department and the State Comptroller;
- negotiate with Bidders responding to this RFP within the requirements to serve the best interests of the State;
- eliminate mandatory requirements unmet by all offerers;
- if the Department of Health is unsuccessful in negotiating a contract with the selected vendor within an acceptable time frame, the Department of Health may begin contract negotiations with the next qualified Bidder(s) in order to serve and realize the best interests of the State..

G. Payment and Reporting

If awarded a contract the Contractor shall submit invoices to the State's designated payment office:

NYS Department of Health
Division of Family Health Fiscal Unit
Corning Tower, Room 878
Empire State Plaza
Albany NY 12237-0657

Payment of such invoices by the State (NYS Department of Health) shall be made in accordance with Article XI-A of the New York State Finance Law. Payment terms will be:

All invoices shall be submitted to the State on a quarterly basis no later than thirty (30) calendar days after the end date of the period for which payment is claimed. Payment of such invoices by the State (NYS Department of Health) shall be made in accordance with Article XI-A of the New York State Finance Law.

1. Early Intervention

In exchange for the provision of comprehensive and focused monitoring encounters, corrective action plan reviews, clinical record reviews, modifications and maintenance of the electronic monitoring data system and provider application reviews, in accordance with the terms and conditions specified in this Request for Proposals and the Department's protocol, and Optionally for services performed as part of the separate program monitoring component, the Contractor will be entitled to receive payment for each deliverable produced to the satisfaction of the Department. Such payment will be based upon the amount enumerated in the Bidder's Proposal, which will be incorporated into the resultant contract as Appendix C.

In order to be eligible for payment, the following information must accompany each invoice submitted by the Contractor. For ease of submission, reporting information may be combined into one quarterly or annual report with separate categories for each of the following areas:

- Monitoring Reviews (comprehensive and focused): a Quarterly Report or Annual Report (as appropriate), summarizing the monitoring review activities in the preceding quarter and contract year, respectively. This report must include a list of providers associated with the delivery of the comprehensive and focused monitoring encounters. The completion date of each review will be utilized to determine the price paid per monitoring review and also as a basis for determining the number of annual reviews completed in a contract year. A review will be considered eligible for 50% of the total payment when the onsite review is completed. The remaining 50% of the payment will be due when a computer generated monitoring report is released to the monitored entity. This report is due by the earlier of either 30 calendar days after the end of the quarter or the date which an invoice is submitted for payment.

- Corrective Action Plans (CAP): a Quarterly or Annual Report (as appropriate), summarizing the CAP activities in the preceding quarter and contract year, respectively. This report must include a list of providers associated with the draft CAP reviews completed. The completion

date of each CAP review will be utilized to determine the price paid per CAP review and also as a basis for determining the number of CAP reviews completed in a contract year. A review will be considered complete and eligible for payment when the CAP response is released to the provider by the Department per the established Department protocols. This report is due by the earlier of either 30 calendar days after the end of the quarter or the date which an invoice is submitted for payment.

- Clinical Record Reviews: a Quarterly or Annual Report (as appropriate), summarizing the record review activities in the preceding quarter and contract year, respectively. This report must include a summary of the status of the clinical record review project being undertaken during the preceding quarter or year (as appropriate). The completion date of each record reviewed will be utilized to determine the price paid per review and also as a basis for determining the number of annual reviews completed in a contract year. A review will be considered complete and eligible for payment when the review findings for all records that are the subject of a particular review are compiled and submitted to the Department in a manner satisfactory to the Department and according to the protocol. This report is due by the earlier of either 30 calendar days after the end of the quarter or the date which an invoice is submitted for payment.

- Provider Application Reviews: a Quarterly or Annual Report (as appropriate), summarizing the provider application review activities in the preceding quarter and contract year, respectively. This report must include a list of provider applications completed and the results of the review. The completion date of each Provider Application Review will be utilized to determine the price paid per review and also as a basis for determining the number of annual reviews completed in a contract year. A review will be considered complete and eligible for payment when a Recommendation of Approval or Disapproval is submitted to the Department with the application, all attachments, and the completed review forms. This report is due by the earlier of either 30 calendar days after the end of the quarter or the date which an invoice is submitted for payment. There shall be no price differential for reviews for approval or reviews for re-approval. Payment for reviews of individual provider applications shall be at a rate of 30% of the rate for reviews of agency provider applications. The Department reserves the right to modify the number and mix of reviews to be conducted by the Contractor.

- Modify Monitoring Application: A Quarterly or Annual Report (as appropriate), delineating the status of each task related to modifications of the monitoring application that have been completed and the tasks (modifications) in progress during the preceding quarter and accomplished throughout the contract year, respectively. The payment for this component of the contract will be paid quarterly, based on hours of modification completed during the quarter and according to the fee in the Contractor's proposal. If the Contractor fails, in the reasonable judgment of the State, to make the required modifications to the Early Intervention monitoring application, full or partial payment for this category may be withheld by the State until such time as the State reasonably determines that the application meets the needs of the State.

- Maintain Monitoring Application and Associated Database: The payment for this component of the contract will be paid quarterly based on hours of maintenance completed during the quarter and according to the fee in the Contractor's Proposal..

  A Quarterly or Annual Report will delineate the activities undertaken related to the ongoing maintenance of the monitoring application during the preceding quarter or contract year, as appropriate. "Ongoing maintenance" of the monitoring application and associated database is defined as all activities involved in keeping the application and database in good working order. The Quarterly or Annual Reports will reflect the status of these activities and the progress made during the preceding quarter. These Reports are due by the earlier of either 30 calendar days after the end of the quarter or the date which an invoice is submitted for payment.
  In addition to the above information, the Annual Report shall include the following documentation regarding the monitoring application:

  - application user and operation manuals;

  - identification of the operating system(s), version and release being used to operate the monitoring application and store the associated database;

  - lists of personnel employed/contracted to perform development/maintenance work on the monitoring application and associated database;

  - one copy of the following documentation:

    1. all software, including computer programs written and all subroutines called, executed, or otherwise used by the Early Intervention monitoring application and associated database;

    2. source code program listings, on paper, for all production programs;
    3. the job control language to operate the elements set forth in the three preceding clauses;

    4. file and record descriptions of all data files, including data elements, used by the Contractor in collecting data during monitoring encounters and producing reports;

    5. description of all manual procedures associated with the elements set forth in all preceding clauses of this Section; and,

    6. description of facilities and equipment related to the monitoring application and associated database.

    The Contractor shall provide the documentation required by this Section to the State as specified, unless the State, in its discretion, waives a particular submission. In the event

documentation is unavailable or incomplete, the Contractor shall report on the status of the unavailable or incomplete documentation, including a projected date for completion, and reason(s). All information and documentation must be in a form acceptable to and usable by the State. Delivery of information and documentation by the Contractor constitutes a material obligation of performance under this Agreement.

Payment Penalty. If at the end of any quarter during the contract period, the Contractor fails, in the reasonable judgment of the State, to properly maintain the Early Intervention monitoring application and associated database, full or partial payment for that category may be withheld by the State until such time as the State reasonably determines that the system meets the needs of the State.

Payment Penalty. Failure of the Contractor to submit the required documentation may result in a 10% penalty forfeiture of the monitoring application ongoing maintenance fee each quarter.

- Administrative Services: The Department will pay the Contractor an administrative services fee in four (4) equal quarterly payments annually based upon the administrative services fee enumerated in the Contractor's Proposal. The Administrative Services price may not exceed 10% of the grand total five year bid price.

  Payment Penalty. If, at the end of any contract operating year, the number of monitoring encounters, CAP reviews, and/or clinical record reviews and/or application reviews acceptable to the State is less than 80% of the target number agreed to under this contract, the Contractor's claim for the administrative services fee may be withheld by the State in an amount equal to the proportional percent of the target deliverables not completed up to 25%, whichever is less. If the Contractor desires to complete more monitoring activities or application reviews than the target number agreed to under this contract, at any time during the contract, they may do so only with the approval of the Department. Completing more monitoring activities or application reviews than the target number agreed to under this contract will not increase the administrative fee.

2. Optional Program Monitoring Component – Documentation will be specific to the charge category

- Preparation for monitoring – Documentation will include all modifications made to the monitoring tools, final versions of these tools, and records of approval of these tools by the Department of Health staff.

- Pre-site visit activities – Documentation will include pre-site visit surveys obtained and other documentation assembled prior to the on-site reviews, as well as summaries of these materials prepared prior to the site visit.

- On-site visit – Documentation will include the site visit report and cover letter sent to each of the providers documenting the areas in need of improvement.

- Post-visit activities – Documentation will include all correspondence to and from the providers about the plan of correction and documentation of any additional activities undertaken to ensure that the plans of correction were not only approved but implemented by the providers.

H. Review of Contract Deliverables

The State will review deliverables submitted by the Contractor, accept or reject those deliverables, and provide written comments and notice of deficiencies, if any, to the Contractor. The Contractor shall correct the deficiencies cited by the State and resubmit the deliverable for approval within ten business days of receipt of the State's comments, unless an extension is requested in writing by the Contractor and approved in writing by the State. In no event shall the Contractor be entitled to additional compensation to correct deficient deliverables. Nothing set forth herein with regard to the formal review process for deliverables shall preclude verbal comments by the State to the Contractor during that process.

I. Type and Term of Contract

It is the intention of the Department to award a five-year contract. This agreement shall be effective upon approval of the NYS Office of the State Comptroller. The anticipated start date of the contract is February 1, 2008

The Early Intervention Component of this contract will be funded in its entirety through the federal grant the Department receives from the U.S. Department of Education under Part C of the Individuals with Disabilities Education Act. The availability of funds is contingent on the availability of funds from the U.S. Department of Education and overall performance of the Contractor. In addition, the needs of the Department will be taken into account during implementation of the contract period.

The "Optional Component" will be funded, at the Department's discretion, using funds identified for this purpose.

The terms and conditions for the funded work products will be specified in a detailed contract, which must be signed by the Department and approved by the Office of the State Comptroller. The successful contractor will be sent a complete contract for execution.

This Agreement may be cancelled at any time by the Department giving to the Contractor not less than thirty calendar days written notice that on or after a date therein specified this agreement shall be deemed terminated and canceled.

J. Prime Contractor/Subcontractor Relationships

The successful firm shall be responsible to the Department as the Prime Contractor. All official communications to the Department concerning the statewide quality improvement initiative shall come from the Prime Contractor. All subcontracting and/or consulting arrangements and

contracts for the project require the Department's prior consent. The Department reserves the right to approve or disapprove certain key personnel to be assigned to the project. The Department requires the resumes of such personnel prior to their assignment to the project. The Prime Contractor is responsible for obtaining the Department's written approval of the key personnel to be assigned to the project prior to the assignment of such personnel. In addition, the Department reserves the right to withdraw such consent of key personnel assigned to the project in the event of unacceptable performance. The Prime Contractor shall take reasonable steps to ensure the continuity of key personnel throughout the project.

The Prime Contractor may make substitutions to key project personnel provided that the substitutes/replacements possess equal or greater qualifications and that the Prime Contractor obtains the Department's prior written approval. Where the Bidder's proposal includes the use of subcontractors or consultants, the proposal shall indicate which firm(s) possesses which qualification(s) as well as the major portion or portions of the proposed effort for which the subcontractor or consultant is responsible.

K. Non-Committal Clause

This RFP does not commit the Department to award a contract, pay any costs incurred in the preparation of a proposal in response to this RFP or for contract negotiations, or to procure or contract for any services or supplies. The Department reserves the right to accept or reject any or all proposals received as a result of this RFP, or to cancel this RFP, in part, or entirety, if the Department believes that it is in the best interest of the Department or the State of New York to do so, or if the federal government withdraws, or does not make available, sufficient funds.

L. State Ownership of Project Products

The State will maintain full ownership rights in the Early Intervention monitoring software, application and database, which the individuals conducting monitoring encounters will use to collect data during monitoring encounters. The Contractor understands and agrees that all computer programs, manual procedures, operating plans and procedures, documentation, data, records and related items arising out of or related to the Early Intervention Program (except for the Contractor's proprietary software or proprietary software leased by the Contractor with Department approval) are owned without qualification by the State, and that such ownership of these elements shall continue in and remain in the Department unimpaired during the term of, and subsequent to termination of, this Agreement. Any enhancements to, changes in, or augmentation or creation of any such elements during the term of this Agreement shall be owned by the State without qualification. It shall be a fundamental duty of the Contractor to ensure State ownership of such elements in such manner and at such times as herein provided. Such obligations by the Contractor and the rights of the State are not subject to limitation in any respect, by failure to claim for the cost thereof. In addition, to assure the continued integrity of the Early Intervention data collection system and compliance with this provision, the Contractor shall obtain prior written approval from the State for all Contractor-initiated changes, modifications and enhancements to the Early Intervention data collection

system and shall permit and facilitate, without restrictions, any access to the operating system required by the State. Such access shall not be utilized to disrupt Contractor operations.

In the event Contractor proprietary software utilities ("Programs") are utilized in the operation of the Early Intervention data collection system, the Contractor hereby grants to the State, at the end of the contract, a nonexclusive, royalty free license in perpetuity to use the Programs required to operate the Early Intervention data collection system subject to the following conditions:

- the Programs shall only be used by the State or the State's successor Contractor to operate the Early Intervention data collection system;

- at no time may the Programs or any of the related documentation be disclosed to third-parties (other than successor Early Intervention data collection system Contractors), sold, assigned, leased or otherwise disposed of, or commercially exploited or marketed in any way, with or without change;

- the State shall keep confidential the Programs and related documentation and will not permit them to be copied or reproduced, in whole or in part, by any person, firm or corporation, at any time;

- the State agrees not to remove or alter proprietary notices of the Contractor in the Programs or on any of the materials associated with the Programs;

- the State agrees to exercise all reasonable precautions to prevent access to all magnetic media and physical portions of the Program by persons not authorized to have such access; in any event, the State shall use at least the same degree of care in safeguarding such Programs as the State uses to protect its own proprietary information;

- the State agrees to notify the Contractor promptly of any circumstances where there is disclosed or unauthorized possession, use of knowledge of any portion of the Programs; and,

- the State will require that any third party entering into a contract with the State to operate the Early Intervention data collection system will execute an agreement with the Contractor incorporating the same covenants and conditions as contained in this Section.

In the event any resulting contract is terminated due to the failure of the Contractor to satisfactorily perform, the Contractor will transfer any software developed by the Contractor with contract funds or proposals purchased by the Contractor with contract funds to the State or successor Contractor at no cost to the State.

M. Scope of Work Alteration

In the event the State, through change in policy, regulation or law, alters the scope or level of required work or reallocates functions, which the State in its sole discretion may do at any time during the term of this Agreement, and thereby causes a substantial increase or decrease in the required effort of the Contractor, the parties will enter into good faith negotiations in order to reach agreement on the actions, if any, to be taken in order to achieve an equitable adjustment to the Agreement terms that will promote the parties' expectations and objectives in entering into this Agreement and not frustrate its fundamental purposes.

N. Retention of Proposals

All proposals submitted on time become the Department property. The Department will not return proposals that are received by the submission deadline. (The Department will return, unopened, proposals that are late.) The Department will make all reasonable efforts to maintain proposals in confidence during the evaluation process and will release proposals only to personnel involved with the evaluation of the project, subject to applicable law.

If a Bidder believes that any information in its proposal constitutes a trade secret and wishes such information not to be disclosed if requested by a member of the public pursuant to the Freedom of Information Law (FOIL), the Bidder shall submit with its proposal, a letter, specifically identifying by page number, line, or other appropriate designation, that information that is alleged to be a trade secret and explaining in detail why such information is allegedly a trade secret.

A Bidder's failure to submit with its proposal such a letter identifying alleged trade secrets is a waiver by the Bidder of any rights it may have under Section 89 (Subdivision 5) of the Public Officers Law relating to the protection of trade secrets.

In no event will the Department consider information to be a trade secret if that information is not the proprietary information or ideas of the Bidder and so designated in the proposal, or if that information:

- was known to the Department before submission of such proposal;
- properly became known to the Department thereafter through other sources; and/or
- is in the public domain.

O. Access to Premises

To assure compliance with this Agreement and for any other reason the State deems appropriate for the effective operation of the Early Intervention Program, Department staff and the Office of the State Comptroller, and their authorized representatives and designees, shall at all times have the right to enter into the Contractor's premises or such other place where duties under this Agreement are being performed, to inspect, monitor, or otherwise evaluate the work performed or to elicit information concerning the provision of Early Intervention Quality Improvement Monitoring Reviews and Application Reviews as well as the provision of Optional

Monitoring Reviews. The Contractor shall provide, and shall require any subcontractor to provide, all reasonable facilities, cooperation and assistance to such representatives or designees in the performance of their duties. All such instances of access shall be undertaken in such a manner as will not unduly disrupt the Contractor's operations or performance under this Agreement.

P. News Releases

All publicity or news releases pertaining to this RFP, or any organization within it, may be made only with the prior written approval of the Department.

Q. Bidders' Debriefing

Once an award has been made, bidders may request a debriefing of their proposal. Please note the debriefing will be limited only to the strengths and weaknesses of the bidder's proposal, and will not include any discussion of other proposals. Request must be received no latter than three months from the date of award announcement.

R. Records Retention

The Contractor agrees to preserve all Agreement-related records for the term this Agreement is in effect and for six (6) years thereafter. On or off-site archiving arrangements must be approved by the Department. Records involving matters in litigation shall be kept for a period of not less than three (3) years following the termination of the litigation. Microfilm copies or other approved electronic files archived of any Agreement-related documents may be substituted for the originals, provided that the microfilming procedures are accepted by the State as reliable and are supported by an adequate retrieval system.

S. **State Consultant Services Reporting**

Chapter 10 of the Laws of 2006 amended certain sections of State Finance Law and Civil Service Law to require disclosure of information regarding contracts for consulting services in New York State.

Winning bidders for procurements involving consultant services must complete a "State Consultant Services Form A (Attachment X), Contractor's Planned Employment From Contract Start Date through End of Contract Term" in order to be eligible for a contract.

Winning bidders must also agree to complete a "State Consultant Services Form B (Attachment Y), Contractor's Annual Employment Report" for each state fiscal year included in the resulting contract. This report must be submitted annually to the Department of Health, the Office of the State Comptroller, and Department of Civil Service. Both of these forms are included as attachments to this document.

T. **Lobbying Statute**

Chapter 1 of the Laws of 2005, as amended by Chapter 596 of the Laws of 2005, provides, among other things, the following as pertains to development of procurement contracts with governmental entities:

1. makes the lobbying law applicable to attempts to influence procurement contracts once the procurement process has been commenced by a state agency, unified court system, state legislature, public authority, certain industrial development agencies and local benefit corporations;
2. requires the above mentioned governmental entities to record all contacts made by lobbyists and contractors about a governmental procurement so that the public knows who is contacting governmental entities about procurements;
3. requires governmental entities to designate persons who generally may be the only staff contacted relative to the governmental procurement by that entity in a restricted period;
4. authorizes the Temporary State Commission on Lobbying to impose fines and penalties against persons/organizations engaging in impermissible contacts about a governmental procurement and provides for the debarment of repeat violators;
5. directs the Office of General Services to disclose and maintain a list of non-responsible bidders pursuant to this new law and those who have been debarred and publish such list on its website;
6. requires the timely disclosure of accurate and complete information from offerers with respect to determinations of non-responsibility and debarment;
7. expands the definition of lobbying to include attempts to influence gubernatorial or local Executive Orders, Tribal–State Agreements, and procurement contracts;
8. modifies the governance of the Temporary State Commission on lobbying;
9. provides that opinions of the Commission shall be binding only on the person to whom such opinion is rendered;
10. increases the monetary threshold which triggers a lobbyists obligations under the Lobbying Act from $2,000 to $5,000; and
11. establishes the Advisory Council on Procurement Lobbying.

Generally speaking, two related aspects of procurements were amended: (i) activities by the business and lobbying community seeking procurement contracts (through amendments to the Legislative Law) and (ii) activities involving governmental agencies establishing procurement contracts (through amendments to the State Finance Law).

Additionally, a new section 1-t was added to the Legislative Law establishing an Advisory Council on Procurement Lobbying (Advisory Council). This Advisory Council is authorized to establish the following model guidelines regarding the restrictions on contacts during the procurement process for use by governmental entities (see Legislative Law §1-t (e) and State Finance Law §139-j). In an effort to facilitate compliance by governmental entities, the Advisory Council has prepared model forms

and language that can be used to meet the obligations imposed by State Finance Law §139-k, Disclosure of Contacts and Responsibility of Offerers. Sections 139-j and 139-k are collectively referred to as "new State Finance Law."

It should be noted that while this Advisory Council is charged with the responsibility of providing advice to the New York Temporary State Commission on Lobbying (Lobbying Commission) regarding procurement lobbying, the Lobbying Commission retains full responsibility for the interpretation, administration and enforcement of the Lobbying Act established by Article 1-A of the Legislative Law (see Legislative Law §1-t (c) and §1-d). Accordingly, questions regarding the registration and operation of the Lobbying Act should be directed to the Lobbying Commission.

U. Accessibility of State Agency Web-based Intranet and Internet Information and Applications

Any web-based intranet and internet information and applications development, or programming delivered pursuant to the contract or procurement will comply with NYS Office for Technology Policy P04-002, "Accessibility of New York State Web-based Intranet and Internet Information and Applications", and NYS Mandatory Technology Standard S04-001, as such policy or standard may be amended, modified or superseded, which requires that state agency web-based intranet and internet information and applications are accessible to persons with disabilities. Web content must conform to NYS Mandatory Technology Standard S04-001, as determined by quality assurance testing. Such quality assurance testing will be conducted by Department of Health, contractor or other, and the results of such testing must be satisfactory to the Department of Health before web content will be considered a qualified deliverable under the contract or procurement.

V. Information Security Breach and Notification Act

Section 208 of the State Technology Law (STL) and Section 899-aa of the General Business Law (GBL) require that State entities and persons or businesses conducting business in New York who own or license computerized data which includes private information including an individual's unencrypted personal information plus one or more of the following: social security number, driver's license number or non-driver ID, account number, credit or debit card number plus security code, access code or password which permits access to an individual's financial account, must disclose to a New York resident when their private information was, or is reasonably believed to have been, acquired by a person without valid authorization. Notification of breach of that private information to all individuals affected or potentially affected must occur in the most expedient time possible without unreasonable delay, after measures are taken to determine the scope of the breach and to restore integrity; provided, however, that notification may be delayed if law enforcement determines that expedient notification would impede a criminal investigation. When notification is necessary, the State entity or person or business conducting business

in New York must also notify the following New York State agencies: the Attorney General, the Office of Cyber Security & Critical Infrastructure Coordination (CSCIC) and the Consumer Protection Board (CPB). Information relative to the law and the notification process is available at: http://www.cscic.state.ny.us/security/securitybreach/

W. New York State Tax Law Section 5-a

Section 5-a of the Tax Law, as amended, effective April 26, 2006, requires certain contractors awarded state contracts for commodities, services and technology valued at more than $100,000 to certify to the Department of Tax and Finance (DTF) that they are registered to collect New York State and local sales and compensating use taxes. The law applies to contracts where the total amount of such contractors' sales delivered into New York State are in excess of $300,000 for the four quarterly periods immediately preceding the quarterly period in which the certification is made, and with respect to any affiliates and subcontractors whose sales delivered into New York State exceeded $300,000 for the four quarterly periods immediately preceding the quarterly period in which the certification is made.

This law imposes upon certain contractors the obligation to certify whether or not the contractor, its affiliates, and its subcontractors are required to register to collect state sales and compensating use tax and contractors must certify to DTF that each affiliate and subcontractor exceeding such sales threshold is registered with DTF to collect New York State and local sales and compensating use taxes. The law prohibits the State Comptroller, or other approving agencies, from approving a contract awarded to an offerer meeting the registration requirements but who is not so registered in accordance with the law.

Contractor must complete and submit directly to the New York State Taxation and Finance, Contractor Certification Form ST-220-TD (Attachment Z) attached hereto. Unless the information upon which the ST-220-TD is based changes, this form only needs to be filed once with DTF. If the information changes for the contractor, its affiliate(s), or its subcontractor(s), a new form (ST-220-TD) must be filed with DTF.

Contractor must complete and submit to the Department of Health the form ST-220-CA (Attachment AA) attached hereto, certifying that the contractor filed the ST-220-TD with DTF. Failure to make either of these filings may render an offerer non-responsive and non-responsible. Offerers shall take the necessary steps to provide properly certified forms within a timely manner to ensure compliance with the law.

VI. APPENDICES

The following will be incorporated as appendices into any contract resulting from this RFP. This RFP will, itself, be referenced as an appendix of the contract:

- Appendix A Standard Clauses for All New York State Contracts

- Appendix B Request for Proposal (RFP)
- Appendix B-1 Bidders' Conference Questions and Answers
- Appendix C Proposal (the Bidders' proposal selected for award), including any Bid Forms
- and all proposal requirements.
- Appendix D General Specifications
- Appendix E

  Unless the CONTRACTOR is a political sub-division of New York State, the CONTRACTOR shall provide proof, completed by the CONTRACTOR's insurance carrier and/or the Workers' Compensation Board, of coverage for:

  - Workers' Compensation, for which one of the following is incorporated into this contract as Appendix E-1:
    1. WC/DB-100, Affidavit For New York Entities And Any Out of State Entities With No Employees, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage Is Not Required; OR
    2. WC/DB-101, Affidavit That An OUT-OF-STATE Or FOREIGN EMPLOYER Working in New York State Does Not Require Specific New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage; OR
    3. C-105.2 - Certificate of Workers' Compensation Insurance. PLEASE NOTE;The State Insurance Fund provides its own version of this form, the U-26.3; OR
    4. SI-12 – Certificate of Workers' Compensation Self-Insurance, OR GSI-105.2 - Certificate of Participation in Workers' Compensation Group Self-Insurance.
  - Disability Benefits coverage, for which one of the following is incorporated into this contract as Appendix E-2:
    1. WC/DB-100, Affidavit For New York Entities And Any Out of State Entities With No Employees, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage Is Not Required; OR
    2. WC/DB-101, Affidavit That An OUT-OF-STATE Or FOREIGN EMPLOYER Working in New York State Does Not Require Specific New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage; OR
    3. DB-120.1 – Certificate of Disability Benefits Insurance OR the DB-820/829 Certificate/Cancellation of Insurance; OR
    4. DB-155 – Certificate of Disability Benefits Self-Insurance
- Appendix H Confidentiality and Security Agreement
- Appendix X Modification Agreement Form
-

VII. ATTACHMENTS TO THE RFP

General: Applicable to both proposal components:

Attachment A	Proposal Checklist
Attachment B	Proposal Cover Sheet
Attachment C	Bid Form/No Bid Form

EI Specific Components:

Attachment C-1	Bid Detail Sheet
Attachment D	Protocols for Comprehensive Monitoring Encounters

Attachment E	Protocols for Focused Monitoring Encounters
Attachment F	Draft Monitoring Tools
Attachment G	Sample Monitoring Report Templates
Attachment H	Sample Protocols for Clinical Record Review (Autism/PDD)
Attachment I	Sample Data Collection Tools for Clinical Record Review (Autism/PDD)
Attachment J	Application for Approval of Individuals
Attachment K	Application for Approval of Agencies
Attachment L	Provider Application Review Protocols
Attachment M	Provider Application Deficiency Forms
Attachment N	Recommendation of Provider Approval/Disapproval Forms

General: Applicable to both program components

Attachment O	Letter of Intent to Bid and Intent to Attend Bidders' Conference
Attachment P	Standard Contract-Miscellaneous/Consultant Services
Attachment Q	Vendor Responsibility Questionnaire
Attachment R	Checklist to Determine ''Reasonable'' Effort

Optional Program Monitoring Component-specific

Attachment C-2	Bid Detail Sheet
Attachment S	Prenatal Care Assistance Program Site Visit Monitoring Form
Attachment T	Prenatal Care Assistance Program 85.40 Standards
Attachment U	Family Planning Site Visit Monitoring Form
Attachment V	Family Planning Title X Requirements
Attachment W	School-Based Health Center Monitoring Form

General: Applicable to both components

Attachment X	State Consultant Form A
Attachment Y	State Consultant Form B
Attachment Z	N.Y.S. Taxation and Finance Contractor Certification Form ST-220-TD
Attachment AA	N.Y.S. Taxation and Finance Contractor Certification Form ST-220-CA

STANDARD CLAUSES FOR NYS CONTRACTS

The parties to the attached contract, license, lease, amendment or other agreement of any kind (hereinafter, "the contract" or "this contract") agree to be bound by the following clauses which are hereby made a part of the contract (the word "Contractor" herein refers to any party other than the State, whether a contractor, licenser, licensee, lessor, lessee or any other party):

1. EXECUTORY CLAUSE. In accordance with Section 41 of the State Finance Law, the State shall have no liability under this contract to the Contractor or to anyone else beyond funds appropriated and available for this contract.

2. NON-ASSIGNMENT CLAUSE. In accordance with Section 138 of the State Finance Law, this contract may not be assigned by the Contractor or its right, title or interest therein assigned, transferred, conveyed, sublet or otherwise disposed of without the previous consent, in writing, of the State and any attempts to assign the contract without the State's written consent are null and void. The Contractor may, however, assign its right to receive payment without the State's prior written consent unless this contract concerns Certificates of Participation pursuant to Article 5-A of the State Finance Law.

3. COMPTROLLER'S APPROVAL. In accordance with Section 112 of the State Finance Law (or, if this contract is with the State University or City University of New York, Section 355 or Section 6218 of the Education Law), if this contract exceeds $50,000 (or the minimum thresholds agreed to by the Office of the State Comptroller for certain S.U.N.Y. and C.U.N.Y. contracts), or if this is an amendment for any amount to a contract which, as so amended, exceeds said statutory amount, or if, by this contract, the State agrees to give something other than money when the value or reasonably estimated value of such consideration exceeds $10,000, it shall not be valid, effective or binding upon the State until it has been approved by the State Comptroller and filed in his office. Comptroller's approval of contracts let by the Office of General Services is required when such contracts exceed $85,000 (State Finance Law Section 163.6.a).

4. WORKERS' COMPENSATION BENEFITS. In accordance with Section 142 of the State Finance Law, this contract shall be void and of no force and effect unless the Contractor shall provide and maintain coverage during the life of this contract for the benefit of such employees as are required to be covered by the provisions of the Workers' Compensation Law.

5. NON-DISCRIMINATION REQUIREMENTS. To the extent required by Article 15 of the Executive Law (also known as the Human Rights Law) and all other State and Federal statutory and constitutional non-discrimination provisions, the Contractor will not discriminate against any employee or applicant for employment because of race, creed, color, sex, national origin, sexual orientation, age, disability, genetic predisposition or carrier status, or marital status. Furthermore, in accordance with Section 220-e of the Labor Law, if this is a contract for the construction, alteration or repair of any public building or public work or for the manufacture, sale or distribution of materials, equipment or supplies, and to the extent that this contract shall be performed within the State of New York, Contractor agrees that neither it nor its subcontractors shall, by reason of race, creed, color, disability, sex, or national origin: (a) discriminate in hiring against any New York State citizen who is qualified and available to perform the work; or (b) discriminate against or intimidate any employee hired for the performance of work under this contract. If this is a building service contract as defined in Section 230 of the Labor Law, then, in accordance with Section 239 thereof, Contractor agrees that neither it nor its subcontractors shall by reason of race, creed, color, national origin, age, sex or disability: (a) discriminate in hiring against any New York State citizen who is qualified and available to perform the work; or (b) discriminate against or intimidate any employee hired for the performance of work under this contract. Contractor is subject to fines of $50.00 per person per day for any violation of Section 220-e or Section 239 as well as possible termination of this contract and forfeiture of all moneys due hereunder for a second or subsequent violation.

6. WAGE AND HOURS PROVISIONS. If this is a public work contract covered by Article 8 of the Labor Law or a building service contract covered by Article 9 thereof, neither Contractor's employees nor the employees of its subcontractors may be required or permitted to work more than the number of hours or days stated in said statutes, except as otherwise provided in the Labor Law and as set forth in prevailing wage and supplement schedules issued by the State Labor Department. Furthermore, Contractor and its subcontractors must pay at least the prevailing wage rate and pay or provide the prevailing supplements, including the premium rates for overtime pay, as determined by the State Labor Department in accordance with the Labor Law.

7. NON-COLLUSIVE BIDDING CERTIFICATION. In accordance with Section 139-d of the State Finance Law, if this contract was awarded based upon the submission of bids, Contractor affirms, under penalty of perjury, that its bid was arrived at independently and without collusion aimed at restricting competition. Contractor further affirms that, at the time Contractor submitted its bid, an authorized and responsible person executed and delivered to the State a non-collusive bidding certification on Contractor's behalf.

8. INTERNATIONAL BOYCOTT PROHIBITION. In accordance with Section 220-f of the Labor Law and Section 139-h of the State Finance Law, if this contract exceeds $5,000, the Contractor agrees, as a material condition of the contract, that neither the Contractor nor any substantially owned or affiliated person, firm, partnership or corporation has participated, is participating, or shall participate in an international boycott in violation of the federal Export Administration Act of 1979 (50 USC App. Sections 2401 et seq.) or regulations thereunder. If such Contractor, or any of the aforesaid affiliates of Contractor, is convicted or is otherwise found to have violated said laws or regulations upon the final determination of the United States Commerce Department or any other appropriate agency of the United States subsequent to the contract's execution, such contract, amendment or modification thereto shall be rendered forfeit and void. The Contractor shall so notify the State Comptroller within five (5) business days of such conviction, determination or disposition of appeal (2NYCRR 105.4).

9. SET-OFF RIGHTS. The State shall have all of its common law, equitable and statutory rights of set-off. These rights shall include, but not be limited to, the State's option to withhold for the purposes of set-off any moneys due to the Contractor under this contract up to any amounts due and owing to the State with regard to this contract, any other contract with any State department or agency, including any contract for a term commencing prior to the term of this contract, plus any amounts due and owing to the State for any other reason including, without limitation, tax delinquencies, fee delinquencies or monetary penalties relative thereto. The State shall exercise its set-off rights in accordance with normal State practices including, in cases of set-off pursuant to an audit, the finalization of such audit by the State agency, its representatives, or the State Comptroller.

10. RECORDS. The Contractor shall establish and maintain complete and accurate books, records, documents, accounts and other evidence directly pertinent to performance under this contract (hereinafter, collectively, "the Records"). The Records must be kept for the balance of the calendar year in which they were made and for six (6) additional years thereafter. The State Comptroller, the Attorney General and any other person or entity authorized to conduct an examination, as well as the agency or agencies involved in this contract, shall have access to the Records during normal business hours at an office of the Contractor

within the State of New York or, if no such office is available, at a mutually agreeable and reasonable venue within the State, for the term specified above for the purposes of inspection, auditing and copying. The State shall take reasonable steps to protect from public disclosure any of the Records which are exempt from disclosure under Section 87 of the Public Officers Law (the "Statute") provided that: (i) the Contractor shall timely inform an appropriate State official, in writing, that said records should not be disclosed; and (ii) said records shall be sufficiently identified; and (iii) designation of said records as exempt under the Statute is reasonable. Nothing contained herein shall diminish, or in any way adversely affect, the State's right to discovery in any pending or future litigation.

11. IDENTIFYING INFORMATION AND PRIVACY NOTIFICATION. (a) FEDERAL EMPLOYER IDENTIFICATION NUMBER and/or FEDERAL SOCIAL SECURITY NUMBER. All invoices or New York State standard vouchers submitted for payment for the sale of goods or services or the lease of real or personal property to a New York State agency must include the payee's identification number, i.e., the seller's or lessor's identification number. The number is either the payee's Federal employer identification number or Federal social security number, or both such numbers when the payee has both such numbers. Failure to include this number or numbers may delay payment. Where the payee does not have such number or numbers, the payee, on its invoice or New York State standard voucher, must give the reason or reasons why the payee does not have such number or numbers.

(b) PRIVACY NOTIFICATION**.** (1) The authority to request the above personal information from a seller of goods or services or a lessor of real or personal property, and the authority to maintain such information, is found in Section 5 of the State Tax Law. Disclosure of this information by the seller or lessor to the State is mandatory. The principal purpose for which the information is collected is to enable the State to identify individuals, businesses and others who have been delinquent in filing tax returns or may have understated their tax liabilities and to generally identify persons affected by the taxes administered by the Commissioner of Taxation and Finance. The information will be used for tax administration purposes and for any other purpose authorized by law.
(2) The personal information is requested by the purchasing unit of the agency contracting to purchase the goods or services or lease the real or personal property covered by this contract or lease. The information is maintained in New York State's Central Accounting System by the Director of Accounting Operations, Office of the State Comptroller, 110 State Street, Albany, New York 12236.

12. EQUAL EMPLOYMENT OPPORTUNITIES FOR MINORITIES AND WOMEN. In accordance with Section 312 of the Executive Law, if this contract is: (i) a written agreement or purchase order instrument, providing for a total expenditure in excess of $25,000.00, whereby a contracting agency is committed to expend or does expend funds in return for labor, services, supplies, equipment, materials or any combination of the foregoing, to be performed for, or rendered or furnished to the contracting agency; or (ii) a written agreement in excess of $100,000.00 whereby a contracting agency is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon; or (iii) a written agreement in excess of $100,000.00 whereby the owner of a State assisted housing project is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon for such project, then:

(a) The Contractor will not discriminate against employees or applicants for employment because of race, creed, color, national origin, sex, age, disability or marital status, and will undertake or continue existing programs of affirmative action to ensure that minority group members and women are afforded equal employment opportunities without discrimination. Affirmative action shall mean recruitment, employment, job assignment, promotion, upgradings, demotion, transfer, layoff, or termination and rates of pay or other forms of compensation;

(b) at the request of the contracting agency, the Contractor shall request each employment agency, labor union, or authorized representative of workers with which it has a collective bargaining or other agreement or understanding, to furnish a written statement that such employment agency, labor union or representative will not discriminate on the basis of race, creed, color, national origin, sex, age, disability or marital status and that such union or representative will affirmatively cooperate in the implementation of the contractor's obligations herein; and

(c) the Contractor shall state, in all solicitations or advertisements for employees, that, in the performance of the State contract, all qualified applicants will be afforded equal employment opportunities without discrimination because of race, creed, color, national origin, sex, age, disability or marital status.

Contractor will include the provisions of "a", "b", and "c" above, in every subcontract over $25,000.00 for the construction, demolition, replacement, major repair, renovation, planning or design of real property and improvements thereon (the "Work") except where the Work is for the beneficial use of the Contractor. Section 312 does not apply to: (i) work, goods or services unrelated to this contract; or (ii) employment outside New York State; or (iii) banking services, insurance policies or the sale of securities. The State shall consider compliance by a contractor or subcontractor with the requirements of any federal law concerning equal employment opportunity which effectuates the purpose of this section. The contracting agency shall determine whether the imposition of the requirements of the provisions hereof duplicate or conflict with any such federal law and if such duplication or conflict exists, the contracting agency shall waive the applicability of Section 312 to the extent of such duplication or conflict. Contractor will comply with all duly promulgated and lawful rules and regulations of the Governor's Office of Minority and Women's Business Development pertaining hereto.

13. CONFLICTING TERMS. In the event of a conflict between the terms of the contract (including any and all attachments thereto and amendments thereof) and the terms of this Appendix A, the terms of this Appendix A shall control.

14. GOVERNING LAW. This contract shall be governed by the laws of the State of New York except where the Federal supremacy clause requires otherwise.

15. LATE PAYMENT. Timeliness of payment and any interest to be paid to Contractor for late payment shall be governed by Article 11-A of the State Finance Law to the extent required by law.

16. NO ARBITRATION. Disputes involving this contract, including the breach or alleged breach thereof, may not be submitted to binding arbitration (except where statutorily authorized), but must, instead, be heard in a court of competent jurisdiction of the State of New York.

17. SERVICE OF PROCESS. In addition to the methods of service allowed by the State Civil Practice Law & Rules ("CPLR"), Contractor hereby consents to service of process upon it by registered or certified mail, return receipt requested. Service hereunder shall be complete upon Contractor's actual receipt of process or upon the State's receipt of the return thereof by the United States Postal Service as refused or undeliverable. Contractor must promptly notify the State, in writing, of each and every change of address to which service of process can be made. Service by the State to the last known address shall be sufficient. Contractor will have thirty (30) calendar days after service hereunder is complete in which to respond.

18. PROHIBITION ON PURCHASE OF TROPICAL HARDWOODS. The Contractor certifies and warrants that all wood products to be used under this contract award will be in accordance with, but not limited to, the specifications and provisions of State Finance Law §165. (Use of Tropical Hardwoods) which prohibits purchase and use of tropical hardwoods, unless specifically exempted, by the State or any governmental agency or political subdivision or public benefit corporation. Qualification for an exemption under this law will be the responsibility of the contractor to establish to meet with the approval of the State.

In addition, when any portion of this contract involving the use of woods, whether supply or installation, is to be performed by any subcontractor, the prime Contractor will indicate and certify in the submitted bid proposal that the subcontractor has been informed and is in compliance with specifications and provisions regarding use of tropical hardwoods as detailed in §165 State Finance Law. Any such use must meet with the approval of the State; otherwise, the bid may not be considered responsive. Under bidder certifications, proof of qualification for exemption will be the responsibility of the Contractor to meet with the approval of the State.

19. MACBRIDE FAIR EMPLOYMENT PRINCIPLES. In accordance with the MacBride Fair Employment Principles (Chapter 807 of the Laws of 1992), the Contractor hereby stipulates that the Contractor either (a) has no business operations in Northern Ireland, or (b) shall take lawful steps in good faith to conduct any business operations in Northern Ireland in accordance with the MacBride Fair Employment Principles (as described in Section 165 of the New York State Finance Law), and shall permit independent monitoring of compliance with such principles.

20. OMNIBUS PROCUREMENT ACT OF 1992. It is the policy of New York State to maximize opportunities for the participation of New York State business enterprises, including minority and women-owned business enterprises as bidders, subcontractors and suppliers on its procurement contracts.

Information on the availability of New York State subcontractors and suppliers is available from:

NYS Department of Economic Development
Division for Small Business
30 South Pearl St -- 7th Floor
Albany, New York 12245
Telephone: 518-292-5220
Fax: 518-292-5884
http://www.empire.state.ny.us

A directory of certified minority and women-owned business enterprises is available from:

NYS Department of Economic Development
Division of Minority and Women's Business Development
30 South Pearl St -- 2nd Floor
Albany, New York 12245
Telephone: 518-292-5250
Fax: 518-292-5803
http://www.empire.state.ny.us

The Omnibus Procurement Act of 1992 requires that by signing this bid proposal or contract, as applicable, Contractors certify that whenever the total bid amount is greater than $1 million:

(a) The Contractor has made reasonable efforts to encourage the participation of New York State Business Enterprises as suppliers and subcontractors, including certified minority and women-owned business enterprises, on this project, and has retained the documentation of these efforts to be provided upon request to the State;

(b) The Contractor has complied with the Federal Equal Opportunity Act of 1972 (P.L. 92-261), as amended;

(c) The Contractor agrees to make reasonable efforts to provide notification to New York State residents of employment opportunities on this project through listing any such positions with the Job Service Division of the New York State Department of Labor, or providing such notification in such manner as is consistent with existing collective bargaining contracts or agreements. The Contractor agrees to document these efforts and to provide said documentation to the State upon request; and

(d) The Contractor acknowledges notice that the State may seek to obtain offset credits from foreign countries as a result of this contract and agrees to cooperate with the State in these efforts.

21. RECIPROCITY AND SANCTIONS PROVISIONS. Bidders are hereby notified that if their principal place of business is located in a country, nation, province, state or political subdivision that penalizes New York State vendors, and if the goods or services they offer will be substantially produced or performed outside New York State, the Omnibus Procurement Act 1994 and 2000 amendments (Chapter 684 and Chapter 383, respectively) require that they be denied contracts which they would otherwise obtain. NOTE: As of May 15, 2002, the list of discriminatory jurisdictions subject to this provision includes the states of South Carolina, Alaska, West Virginia, Wyoming, Louisiana and Hawaii. Contact NYS Department of Economic Development for a current list of jurisdictions subject to this provision.

22. PURCHASES OF APPAREL. In accordance with State Finance Law 162 (4-a), the State shall not purchase any apparel from any vendor unable or unwilling to certify that: (i) such apparel was manufactured in compliance with all applicable labor and occupational safety laws, including, but not limited to, child labor laws, wage and hours laws and workplace safety laws, and (ii) vendor will supply, with its bid (or, if not a bid situation, prior to or at the time of signing a contract with the State), if known, the names and addresses of each subcontractor and a list of all manufacturing plants to be utilized by the bidder.

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CONTRACT APPENDIX B

COPY RFP

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CONTRACT APPENDIX B-1

Bidders Conference Questions and Answers

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CONTRACT APPENDIX C

CONTRACTOR'S PROPOSAL

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APPENDIX D
GENERAL SPECIFICATIONS

A. By signing the "Bid Form" each bidder attests to its express authority to sign on behalf of this company or other entity and acknowledges and accepts that:

All specifications, general and specific appendices, including Appendix-A, the Standard Clauses for all New York State contracts, and all schedules and forms contained herein will become part of any contract entered, resulting from the Request for Proposal. Anything which is not expressly set forth in the specification, appendices and forms and resultant contract, but which is reasonable to be implied, shall be furnished and provided in the same manner as if specifically expressed.

B. The work shall be commenced and shall be actually undertaken within such time as the Department of Health may direct by notice, whether by mail, telegram, or other writing, whereupon the undersigned will give continuous attention to the work as directed, to the end and with the intent that the work shall be completed within such reasonable time or times, as the case may be, as the Department may prescribe.

C. The Department reserves the right to stop the work covered by this proposal and the contract at any time that the Department deems the successful bidder to be unable or incapable of performing the work to the satisfaction of the Department and in the event of such cessation of work, the Department shall have the right to arrange for the completion of the work in such manner as the Department may deem advisable and if the cost thereof exceeds the amount of the bid, the successful bidder and its surety be liable to the State of New York for any excess cost on account thereof.

D. Each bidder is under an affirmative duty to be informed by personal examination of the specifications and location of the proposed work and by such other means as it may select, of character, quality, and extent of work to be performed and the conditions under which the contract is to be executed.

E. The Department of Health will make no allowances or concession to a bidder for any alleged misunderstanding or deception because of quantity, quality, character, location or other conditions.

F. The bid price is to cover the cost of furnishing all of the said services, materials, equipment, and labor to the satisfaction of the Department of Health and the performance of all work set forth in said specifications.

G. The successful bidder will be required to complete the entire work, or any part thereof as the case may be, to the satisfaction of the Department of

Health in strict accordance with the specifications and pursuant to a contract therefore.

H. Contractor will possess, at no cost to the State, all qualifications, licenses and permits to engage in the required business as may be required within the jurisdiction where the work specified is to be performed. Workers to be employed in the performance of this contract will possess the qualifications, training, licenses and permits as may be required within such jurisdiction.

I. Non-Collusive Bidding

By submission of this proposal, each bidder and each person signing on behalf of any bidder certifies, and in the case of a joint bid each party thereto certifies as to its own organization, under penalty of perjury, that to the best of their knowledge and belief:

a. The prices of this bid have been arrived at independently without collusion, consultation, communication, or agreement, for the purpose of restricting competition, as to any matter relating to such prices with any other bidder or with any competitor;

b. Unless otherwise required by law, the prices which have been quoted in this bid have not been knowingly disclosed by the bidder and will not knowingly be disclosed by the bidder prior to opening, directly or indirectly to any other person, partnership or corporation to submit or not to submit a bid for the purpose of restricting competition;

c. No attempt has been made or will be made by the bidder to induce any other person, partnership or corporation to submit or not to submit a bid for the purpose of restricting competition.

NOTE: Chapter 675 of the Laws of New York for 1966 provides that every bid made to the state or any public department, agency or official thereof, where competitive bidding is required by statute, rule or regulation, for work or services performed or to be performed or goods sold or to be sold, shall contain the foregoing statement subscribed by the bidder and affirmed by such bidder as true under penalties of perjury.

A bid shall not be considered for award nor shall any award be made where (a), (b) and (c) above have not been complied with; provided however, that if in any case the bidder cannot make the foregoing certification, the bidder shall so state and shall furnish with the bid a signed statement which sets forth in detail the reasons therefore. Where (a), (b) and (c) above have not been complied with, the bid shall not be considered for award nor shall any award be made unless the head of the purchasing unit of the state, public department or agency to which the bid is made or its designee, determines that such disclosure was not made for the purpose of restricting competition.

The fact that a bidder has published price lists, rates, or tariffs covering items being procured, has informed prospective customers of proposed or pending publication of new or revised price lists for such items, or has sold the same items to other customers at the same price being bid, does not constitute, without more, a disclosure within the meaning of the above quoted certification.

Any bid made to the State or any public department, agency or official thereof by a corporate bidder for work or services performed or to be performed or goods, sold or to be sold, where competitive bidding is required by statute, rule or regulation and where such bid contains the certification set forth above shall be deemed to have been authorized by the board of directors of the bidder, and such authorization shall be deemed to include the signing and submission of the bid and the inclusion therein of the certificate as to non-collusion as the act and deed of the corporation.

J. A bidder may be disqualified from receiving awards if such bidder or any subsidiary, affiliate, partner, officer, agent or principal thereof, or anyone in its or its employ, has previously failed to perform satisfactorily in connection with public bidding or contracts.

K. The Department reserves the right to make awards within ninety (90) days after the date of the bid opening, during which period bids shall not be withdrawn unless the bidder distinctly states in the bid that acceptance thereof must be made within a shorter specified time.

L. Work for Hire Contract
Any contract entered into resultant from this request for proposal will be considered a "Work for Hire Contract." The Department will be the sole owner of all source code and any software which is developed or included in the application software provided to the Department as a part of this contract.

M. Technology Purchases Notification -- The following provisions apply if this Request for Proposal (RFP) seeks proposals for "Technology"

1. For the purposes of this policy, "technology" applies to all services and commodities, voice/data/video and/or any related requirement, major software acquisitions, systems modifications or upgrades, etc., that result in a technical method of achieving a practical purpose or in improvements of productivity. The purchase can be as simple as an order for new or replacement personal computers, or for a consultant to design a new system, or as complex as a major systems improvement or innovation that changes how an agency conducts its business practices.

2. If this RFP results in procurement of software over $20,000, or of other technology over $50,000, or where the department determines that the potential exists for coordinating purchases among State agencies and/or the purchase may be of interest to one or more other State agencies, PRIOR TO AWARD SELECTION, this RFP and all responses thereto are subject to review by the New York State Office for Technology.

3. Any contract entered into pursuant to an award of this RFP shall contain a provision which extends the terms and conditions of such contract to any other State agency in New York. Incorporation of this RFP into the resulting contract also incorporates this provision in the contract.

4. The responses to this RFP must include a solution to effectively handle the turn of the century issues related to the change from the year 1999 to 2000.

N. YEAR 2000 WARRANTY

1. Definitions

For purposes of this warranty, the following definitions shall apply:

a. Product shall include, without limitation: any piece or component of equipment, hardware, firmware, middleware, custom or commercial software, or internal components or subroutines therein which perform any date/time data recognition function, calculation, comparing or sequencing. Where services are being furnished, e.g. consulting, systems integration, code or data conversion or data entry, the term Product shall include resulting deliverables.

b. Vendor's Product shall include all Product delivered under this Agreement by Vendor other than Third Party Product.

c. Third Party Product shall include products manufactured or developed by a corporate entity independent from Vendor and provided by Vendor on a non-exclusive licensing or other distribution Agreement with the third party manufacturer. Third Party Product does not include product where Vendor is: a) corporate subsidiary or affiliate of the third party manufacturer/developer; and/or b) the exclusive re-seller or distributor of product manufactured or developed by said corporate entity.

2. Warranty Disclosure

At the time of bid, Product order or Product quote, Vendor is required to disclose the following information in writing to Authorized User:

a. For Vendor Product and for Products (including, but not limited to, Vendor and/or Third Party Products and/or Authorized User's Installed Product) which have been specified to perform as a system: Compliance or non-compliance of the Products individually or as a system with the Warranty Statement set forth below; and

b. For Third Party Product Not Specified as Part of a System: Third Party Manufacturer's statement of compliance or non-compliance of any Third Party Product being delivered with Third Party Manufacturer/Developer's Year 2000 warranty. If such Third Party Product is represented by Third Party Manufacturer/Developer as compliant with Third Party Manufacturer/Developer's Year 2000 Warranty, Vendor shall pass through said third party warranty from the third party manufacturer to the Authorized User but shall not be liable for the testing or verification of Third Party's compliance statement. .

An absence or failure to furnish the required written warranty disclosure shall be deemed a statement of compliance of the product(s) or system(s) in question with the year 2000 warranty statement set forth below.

3. Warranty Statement

Year 2000 warranty compliance shall be defined in accordance with the following warranty statement:

Vendor warrants that Product(s) furnished pursuant to this Agreement shall, when used in accordance with the Product documentation, be able to accurately process date/time data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries, and the years 1999 and 2000, including leap year calculations. Where a purchase requires that specific Products must perform as a package or system, this warranty shall apply to the Products as a system.

In the event of any breach of this warranty, Vendor shall restore the Product to the same level of performance as warranted herein, or repair or replace the Product with conforming Product so as to minimize interruption to Authorized User's ongoing business processes, time being of the essence, at Vendor's sole cost and

expense. This warranty does not extend to correction of Authorized User's errors in data entry or data conversion.

This warranty shall survive beyond termination or expiration of the Agreement.

Nothing in this warranty shall be construed to limit any rights or remedies otherwise available under this Agreement.

O. No Subcontracting
Subcontracting by the contractor shall not be permitted except by prior written approval and knowledge of the Department of Health.

P. Superintendence by Contractor
The Contractor shall have a representative to provide supervision of the work which Contractor employees are performing to ensure complete and satisfactory performance with the terms of the Contract. This representative shall also be authorized to receive and put into effect promptly all orders, directions and instructions from the Department of Health. A confirmation in writing of such orders or directions will be given by the Department when so requested from the Contractor.

Q. Sufficiency of Personnel and Equipment
If the Department of Health is of the opinion that the services required by the specifications cannot satisfactorily be performed because of insufficiency of personnel, the Department shall have the authority to require the Contractor to use such additional personnel, to take such steps necessary to perform the services satisfactorily at no additional cost to the State.

R. Experience Requirements
The Contractor shall submit evidence to the satisfaction of the Department that it possesses the necessary experience and qualifications to perform the type of services required under this contract and must show that it is currently performing similar services. The Contractor shall submit at least two references to substantiate these qualifications.

S. Contract Amendments
This agreement may be amended by written agreement signed by the parties and subject to the laws and regulations of the State pertaining to contract amendments. This agreement may not be amended orally.

The contractor shall not make any changes in the scope of work as outlined herein at any time without prior authorization in writing from the Department of Health and without prior approval in writing of the amount of compensation for such changes.

T. Provisions Upon Default

1. In the event that the Contractor, through any cause, fails to perform any of the terms, covenants or promises of this agreement, the Department acting for and on behalf of the State, shall thereupon have the right to terminate this agreement by giving notice in writing of the fact and date of such termination to the Contractor

2. If, in the judgement of the Department of Health, the Contractor acts in such a way which is likely to or does impair or prejudice the interests of the State, the Department acting on behalf of the State, shall thereupon have the right to terminate this agreement by giving notice in writing of the fact and date of such termination to the Contractor. In such case the Contractor shall receive equitable compensation for such services as shall, in the judgement of the State Comptroller, have been satisfactorily performed by the Contractor up to the date of the termination of this agreement, which such compensation shall not exceed the total cost incurred for the work which the Contractor was engaged in at the time of such termination, subject to audit by the State Comptroller.

U. Termination Provision

Upon termination of this agreement, the following shall occur:

1. Contractor shall make available to the State for examination all data, records and reports relating to this Contract; and

2. Except as otherwise provided in the Contract, the liability of the State for payments to the Contractor and the liability of the Contractor for services hereunder shall cease.

V. Conflicts

If, in the opinion of the Department of Health, (1) the specifications conflict, or (2) if the specifications are not clear as to (a) the method of performing any part of the work, or as to (b) the types of materials or equipment necessary, or as to (c) the work required to be done in every such situation, the Contractor shall be deemed to have based his bid upon performing the work and furnishing materials or equipment in the most inexpensive and efficient manner. If such conflicts and/or ambiguities arise, the Department of Health will furnish the Contractor supplementary information showing the manner in which the work is to be performed and the type or types of material or equipment that shall be used.

W. MINORITY AND WOMEN OWNED BUSINESS POLICY STATEMENT

The New York State Department of Health recognizes the need to take

affirmative action to ensure that Minority and Women Owned Business Enterprises are given the opportunity to participate in the performance of the Department of Health's contracting program. This opportunity for full participation in our free enterprise system by traditionally, socially and economically disadvantaged persons is essential to obtain social and economic equality and improve the functioning of the State economy.

It is the intention of the New York State Department of Health to fully execute the mandate of Executive Law, Article 15-A and provide Minority and Women Owned Business Enterprises with equal opportunity to bid on contracts awarded by this agency in accordance with the State Finance Law.

To implement this affirmative action policy statement, the contractor agrees to file with the Department of Health within 10 days of notice of award, a staffing plan of the anticipated work force to be utilized on this contract or, where required, information on the contractor's total work force, including apprentices, broken down by specified ethnic background, gender, and Federal occupational categories or other appropriate categories specified by the Department. The form of the staffing plan shall be supplied by the Department.

After an award of this contract, the contractor agrees to submit to the Department a work force utilization report, in a form and manner required by the Department, of the work force actually utilized on this contract, broken down by specified ethnic background, gender and Federal occupational categories or other appropriate categories specified by the Department.

X. Contract Insurance Requirements

1. The successful bidder must without expense to the State procure and maintain, until final acceptance by the Department of Health of the work covered by this proposal and the contract, insurance of the kinds and in the amounts hereinafter provided, in insurance companies authorized to do such business in the State of New York covering all operations under this proposal and the contract, whether performed by it or by subcontractors. Before commencing the work, the successful bidder shall furnish to the Department of Health a certificate or certificates, in a form satisfactory to the Department, showing that it has complied with the requirements of this section, which certificate or certificates shall state that the policies shall not be changed or canceled until thirty days written notice has been given to the Department. The kinds and amounts of required insurance are:

    a. A policy covering the obligations of the successful bidder in accordance with the provisions of Chapter 41, Laws of 1914, as amended, known as the Workers' Compensation Law, and the

contract shall be void and of no effect unless the successful bidder procures such policy and maintains it until acceptance of the work (reference Appendix E).

b. Policies of Bodily Injury Liability and Property Damage Liability Insurance of the types hereinafter specified, each within limits of not less than $500,000 for all damages arising out of bodily injury, including death at any time resulting therefrom sustained by one person in any one occurrence, and subject to that limit for that person, not less than $1,000,000 for all damages arising out of bodily injury, including death at any time resulting therefrom sustained by two or more persons in any one occurrence, and not less than $500,000 for damages arising out of damage to or destruction or property during any single occurrence and not less than $1,000,000 aggregate for damages arising out of damage to or destruction of property during the policy period.

i. Contractor's Liability Insurance issued to and covering the liability of the successful bidder with respect to all work performed by it under this proposal and the contract.

ii. Protective Liability Insurance issued to and covering the liability of the People of the State of New York with respect to all operations under this proposal and the contract, by the successful bidder or by its subcontractors, including omissions and supervisory acts of the State.

iii. Automobile Liability Insurance issued to and covering the liability of the People of the State of New York with respect to all operations under this proposal and the contract, by the successful bidder or by its subcontractors, including omissions and supervisory acts of the State.

Y. Certification Regarding Debarment and Suspension

Regulations of the Department of Health and Human Services, located at Part 76 of Title 45 of the Code of Federal Regulations (CFR), implement Executive Orders 12549 and 12689 concerning debarment and suspension of participants in federal programs and activities. Executive Order 12549 provides that, to the extent permitted by law, Executive departments and agencies shall participate in a government-wide system for non-procurement debarment and suspension. Executive Order 12689 extends the debarment and suspension policy to procurement activities of the federal government. A person who is debarred or suspended by a federal agency is excluded from federal financial and non-financial assistance and

benefits under federal programs and activities, both directly (primary covered transaction) and indirectly (lower tier covered transactions). Debarment or suspension by one federal agency has government-wide effect.

Pursuant to the above-cited regulations, the New York State Department of Health (as a participant in a primary covered transaction) may not knowingly do business with a person who is debarred, suspended, proposed for debarment, or subject to other government-wide exclusion (including any exclusion from Medicare and State health care program participation on or after August 25, 1995), and the Department of Health must require its prospective contractors, as prospective lower tier participants, to provide the certification in Appendix B to Part 76 of Title 45 CFR, as set forth below:

1. APPENDIX B TO PART 76-CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILITY AND VOLUNTARY EXCLUSION-LOWER TIER COVERED TRANSACTIONS

   Instructions for Certification

   a. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.

   b. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered and erroneous certification, in addition to other remedies available to the Federal Government the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

   c. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or had become erroneous by reason of changed circumstances.

   d. The terms covered transaction, debarred, suspended, ineligible, lower tier covered transaction, participant, person, primary covered Transaction, principal, proposal, and voluntarily excluded, as used in this clause, have the meaning set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of

those regulations.

e. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.

f. The prospective lower tier participant further agrees by submitting this proposal that it will include this clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transaction," without modification, in all lower tier covered transactions.

g. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from covered transactions, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the List of parties Excluded from Federal Procurement and Non-procurement Programs.

h. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

i. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

2. Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion – Lower Tier Covered Transactions

   a. The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily exclude from participation in this transaction by any Federal department agency.

   b. Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Z. Confidentiality Clauses

1. Any materials, articles, papers, etc., developed by the CONTRACTOR under or in the course of performing this AGREEMENT shall contain the following, or similar acknowledgment: "Funded by the New York State Department of Health". Any such materials must be reviewed and approved by the STATE for conformity with the policies and guidelines for the New York State Department of Health prior to dissemination and/or publication. It is agreed that such review will be conducted in an expeditious manner. Should the review result in any unresolved disagreements regarding content, the CONTRACTOR shall be free to publish in scholarly journals along with a disclaimer that the views within the Article or the policies reflected are not necessarily those of the New York State Department of Health. The Department reserves the right to disallow funding for any educational materials not approved through its review process.

2. Any publishable or otherwise reproducible material developed under or in the course of performing this AGREEMENT, dealing with any aspect of performance under this AGREEMENT, or of the results and accomplishments attained in such performance, shall be the sole and exclusive property of the STATE, and shall not be published or otherwise disseminated by the CONTRACTOR to any other party unless prior written approval is secured from the STATE or under circumstances as indicated in paragraph 1 above. Any and all net proceeds obtained by the CONTRACTOR resulting from any such publication shall belong to and be paid over to the STATE. The STATE shall have a perpetual royalty-free, non-exclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to use, any such material for governmental purposes.

3. No report, document or other data produced in whole or in part with the funds provided under this AGREEMENT may be copyrighted by the CONTRACTOR or any of its employees, nor shall any notice of copyright be registered by the CONTRACTOR or any of its employees in connection with any report, document or other data developed pursuant to this AGREEMENT.

4. All reports, data sheets, documents, etc. generated under this contract shall be the sole and exclusive property of the Department of Health. Upon completion or termination of this AGREEMENT the CONTRACTOR shall deliver to the Department of Health upon its demand all copies of materials relating to or pertaining to this AGREEMENT. The CONTRACTOR shall have no right to disclose or use any of such material and documentation for any purpose whatsoever, without the prior written approval of the Department of Health or its authorized agents.

5. The CONTRACTOR , its officers, agents and employees and subcontractors shall treat all information, which is obtained by it through its performance under this AGREEMENT, as confidential information to the extent required by the laws and regulations of the United States and laws and regulations of the State of New York.

6. All subcontracts shall contain provisions specifying:

   a. that the work performed by the subcontractor must be in accordance with the terms of this AGREEMENT, and

   b. that the subcontractor specifically agrees to be bound by the confidentiality provisions set forth in the AGREEMENT between the STATE and the CONTRACTOR.

AA. Provision Related to Consultant Disclosure Legislation

1. If this contract is for the provision of consulting services as defined in Subdivision 17 of Section 8 of the State Finance Law, the CONTRACTOR shall submit a "State Consultant Services Form B, Contractor's Annual Employment Report" no later than May 15th following the end of each state fiscal year included in this contract term. This report must be submitted to:

   a. The NYS Department of Health, at the STATE's designated payment office address included in this AGREEMENT; and

b. The NYS Office of the State Comptroller, Bureau of Contracts, 110 State Street, 11th Floor, Albany NY 12236 ATTN: Consultant Reporting - or via fax at (518) 474-8030 or (518) 473-8808; and

c. The NYS Department of Civil Service, Alfred E. Smith Office Building, Albany NY 12239, ATTN: Consultant Reporting.

BB. Provisions Related to New York State Procurement Lobbying Law

1. The STATE reserves the right to terminate this AGREEMENT in the event it is found that the certification filed by the CONTRACTOR in accordance with New York State Finance Law §139-k was intentionally false or intentionally incomplete. Upon such finding, the STATE may exercise its termination right by providing written notification to the CONTRACTOR in accordance with the written notification terms of this AGREEMENT.

CC. Provisions Related to New York State Information Security Breach and Notification Act

1. CONTRACTOR shall comply with the provisions of the New York State Information Security Breach and Notification Act (General Business Law Section 899-aa; State Technology Law Section 208). CONTRACTOR shall be liable for the costs associated with such breach if caused by CONTRACTOR'S negligent or willful acts or omissions, or the negligent or willful acts or omissions of CONTRACTOR'S agents, officers, employees or subcontractors.

CONTRACT APPENDIX E-1

Proof of Workers' Compensation

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CONTRACT APPENDIX E-2

Proof of Disability Insurance Coverage

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Appendix H

Federal Health Insurance Portability and Accountability Act (○HIPAA○)
Business Associate Agreement ("Agreement○) Governing Privacy and Security

I. <u>Definitions</u>:

(a) Business Associate shall mean the CONTRACTOR.

(b) Covered Program shall mean the STATE.

(c) Other terms used, but not otherwise defined, in this agreement shall have the same meaning as those terms in the federal Health Insurance Portability and Accountability Act of 1996 (○HIPAA○) and its implementing regulations, including those at 45 CFR Parts 160 and 164.

II. Obligations and Activities of the Business Associate:

(a) The Business Associate agrees to not use or further disclose Protected Health Information other than as permitted or required by this Agreement or as required by law.

(b) The Business Associate agrees to use the appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement and to implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of any electronic Protected Health Information that it creates receives, maintains or transmits on behalf of the Covered Entity pursuant to this Agreement.

(c) The Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to the Business Associate of a use or disclosure of Protected Health Information by the Business Associate in violation of the requirements of this Agreement.

(d) The Business Associate agrees to report to the Covered Program, any use or disclosure of the Protected Health Information not provided for by this Agreement, as soon as reasonably practicable of which it becomes aware. The Business Associate also agrees to report to the Covered Entity any security incident of which it becomes aware.

(e) The Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from,

or created or received by the Business Associate on behalf of the Covered Program agrees to the same restrictions and conditions that apply through this Agreement to the Business Associate with respect to such information.

(f) The Business Associate agrees to provide access, at the request of the Covered Program, and in the time and manner designated by the Covered Program, to Protected Health Information in a Designated Record Set, to the Covered Program or, as directed by the Covered Program, to an Individual in order to meet the requirements under 45 CFR 164.524, if the business associate has protected health information in a designated record set.

(g) The Business Associate agrees to make any amendment(s) to Protected Health Information in a designated record set that the Covered Program directs or agrees to pursuant to 45 CFR 164.526 at the request of the Covered Program or an Individual, and in the time and manner designated by Covered Program, if the business associate has protected health information in a designated record set.

(h) The Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by the Business Associate on behalf of, the Covered Program available to the Covered Program, or to the Secretary of Health and Human Services, in a time and manner designated by the Covered Program or the Secretary, for purposes of the Secretary determining the Covered Program's compliance with the Privacy Rule.

(i) The Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Program to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

(j) The Business Associate agrees to provide to the Covered Program or an Individual, in time and manner designated by Covered Program, information collected in accordance with this Agreement, to permit Covered Program to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

III. <u>Permitted Uses and Disclosures by Business Associate</u>

(a) General Use and Disclosure Provisions

Except as otherwise limited in this Agreement, the Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, the Covered Program as specified in the Agreement to which this is an addendum, provided that such use or disclosure would not violate the Privacy Rule if done by Covered Program.

(b) Specific Use and Disclosure Provisions:

(1) Except as otherwise limited in this Agreement, the Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are required by law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(2) Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information for the proper management and administration of the business associate or to carry out its legal responsibilities and to provide Data Aggregation services to Covered Program as permitted by 45 CFR 164.504(e)(2)(i)(B). Data Aggregation includes the combining of protected information created or received by a business associate through its activities under this contract with other information gained from other sources.

(3) The Business Associate may use Protected Health Information to report violations of law to appropriate federal and State authorities, consistent with 45 CFR §164.502(j)(1).

IV. Obligations of Covered Program

Provisions for the Covered Program To Inform the Business Associate of Privacy Practices and Restrictions

(a) The Covered Program shall notify the Business Associate of any limitation(s) in its notice of privacy practices of the Covered Entity in accordance with 45 CFR 164.520, to the extent that such limitation may affect the Business Associate's use or disclosure of Protected Health Information.

(b) The Covered Program shall notify the Business Associate of any changes in, or revocation of, permission by the Individual to use or disclose Protected Health Information, to the extent that such changes may affect the Business Associate's use or disclosure of Protected Health Information.

(c) The Covered Program shall notify the Business Associate of any restriction to the use or disclosure of Protected Health Information that the Covered Program has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction

may affect the Business Associate's use or disclosure of Protected Health Information.

V. Permissible Requests by Covered Program

The Covered Program shall not request the Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Program, except if the Business Associate will use or disclose protected health information for, and the contract includes provisions for, data aggregation or management and administrative activities of Business Associate.

VI. Term and Termination

(a) ***Term.*** **The Term of this Agreement shall be effective during the dates noted on page one of this agreement, after which time all of the Protected Health Information provided by Covered Program to Business Associate, or created or received by Business Associate on behalf of Covered Program, shall be destroyed or returned to Covered Program, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in The Agreement.**

(b) ***Termination for Cause.*** **Upon the Covered Program's knowledge of a material breach by Business Associate, Covered Program may provide an opportunity for the Business Associate to cure the breach and end the violation or may terminate this Agreement and the master Agreement if the Business Associate does not cure the breach and end the violation within the time specified by Covered Program, or the Covered Program may immediately terminate this Agreement and the master Agreement if the Business Associate has breached a material term of this Agreement and cure is not possible.**

(c) ***Effect of Termination.***

(1) Except as provided in paragraph (c)(2) below, upon termination of this Agreement, for any reason, the Business Associate shall return or destroy all Protected Health Information received from the Covered Program, or created or received by the Business Associate on behalf of the Covered Program. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of the Business Associate. The Business Associate shall retain no copies of the Protected Health Information.

(2) In the event that the Business Associate determines that returning or destroying the Protected Health Information is infeasible, the Business Associate shall provide to the Covered Program notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the

Parties that return or destruction of Protected Health Information is infeasible, the Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

VII. <u>Violations</u>

(a) It is further agreed that any violation of this agreement may cause irreparable harm to the State, therefore the State may seek any other remedy, including an injunction or specific performance for such harm, without bond, security or necessity of demonstrating actual damages.

(b) The business associate shall indemnify and hold the State harmless against all claims and costs resulting from acts/omissions of the business associate in connection with the business associate's obligations under this agreement.

Miscellaneous

(a) *Regulatory References*. A reference in this Agreement to a section in the HIPAA Privacy Rule means the section as in effect or as amended, and for which compliance is required.

(b) *Amendment*. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Program to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act, Public Law 104-191.

(c) *Survival*. The respective rights and obligations of the Business Associate under Section VI of this Agreement shall survive the termination of this Agreement.

(d) *Interpretation*. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits the Covered Program to comply with the HIPAA Privacy Rule.

(e) If anything in this agreement conflicts with a provision of any other agreement on this matter, this agreement is controlling.

(f) HIV/AIDS. If HIV/AIDS information is to be disclosed under this agreement, the business associate acknowledges that it has been informed of the confidentiality requirements of Public Health Law Article 27-F.

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APPENDIX X

Agency Code _____ Contract No.
Period _____ Funding Amount for Period

This is an AGREEMENT between THE STATE OF NEW YORK, acting by and through _____, having its principal office at _____, hereinafter referred to as the STATE), and _____ (hereinafter referred to as the CONTRACTOR), for modification of Contract Number as amended in attached Appendix(ices) _____.

All other provisions of said AGREEMENT shall remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have executed this AGREEMENT as of the dates appearing under their signatures.

_____

CONTRACTOR SIGNATURE

By: _____

_____
Printed Name

Title: _____

Date: _____

STATE AGENCY SIGNATURE

By:

Printed Name

Title: _____

Date: _____

State Agency Certification:
"In addition to the acceptance of this contract, I also certify that original copies of this signature page will be attached to all other exact copies of this contract."

_____

STATE OF NEW YORK)
) SS.:
County of _____)

On the ___ day of _____ in the year _____ before me, the undersigned, personally appeared _____, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) is(are) subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their/ capacity(ies), and that by his/her/their signature(s) on the instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument.

_____
(Signature and office of the individual taking acknowledgement)

STATE COMPTROLLER'S SIGNATURE

Title: _____

Date: _____

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ATTACHMENT A-1

PROPOSAL CHECKLIST
Early Intervention Monitoring Component

Use this checklist to confirm that all sections are included and in the proper sequence in your proposal for submission to the Early Intervention Program.

_____ TECHNICAL PROPOSAL

_____ Proposal Cover Sheet – Attachment B (original signature required)

_____ Project Narrative – Technical Proposal

_____ a. Project Narrative

_____ b. Bidder Qualifications and References

_____ c. Contractor Disclosure of Contacts (REQUIRED)

_____ d. Contract Disclosure of Prior Non-Responsibility Determinations (REQUIRED)

_____ Vitae/Resumes of Key Personnel

_____ Letters of Support

_____ COST PROPOSAL

_____ a. Bid Detail Sheet – Attachment C

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ATTACHMENT A-2

PROPOSAL CHECKLIST
Optional Monitoring Component for other Department of Health programs

Use this checklist to confirm that all sections are included and in the proper sequence in your proposal for submission to the Early Intervention Program.

_____ TECHNICAL PROPOSAL

_____ Proposal Cover Sheet – Attachment B (original signature required)

_____ Project Narrative – Technical Proposal

_____ a. Project Narrative

_____ b. Bidder Qualifications and References

_____ c. Contractor Disclosure of Contacts (REQUIRED)

_____ d. Contract Disclosure of Prior Non-Responsibility Determinations (REQUIRED)

_____ Vitae/Resumes of Key Personnel

_____ Letters of Support

_____ COST PROPOSAL

_____ a. Bid Detail Sheet – Attachment C

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ATTACHMENT B

COVER SHEET

ORGANIZATION NAME:	
ORGANIZATION ADDRESS:	
ORGANIZATION PHONE NUMBER: **ORGANIZATION FAX NUMBER:** **E-MAIL:**	
ORGANIZATION'S FEDERAL TAX IDENTIFICATION NUMBER:	
SIGNATURE OF RESPONSIBLE PERSON:	**NAME OF RESPONSIBLE PERSON: (please print)**
INCORPORATION: ☐ **Incorporated** ☐ **Not Incorporated** **Identify state in which organization is Incorporated:** _____ **Check Type Of Corporation:** ☐ **Business** ☐ **Membership** ☐ **Religious** ☐ **Other (please specify)**	**NON INCORPORATED:** **Is organization authorized to do business in NY:** ☐ **Yes** ☐ **No** **Check Type Of Organization:** ☐ **Not For Profit** ☐ **Partnership** ☐ **Unincorporated Association** ☐ **Other (please specify)**_____ _____ **NYS Department Of State Charitable Registration Number:** _____ **Or Exemption (please specify):**_____ _____

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NEW YORK STATE
DEPARTMENT OF HEALTH
ATTACHMENT C

BID FORM

PROCUREMENT TITLE: _____FAU #_____

Bidder Name:
Bidder Address:

Bidder Fed ID No:

A. _____bids a total price of $_____
(Name of Offerer/Bidder)

B. Affirmations & Disclosures related to State Finance Law §§ 139-j & 139-k:

Offerer/Bidder affirms that it understands and agrees to comply with the procedures of the Department of Health relative to permissible contacts (provided below) as required by State Finance Law §139-j (3) and §139-j (6) (b).

Pursuant to State Finance Law §§139-j and 139-k, this *Invitation for Bid or Request for Proposal* includes and imposes certain restrictions on communications between the Department of Health (DOH) and an Offerer during the procurement process. An Offerer/bidder is restricted from making contacts from the earliest notice of intent to solicit *bids/proposals* through final award and approval of the Procurement Contract by the DOH and, if applicable, Office of the State Comptroller ("restricted period") to other than designated staff unless it is a contact that is included among certain statutory exceptions set forth in State Finance Law §139-j(3)(a). Designated staff, as of the date hereof, is/are identified on the first page of this *Invitation for Bid, Request for Proposal, or other solicitation document.* DOH employees are also required to obtain certain information when contacted during the restricted period and make a determination of the responsibility of the Offerer/bidder pursuant to these two statutes. Certain findings of non-responsibility can result in rejection for contract award and in the event of two findings within a 4 year period, the Offerer/bidder is debarred from obtaining governmental Procurement Contracts. Further information about these requirements can be found on the Office of General Services Website at: http://www.ogs.state.ny.us/aboutOgs/regulations/defaultAdvisoryCouncil.html

1. Has any Governmental Entity made a finding of non-responsibility regarding the individual or entity seeking to enter into the Procurement Contract in the previous four years? (Please circle):
   No Yes
   If yes, please answer the next questions:

   1a. Was the basis for the finding of non-responsibility due to a violation of State Finance Law §139-j (Please circle):
   No Yes

1b. Was the basis for the finding of non-responsibility due to the intentional provision of false or incomplete information to a Governmental Entity? (Please circle):

No Yes

1c. If you answered yes to any of the above questions, please provide details regarding the finding of non-responsibility below.

Governmental Entity:_____

Date of Finding of Non-responsibility: _____

Basis of Finding of Non-Responsibility:

_____
_____
_____
_____
_____
_____

(Add additional pages as necessary)

1d. Has any Governmental Entity or other governmental agency terminated or withheld a Procurement Contract with the above-named individual or entity due to the intentional provision of false or incomplete information? (Please circle):

No Yes

1e. If yes, please provide details below.

Governmental Entity: _____

Date of Termination or Withholding of Contract: _____

Basis of Termination or Withholding:

_____
_____
_____
_____
_____
_____

(Add additional pages as necessary)

C. Offerer/Bidder certifies that all information provided to the Department of Health with respect to State Finance Law §139-k is complete, true and accurate.

D. Offerer/Bidder agrees to provide the following documentation either *with their submitted bid/proposal or upon award* as indicated below:

With Bid	Upon Award	
☐	☐	1. A completed N.Y.S Taxation and Finance Contractor Certification Form ST-220.
☐	☐	2. A completed N.Y.S. Office of the State Comptroller Vendor Responsibility Questionnaire (for procurements greater than or equal to $100,000)
☐	☐	3. A completed State Consultant Services Form A, Contractor's Planned Employment From Contract Start Date through End of Contract Term

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_____ (Officer Signature)

_____ (Date)

_____ (Officer Title)

_____ (Telephone)

_____ (e-mail Address)

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NEW YORK STATE
DEPARTMENT OF HEALTH

NO-BID FORM

PROCUREMENT TITLE: _____FAU #_____

Bidders choosing not to bid are requested to complete the portion of the form below:

☐ We do not provide the requested services. Please remove our firm from your mailing list

☐ We are unable to bid at this time because:

_____

_____

_____

_____

❑ Please retain our firm on your mailing list.

_____
(Firm Name)

_____ _____
(Officer Signature) (Date)

_____ _____
(Officer Title) (Telephone)

_____
(e-mail Address)

FAILURE TO RESPOND TO BID INVITATIONS MAY RESULT IN YOUR FIRM BEING REMOVED FROM OUR MAILING LIST FOR THIS SERVICE.

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ATTACHMENT C-1

EARLY INTERVENTION BID DETAIL SHEET

INSTRUCTIONS:

Complete this chart to calculate the total price for the 5-year contract period. The price must be inclusive of all costs to the Department.

* The total number of activities by Type is provided for proposal evaluation purposes only. The total number of completed encounters and reviews completed may vary from these estimates.

****** Payment will be based on the actual number of encounters and reviews completed under the contract. Reviews will be paid 50% of the total payment when the onsite review is complete and 50% when a report is released.

******* The total number of hours required to modify and maintain the Monitoring Application is provided for proposal evaluation purposes only. The total number of hours completed may vary from these estimates. Payment will be based on actual number of hours completed under the contract.

******** The Administrative Services price, as described in section III (A)(2) of this RFP, may not exceed 10% of the grand total five year bid price.

ATTESTATION:

I, _____, for and on behalf of the Bidder organization(s), signify that the following information is true and accurate to the best of my knowledge and that the Bidder organization(s) agrees to abide by the terms of the approved proposal and is fully able and willing to carry out the deliverables contained herein. The prices presented in this proposal shall remain in effect for 270 days from the last day to submit a proposal.

_____ _____ _____

Signature *Title* *Date*

_____

Print Name

ATTACHMENT C-1

EARLY INTERVENTION BID DETAIL SHEET

A	B	C	D	E	F	G	H	I
		YEARS 1, 2 and 3 of Contract			**YEARS 4 and 5 of Contract**			
CONTRACT DELIVERABLES	**# of Reviews Each Year of the 5-Year Contract ***	**Price per Type of Review for first 3 Years of Contract**	**Multiply**	**Price of Reviews for first 3 Years of Contract**** (B x C x D = E)	**Price per Type of Review for Years 4 and 5 of Contract**	**Multiply**	**Price of Reviews for Years 4 and 5 of Contract**** (B x F x G = H)	**TOTALS 5-Year Prices for Contract Deliverables** (E + H = I)
Comprehensive/Priority Reviews								
Agency Encounters	128	$	x 3	$	$	x 2	$	
Individual Encounters	256	$	x 3	$	$	x 2	$	
Municipality Encounters	20	$	x 3	$	$	x 2	$	
Focused Reviews	184	$	x 3	$	$	x 2	$	
Corrective Action Plan Reviews	588	$	x 3	$	$	x 2	$	
Records Reviewed	200	$	x 3	$	$	x 2	$	
Agency Provider Application Reviews	325	$	x 3	$	$	x 2	$	
Subtotal Reviews				$			$	$
	# of Hours Each Year of the 5-Year Contract***	**Price Per Hour**		**Price of Data System for first 3 Years of Contract** (B x C x D = E)	**Price Per Hour**		**Price of Data System for Years 4 and 5 of Contract** (F x G = H)	
Modify Monitoring Application	80	$	x 3	$	$	x 2	$	
Maintain Monitoring Application & House Data	120	$	x 3	$	$	x 2	$	
Subtotal Monitoring Application & Data				$			$	$
		Price Per Year		**Admin Services Price for first 3 Years of Contract** (C x D = E)	**Price Per Year**		**Admin Services Price for Years 4 and 5 of Contract** (F x G = H)	**Admin Service Price May not exceed 10% of Grand Total**
Administrative Services ******		$	x 3	$	$	x 2	$	$
							GRAND TOTAL 5-YEAR BID PRICE	$

ATTACHMENT C-2

OPTIONAL DOH PROGRAM MONITORING BID DETAIL SHEET

INSTRUCTIONS:

Complete this chart to calculate the total price for the 5-year contract period. The price must be inclusive of all costs to the Department.

* The total number of activities by Type is provided for proposal evaluation purposes only. The total number of completed encounters and reviews completed may vary from these estimates.

****** Payment will be based on the actual number of encounters and reviews completed under the contract.

******* It is anticipated that more complex and numerous revisions to the monitoring tools will occur in years 1 to 3.

**** The Administrative Services price as described in section IV (2) of this RFP, may not exceed 10% of the grand total five year bid price.

ATTESTATION:

I, _____, for and on behalf of the Bidder organization(s), signify that the following information is true and accurate to the best of my knowledge and that the above named organization agrees to abide by the terms of the approved proposal and is fully able and willing to carry out deliverables contained herein. The prices presented in this proposal shall remain in effect for 270 days from the last day to submit a proposal.

_____ _____ _____

Signature *Title* *Date*

_____

Print Name

ATTACHMENT C-2

OPTIONAL DOH PROGRAM MONITORING BID DETAIL SHEET

A	B	C	D	E	F	G	H	I
		YEARS 1, 2 and 3 of Contract			**YEARS 4 and 5 of Contract**			
CONTRACT DELIVERABLES	**# of Days for each Activity Each Year of the 5-Year Contract ***	**Price per Type of Review for First 3 Years of Contract**	**Multiply**	**Price of Reviews for First 3 Years of Contract**** (B x C x D = E)	**Price per Type of Review for Years 4 and 5 of Contract**	**Multiply**	**Price of Reviews for Years 4 and 5 of Contract**** (B x F x G = H)	**TOTALS 5-Year Prices for Contract Deliverables** (E + H = I)
Comprehensive Reviews								
Pre-site visit Prep	100	$	x 3	$	$	x 2	$	
On-site Visits(100 visits – average 3 days each)	300	$	x 3	$	$	x 2	$	
Post-Review activities	100	$	x 3	$	$	x 2	$	
Corrective Action Plan Reviews	100	$	x 3	$	$	x 2	$	
Subtotal Reviews				$			$	$
		Price Per Year ***		**Price of Revisions for First 3 Years of Contract** (C x D = E)	**Price Per Year *****		**Price of Revisions for Years 4 and 5 of Contract** (F x G = H)	
Monitoring Tool Revisions		$	x 3	$	$	x 2	$	$
		Price Per Year****		**Price of Revisions for First 3 Years of Contract** (C x D = E)	**Price Per Year**		**Price of Revisions for Years 4 and 5 of Contract** (F x G = H)	**Admin Service Price May not exceed 10% of Grand Total**
Administrative Fees		$	x 3	**$**	$	x 2	**$**	$
							GRAND TOTAL 5-YEAR BID PRICE	$

- * The total number of activities by Type is provided for proposal evaluation purposes only. The total number of completed reviews completed may vary from these estimates.
- ** Payment will be based on the actual number of reviews completed under the contract.
- *** It is anticipated that the number of revisions to the monitoring tool will be greater in years 1-3 than in years 4 & 5.
- **** Administrative Fees include costs related to administrative staff overseeing monitoring activities, quality assurance staff and costs for travel to Albany for Department meetings as required, up to six meeting in Albany annually. Administrative fees must not exceed 10 % of the total cost of reviews plus the cost of revising the monitoring tools.

ATTACHMENT D

Early Intervention Program

PROTOCOLS FOR COMPREHENSIVE MONITORING ENCOUNTERS

I. Comprehensive Monitoring Encounters

A. Pre-Review Monitoring Activities

1. The Contractor produces a monthly schedule of providers that will receive a comprehensive and focused monitoring reviews. The Contractor will provide counties in contract with providers with the final upcoming month's schedule.

2. Thirty (30) days in advance of the monitoring review:

The Contractor calls the provider or municipality targeted for monitoring to confirm their availability, discuss the purpose of the visit, the proposed agenda, the self-assessment process, and materials needed for review. The Contractor advises the provider or municipality to have available, at the start of the monitoring review, a complete list of children served during the past year (or, if this yields less than 20 child records, the provider may go back up to the last 2 years in order to obtain up to 20 records). This is the list the Contractor will use to select a sample of child records to review during the monitoring visit. The Contractor must advise the provider that these records have to be readily available during the onsite monitoring review.

The Contractor sends a letter to the provider/municipality confirming the date of the review and sends the following documents to the provider or municipality targeted for monitoring:

- Tools for a Self-Assessment review. The provider or municipality will be asked to voluntarily complete the self-assessment record review tool to evaluate two child records selected from the same sample that the contractor will review. They will also be asked to voluntarily complete the self-assessment policy and practice review tool by reviewing their own policies/practices. The provider or municipality will be instructed to return the completed tools, if they wish to participate in this activity, to the contractor within two weeks;
- The Onsite Visit Agenda;
- The list of items to be available during the monitoring review process; and
- Health and Safety and Confidentiality attachments.

The contractor sends a letter to the Early Intervention Official (EIO) of the municipality where the provider is geographically located, inviting a municipal representative to participate in the monitoring review.

3. Fifteen (15) to thirty (30) days in advance of monitoring review:

The EIO receiving the invitation to participate in a provider monitoring review consults with other counties in contract with the provider and coordinates which county, if any, will attend the on-site monitoring review. Participation of a municipal representative during the on-site review is strictly voluntary. The counties advise the contractor which municipal representative will participate in the review. Municipal participation is recommended to be limited to (2) participants. The municipal representative attending the monitoring review may participate in the entrance, staff and exit interviews, observation of the facility, may review provider policies/procedures and child records the Contractor reviews from their own county. Counties may also observe and/or conduct their own review, based on their municipal contract with the provider.

For a municipal monitoring review, the Contractor sends letters with surveys to a randomly selected sample of all or up to 25 randomly selected providers who contract with the municipality (whichever is less). The survey should be completed and returned prior to the on-site review. For a provider monitoring review, the Contractor sends letters with surveys to all municipality(s) that contract with the provider. Completion of the surveys is voluntary. The survey results will be used for preparation and background information, to determine if there are any problems or issues that the review team should consider while conducting the on-site reviews, The survey data will not be reported in the monitoring report, but will be used as background information for the review teams and may be used for statewide data analysis.

4. Up to fifteen (15) days in advance of the monitoring review:

The Department will provide the Contractor with information regarding outstanding problems concerning particular providers and municipalities targeted for monitoring. Information is provided so that the contractor can focus on any outstanding issues during the monitoring review process. This information will be provided from the EI Program's issue files, from the system complaint database and from the municipal monitoring file system. Any previous corrective action plans for providers and municipalities will also be provided to the contractor.

Periodic conference calls with municipal representatives and the Contractor may also be scheduled to review county concerns with the provider, any previous Corrective Action Plans, etc.

The Contractor reviews all Self-Assessment forms returned by providers and municipalities who are targeted for monitoring.

The Contractor reviews returned survey responses from providers/municipalities.

All information obtained from Self-Assessments and surveys is reviewed by the Contractor to inform the reviewers prior to conducting on-site monitoring.

5. One (1) week in advance of the monitoring review:

The Contractor confirms the on-site monitoring visit via phone with the provider or municipality targeted for monitoring.

The Contractor provides the start time for the monitoring review to the municipal representative (if they will be attending).

B. On- Site Review Activities

1. The Contractor conducts the on-site monitoring review at the provider site or municipality's main place of business. If an individual provider delivering only home and community services, the review may be conducted at a neutral site. All of the activities per the agenda will be completed. These include: entrance and exit interviews with the EI Official or Manager (municipality), or Agency Director (agency provider) or individual provider; staff interviews; review of children's records; observation of facility; and review of policy/procedure manuals/materials, personnel files, and fiscal documentation.

When the review team arrives at the site, the provider provides the Contractor with a complete list of children served during the past year (or, if this yields less than 20 child records, all records of children served in the last 2 years). Using a methodology proposed by the Contractor and approved by the Department, the Contractor will use this list to select a sample of up to 20 child records to review during the monitoring visit.

For a municipal review, the municipality provides the Contractor with a complete list of children served during the past year. Using a methodology proposed by the Contractor and approved by the Department, the Contractor will use this list to select a sample of up to 30 child records to review during the monitoring visit. The team may request additional records of whatever type is needed if, during their review of the sample, any irregularities are found or if they need to confirm or clarify findings.

The review will include an examination of all documentation, including fiscal records, associated with the selected sample. The team may request additional records of whatever type is needed if, during their review of the sample, any irregularities are found or if they need to confirm or clarify findings.

The Department reserves the right to select other sampling methodologies over the period of the contract.

The Contractor completes appropriate monitoring tools and enters monitoring findings into an EI monitoring data system.

2. For provider reviews, if municipal representatives accompany Contractor reviewers, they may participate in the entrance and exit interviews, staff interviews, and observation of the facility. The representative may be asked to leave the immediate area where child records are being reviewed when records for children from another municipality are being discussed or reviewed by the Contractor team members. The review of child records and policies and procedures, etc. should be coordinated with the municipal representative to avoid duplication of

effort and to ensure the Contractor monitoring schedule and agenda are maintained. The municipal representatives may complete a review of municipal contract requirements. The Contractor review team and county representative should discuss their findings, in regard to their respective reviews, prior to reporting out to the provider during the exit conference. The Contractor team is responsible for presenting general preliminary determinations of State regulatory deficiencies or areas needing improvement. The municipal representative is responsible to present concerns with contract-specific requirements.

C. Post Review Monitoring Protocol

1. Immediate Notification of Health & Safety Issues

Within 36 hours of the review, or sooner, the Contractor notifies the Early Intervention Program, by phone and/or email, of serious situations identified during monitoring which may immediately compromise the health and safety of children. This includes, but is not limited to:

- a dangerous physical environment
- service delivery by unqualified personnel.

The Contractor will provide as specific information as possible to the Department regarding these serious concerns. Within one week of the review, the Contractor will send a weekly report (in spreadsheet format) of any health and safety finding, regardless of the potential seriousness. The Contractor will work closely with the Department to ensure the monitoring reports for providers or municipalities with health and safety findings are produced timely and contain appropriate notice of the health and safety issue.

In addition to including health and safety findings in the monitoring report, the Early Intervention Program is responsible for putting the provider on notice and contacting municipalities in contract with the provider when certain health and safety deficiencies are identified. The Department will work with those municipalities to address the deficiencies, including transfer of children if necessary; reporting unqualified providers or other licensing issues to the State Education Department; and taking any other appropriate enforcement actions.

2. Report Release

Within 30 calendar days of the last day of the visit, the Contractor:

- completes drafts of all provider and municipal monitoring reports which identifies variances of practices at multiple service delivery sites operated by the same provider;
- sends all draft municipal monitoring reports to the Department Early Intervention Program for review and approval before release;
- sends any draft provider monitoring reports with serious health and safety findings, or other findings identified by the Department, to the Early Intervention Program, for review and approval before release.

Within 45 calendar days of the last day of the visit, the Contractor:

- releases provider monitoring reports to the provider.

The Contractor will exchange spreadsheet reports with the Department that contain draft report comments or statements for the Department to approve prior to release by the Contractor.

All draft and final reports will be contained in the Contractor's monitoring data system, which must be accessible to designated Early Intervention Program staff.

Upon release of provider monitoring reports, the Contractor is responsible for sending a copy of the report, with a Department-approved letter, to each municipality in contract with the provider.

Upon release of municipal monitoring reports, the Contractor is responsible for sending a copy of the report, with a Department-approved letter, to the regional office assigned to the municipality.

If the report has no findings, the provider/municipality is informed: there are no findings; if they wish, they may provide comments that will become part of the record, and in 30 days from the date the monitoring report was sent to the provider, the report and any comments will be considered final and may be subject to the Freedom of Information Law. A copy of this letter is sent to each municipality in contract with the provider (for provider reviews), or assigned regional office (for municipal reviews).

If a Corrective Action Plan (CAP) is required as a result of findings identified during the review, the report will contain Department-approved instructions for providers and municipalities to complete and return their CAP and any comments to the Contractor.

Copies of any letters exchanged with the provider or municipality are sent to the Department.

D. Receipt of Corrective Action Plans

1. When a provider report requires a CAP, the provider has 45 calendar days from receipt of the monitoring report to develop and submit a CAP to the Contractor. Providers are directed to send a copy of the CAP to each municipality with whom they contract at the same time their CAP is sent to the contractor. Municipalities in contract with the provider are instructed to obtain a copy of the CAP from the provider, if one is not sent to them, and send comments they have regarding the provider CAP to the Contractor within 15 calendar days of receipt of the CAP.

When a municipal report requires a CAP, the municipality has 60 calendar days from receipt of the monitoring report to develop and return the CAP. Municipalities are directed to send a copy of the CAP to the assigned regional office at the same time its CAP is sent to the Contractor.

2. The Contractor may grant a provider or municipality a 15-day extension, in writing, to submit a CAP for extenuating circumstances. The Contractor is responsible to track receipt and extensions of all provider and municipal CAPs and report this to the Department monthly.

3. The Contractor receives all provider and municipal CAPs and provider CAP feedback from municipalities. Using a standardized review tool approved by the Department, the Contractor screens CAPs received to ensure all essential components are included. If components are missing or do not meet the screening requirements, the Contractor immediately corresponds with the provider/municipality to request that they submit corrections or additions within 15 calendar days. The Contractor reports CAP screening data to the Department monthly.

4. Within 7 days of a successful screen, the Contractor forwards municipal CAPs to the Department for review and follow up.

5. If a provider or municipality fails to submit the required CAP to the Contractor, the Contractor will follow up, in writing, with the provider. The Contractor will direct submission of the CAP within 10 calendar days or direct the provider/municipality to request an extension.

6. If the provider or municipality did not respond to the initial request for a CAP and the three follow up attempts by the Contractor, the Department sends a letter informing the provider/municipality that the Department may now take additional enforcement action. Counties which contract with the provider will be notified that the provider failed to submit a CAP and will be advised to consider taking contractual action against the provider.

F. Review/Approval of Corrective Action Plans

After a provider CAP passes the screen, the Contractor reviews the CAP, including all materials submitted with the CAP. If the materials are voluminous, the Department will work with the Contractor to determine which information may be considered extraneous and can be excluded from the CAP review. The Department is available for technical assistance to the Contractor staff during their CAP review process.

The Contractor is responsible for reviewing the provider's proposed corrective actions for each indicator with a finding. Using a format and consistent language approved by the Department, the Contractor then develops a document with individualized responses to the provider's proposed corrective actions for each indicator.

1. Accepted corrective action

When the provider's proposed corrective actions for an indicator demonstrate a clear understanding of program requirements with steps that will result in effective correction and, for an agency provider the CAP recognizes that staff or contractors acting on behalf of the agency provider must be made aware of and carry out the new/revised policies and procedures, the Contractor will consider the CAP response for the indicator "accepted" and will insert appropriate Department-approved language into the CAP response document for that indicator.

2. Partially Acceptable corrective action

When the provider's proposed corrective actions for an indicator demonstrate a basic understanding of program requirements, and/or the proposed corrective actions need only minor correction or additions to be considered accepted, the Contractor will consider the CAP response

for the indicator "partially acceptable" and will insert appropriate Department-approved language into the CAP response document for that indicator. The indicator language includes feedback to clarify program regulations, statute, or guidance and informational worksheets with criteria for those findings may be provided to assist the provider to revise their corrective action to include all relevant criteria. Resubmission for indicators found "partially accepted" is not required

3. Needs Correction corrective action

When the provider's proposed corrective actions for an indicator fail to demonstrate even a basic understanding of program requirements, and/or the proposed corrective actions need major correction or additions to be considered accepted, the Contractor will consider the CAP response for the indicator a "needs correction" and will insert appropriate Department-approved language into the CAP response document for that indicator. The indicator language includes feedback to clarify program regulations, statute, or guidance and informational worksheets with criteria for those findings may be provided to assist the provider to revise their corrective action to include all relevant criteria. Resubmission is required for indicators that need correction.

The Contractor must be available to provide technical assistance to providers to correct their resubmissions. Resubmitted CAPs will be sent to the Contractor to be screened, tracked, re-reviewed. Should a 2nd CAP response result in another "needs correction" determination for one or more indicators, the provider will be directed to resubmit directly to the Department for follow up and possible enforcement action.

If a provider submits substantive comments with their CAP regarding the monitoring process, or challenges the contractor's findings, the Contractor forwards copies of that documentation to the Department Early Intervention Program for technical assistance. This may result in the provider receiving a customized letter with their CAP response, acknowledging their observations of the monitoring process or accepting or disagreeing with their comments regarding the findings.

Within 45 days after a provider CAP is successfully screened, the Department sends the CAP response to the provider, with a letter signed by the Director of the Early Intervention Program which notifies the provider that the CAP is accepted in full; partially acceptable without need for a resubmission; or that one or more indicators need correction and additional corrective actions must be resubmitted for those indicators. When the letter indicates the CAP does not require resubmission (all indicators have been found to either be "accepted" or "partially acceptable"), the letter also informs the provider that the monitoring report, CAP and any comments received are considered final, public documents, which may be subject to the Freedom of Information Laws. The Department also sends copies of the CAP response and letter to municipalities in contract with the provider. The Contractor forwards the original provider CAP, copies of the draft CAP response, any provider comments, and CAP feedback from municipalities in contract with the provider to the Department.

The Department follows a similar protocol when reviewing/approving a municipal CAP.

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ATTACHMENT E

Early Intervention Program

PROTOCOLS FOR FOCUSED MONITORING ENCOUNTERS

A focused monitoring review is a systematic review of a provider or municipality to determine if the provider or municipality has (1) complied with the terms of their Corrective Action Plan (CAP), (2) remediated health and safety or unqualified personnel issues, or (3) addressed other specific issues identified by the Department.

Each quarter, the Department provides to the Contractor a listing of agency and individual providers or municipalities targeted for a focused monitoring review.

A focused monitoring review will be conducted by the same review teams conducting comprehensive monitoring encounters, who will follow the following protocol:

A. Pre-Review Monitoring Activities

1. Up to fifteen (15) days in advance of the focused review:

Wherever possible, the Contractor will give the municipality or provider notice in as short an amount of time as possible prior to the focused review, not to exceed 15 calendar days' notice. At the Department's discretion, there may be instances where additional notice will be given or, there may be no prior notice at all (e.g. to follow-up on health and safety issues involving instances of imminent danger).

When notice is given, the Contractor will discuss the review, proposed agenda, and materials to be available during the review. For provider focused reviews, the Contractor will extend an invitation to the municipality in contract with the provider to attend the focused review, via telephone and facsimile follow up.

B. On-Site Monitoring Activities

The review is conducted at one of the provider's sites, or at the municipality's offices. For an individual provider, the review may be conducted at a neutral location or the individual provider's home or office; whichever is most appropriate for the provider's practice.

Depending on the reason for the Focused Review, the review may include some or all of the following activities:

- Entrance and exit interviews with the Agency/Program Director, or for municipalities, the EIO and EI Manager;
- Interviews with selected staff;
- Spontaneous review of current child records;
- Observations within the facility;
- Review of written policies/procedures;
- Review of personnel files; and,

- Completion of appropriate monitoring tools or sections of monitoring tools.

Focused reviews are conducted to follow up on health and safety issues identified during a comprehensive monitoring review, and to follow up on implementation of corrective actions delineated in a provider's CAP. The focused review is conducted, specific to the circumstances or "triggers" which have targeted the municipality or provider for the review. Examples:

- A focused review of a provider previously cited for unqualified personnel issues may consist of a review of a large number or all personnel records and a review of all policies/procedures related to hiring and process to periodically check credentials;
- A focused review of a provider found to be in violation of the majority of evaluation indicators may consist of a review of evaluation records, interviews with MDE team members; and completion of all indicators related to evaluations in the Child Record Review Tool and the Policy Practice Review Tool.

It is projected that the onsite portion of a follow-up monitoring review will take an average of 2-3 hours for an individual provider and up to 2 days for an agency or municipality.

C. Post-Review Activities

Immediately, upon completion of the review, the Contractor will notify the Department of issues that have the potential for further action and/or sanctions. These issues may include, but are not limited to:

- New health and safety or unqualified personnel issues;
- Lack of remediation of previously cited health and safety or unqualified personnel issues;
- Poor or lack of implementation of a previously accepted CAP.

D. Report Release

1. Within 30 calendar days of the last day of the visit, the Contractor:

    - completes drafts of all provider and municipal focused monitoring reports, using the format approved by the Department;
    - notifies the Department the draft report is available for review and comment before release;
    - follows the same protocol for draft provider monitoring reports with serious health and safety findings as the comprehensive monitoring protocol, including the exchange of spreadsheet reports for comment and approval by the Department prior to release by the Contractor.

2. Within 45 calendar days of the last day of the visit and after Department review and approval, the Contractor releases focused monitoring reports to the provider or municipality.

All draft and final focused monitoring reports will be maintained in the Contractor's monitoring data system, which must be accessible to designated Department staff.

Upon release of provider focused monitoring reports, the Contractor is responsible for sending a copy of the report, with a Department-approved letter, to each municipality in contract with the provider.

Upon release of municipal focused monitoring reports, the Contractor is responsible for sending a copy of the report, with a Department-approved letter, to the regional office assigned to the municipality.

If the focused review results in no findings, the provider/municipality is informed in writing that there are no findings, and invited to provide comments that will become part of the record. In 30 days from the date the focused monitoring report was sent to the provider, the report and any comments will be considered final and may be subject to the Freedom of Information Law. A copy of this letter is sent to each municipality in contract with the provider (for provider reviews), or assigned regional office (for municipal reviews).

If another Corrective Action Plan (CAP) is required as a result of findings identified during the focused review, the report will contain Department-approved instructions for providers and municipalities to complete and return their CAP and any comments to the Contractor.

Copies of any letters exchanged among the provider or municipality and Contractor are sent to the Department.

E. Receipt of Corrective Action Plans for Focused Monitoring Reviews

1. When a provider or municipal focused monitoring report requires a CAP, the provider or municipality has 45 calendar days from receipt of the focused monitoring report to develop and submit a CAP to the Contractor. Providers are directed to send a copy of the CAP to each municipality with whom they contract at the same time their CAP is sent to the Contractor. Municipalities in contract with the provider are instructed to obtain a copy of the CAP from the provider, if one is not sent to them, and send comments they have regarding the provider CAP to the Contractor within 15 calendar days of receipt of the CAP.

Municipalities are directed to send a copy of the CAP to the assigned regional office at the same time its CAP is sent to the Contractor.

2. The Contractor is responsible to track receipt of all provider and municipal focused review CAPs and report this data to the Department monthly.

3. The Contractor receives all provider and municipal focused review CAPs and provider CAP feedback from municipalities. Using a standardized review tool approved by the Department, the Contractor screens CAPs received to ensure all essential components are included. If components are missing or do not meet the screening requirements, the Contractor immediately corresponds with the provider/municipality to request that they submit corrections or additions within 15 calendar days. The Contractor reports CAP screening data to the Department monthly.

4. The Contractor immediately forwards municipal focused review CAPs that pass the initial screen to the Department for review and follow up.

5. If a provider or municipality fails to submit the required focused review CAP to the Contractor, the Contractor will follow up, in writing, by certified mail, return receipt requested. The Contractor will direct submission of the focused review CAP within 10 calendar days or the file will be referred to the Department for follow-up action. A copy of the certified letter, with receipts, is sent to the Department and, for providers, to each municipality in contract with the provider. If the provider or municipality did not respond to the initial request for a CAP and the follow up certified letter from the Contractor, the Department sends a letter informing the provider/municipality that the Department may now take additional enforcement action. Counties which contract with the provider will be notified that the provider failed to submit a focused review CAP and will be advised to consider taking contractual action against the provider.

F. Review/Approval of Provider Focused Review Corrective Action Plans

After a provider focused review CAP passes the screen, the Contractor reviews the CAP, including all materials submitted with the CAP. If the materials are voluminous, the Department will work with the Contractor to determine which information may be considered extraneous and can be excluded from the CAP review. The Department is available for technical assistance to the Contractor staff during their CAP review process.

The Contractor is responsible for reviewing the provider's proposed corrective actions for each indicator with a finding. Using a format and consistent language approved by the Department, the Contractor then develops a document with individualized responses to the provider's proposed corrective actions for each indicator.

1. Accepted corrective action

When the provider's proposed corrective actions for an indicator demonstrate a clear understanding of program requirements with steps that will result in effective correction and, for an agency provider the CAP recognizes that staff or contractors acting on behalf of the agency provider must be made aware of and carry out the new/revised policies and procedures, the Contractor will consider the CAP response for the indicator "accepted" and will insert appropriate Department-approved language into the CAP response document for that indicator.

2. Partially Acceptable corrective action

When the provider's proposed corrective actions for an indicator demonstrate a basic understanding of program requirements, and/or the proposed corrective actions need only minor correction or additions to be considered accepted, the Contractor will consider the CAP response for the indicator "partially acceptable" and will insert appropriate Department-approved language into the CAP response document for that indicator. The indicator language includes feedback to clarify program regulations, statute, or guidance and informational worksheets with criteria for those findings may be provided to assist the provider to revise their corrective action to include all relevant criteria. Resubmission for indicators found "partially accepted" is not required

3. Needs Correction corrective action

When the provider's proposed corrective actions for an indicator continue to fail to demonstrate even a basic understanding of program requirements, and/or the proposed corrective actions need major correction or additions to be considered accepted, the Contractor will consider the focused review CAP response for that indicator a "needs correction" and will insert appropriate Department-approved language into the CAP response document for that indicator. The indicator language includes feedback to clarify program regulations, statute, or guidance and informational worksheets with criteria for those findings may be provided to assist the provider to revise their corrective action to include all relevant criteria. Resubmission is required for indicators that need correction.

The Contractor must be available to provide technical assistance to providers to correct their focused review CAP resubmissions.

When their proposed corrective action in response to a focused review for any indicator continues to be deemed "needs correction," providers will be directed to resubmit another CAP directly to the Contractor. The Contractor will again screen, track and review the resubmissions, inform the Department of the identity of such providers, and refer the resubmissions to the Department for follow up and possible enforcement action.

If a provider submits substantive comments with their focused review CAP regarding the focused review monitoring process, or challenges the Contractor's findings, the Contractor forwards copies of that documentation to the Department Early Intervention Program for technical assistance. This may result in the provider receiving a customized letter with their CAP response, acknowledging their observations of the monitoring process or accepting or disagreeing with their comments regarding the findings.

The Department sends focused review CAP responses to providers, with a letter signed by the Director of the Early Intervention Program, notifying providers that their focused review CAP is accepted in full; partially acceptable without need for a resubmission; or that one or more indicators need correction and additional corrective actions must be resubmitted for those indicators. When a letter indicating the CAP does not require resubmission (all indicators have been found to either be "accepted" or "partially acceptable"), the letter also informs the provider that the monitoring report, CAP and any comments received are considered final, public documents, which may be subject to the Freedom of Information Laws. The Department sends copies of the focused review CAP response and letter to municipalities in contract with the provider. The Contractor forwards the original provider focused review CAP, copies of the draft focused review CAP response, any provider comments, and focused review CAP feedback from municipalities in contract with the provider, to the Department.

The Department follows a similar protocol when reviewing/approving a municipal focused review CAP.

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EI Adm Contract Requirement	Indicator	Art. 6 requirement	Cluster ADM=Admin & Oversite CF=Child Find FC=Family Cent'd S=SvcDeliv & NatEnv T=Transition	Main Indicator GREEN = new	Sub Indicators	REVIEW PROCESS *if county is the service provider of record on the IFSP, validation should occur thru record review
		x		**The EIO identifies & locates potentially eligible children within the municipality**		
x	MP01		CF		A Child Find plan is in place & builds on community resources	Interview; review policies & procedures, schedules, calendars, training announcements, etc.
x	MP02		CF		Municipality ensures that children involved in substantiated cases of child abuse and neglect and those affected by illegal substance abuse are included in child find efforts.	Review muni child find plan
	MP03		CF		Outreach/education activities are conducted to ensure referrals of infants or toddlers suspected of having a developmental delay or disability or at risk of developmental delay are received from multiple sources, including from other county programs.	Interview; review policies & procedures, schedules, calendars, training announcements, etc.
				The EIO accepts referrals of infants or toddlers suspected of having a developmental delay or disability or at risk children from primary referral sources		
x	MP04	x	CF		There is a single point of entry to receive referrals	Interview; review policies & procedures, content of outreach materials, description of unit or staff responsibilities, 1-800 referral lines, etc.
	MR01		CF		When referral point of entry is PH Officer, (s)he transmits referral info to the local EI Program within 2 working days	Interview, review policies & procedures
x	MP06		CF		There is a procedure to track and follow up at risk children	Interview; review policies & procedures

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x	MR04	x	CF		Muni ensures the Parent Guide is sent to the parent by mail or other suitable means	If EIO mails Parent Guide, conduct record review; if SCs distribute Parent Guide, description of process EIO follows to ensure contracted ISCs and county ISCs* do this
				The EIO ensures that each referred child/family has an initial service coordinator to inform them about rights, responsibilities and options under the EIP and to secure information to facilitate an evaluation to determine eligibility and a timely IFSP		
x	MR02		CF		An ISC is promptly designated for children suspected of having a disability or delay	Record review
x	MR03	x	CF		Written notice of designation of an ISC is sent to the parent (and for children in care, the commissioner of social services or designee)	Record review - Muni should have no prescreening policy
x				**The municipality ensures its county ISCs and contracted ISC providers complete required ISC activities.**		
			CF		The municipality ensures its county ISCs and contracted ISCs provide parents with required information regarding the EIP.	Interview; review policies & procedures, schedules, calendars, training announcements, etc.
			CF		The municipality ensures its county ISCs and contracted ISCs arrange evaluations so that children receive a timely evaluation to determine eligibility.	Interview; review policies & procedures, schedules, calendars, training announcements, etc.

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			CF		The municipality ensures its county ISCs and contracted ISCs complete activities so that a timely IFSP is developed.	Interview; review policies & procedures, schedules, calendars, training announcements, etc
			CF	**The EIO ensures that the initial evaluation to determine eligibility is conducted appropriately and timely**		
	MP20		CF	***No regulatory requirement***	There are no waiting lists for evaluations	Interview; review policies & procedures; compare to county 45-day data provided by SDOH
	MR09		FC		Muni ensures evaluators obtain parent consent before conducting an evaluation.	Interview; policies & procedures; description of process EIO follows to ensure contracted evaluators and county evaluators* do this
	MR08		FC		The eval report was received prior to the initial IFSP meeting	Record review
x	MR		FC		Written & oral eval summaries use dominant language, and are understandable to the parent	Record review
x	MR07	x	CF		When appropriate, a second evaluation or component to determine initial eligibility is authorized, or certain supplemental evaluation and assessment procedures are authorized. Reasons are documented in the IFSP	Record review

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		x	FC	**The municipality contracts with evaluation providers that conduct the evaluation per regulatory requirements.**		Description of process EIO follows to ensure contracted evaluators and county evaluators* do this; provider-specific monitoring data to determine county follow up
			CF		The multidisciplinary (MDE) team included at least 2 qualified personnel from different disciplines and one specialist in the area of suspected delay or disability.	Record review
x			CF		The MDE included all 5 domains and considered the unique needs of the child.	Record review
			CF		The MDE included a health assessment.	Record review
			CF		As appropriate, and with parent consent, the evaluation included findings from other current evaluations.	Record review
			CF		The evaluation was based on standardized, valid, norm-referenced instruments. Informed clinical opinion was used when instruments were not appropriate; clinical opinion refers back to required eligibility criteria.	Record review
			CF		No single procedure or instrument used as sole indicator of eligibility.	Record review
			FC		The evaluation included a parent interview about the family's resources, priorities and concerns related to the child's development.	Record review
			CF		The eveluation report and summary includes a statement of the child's eligibilty, including a diagnosed condition and/or developmental delay.	Record review
			CF		The evaluation summary provided to the parent and the report and summery submitted to the EIO, timely so the initial IFSP meeting occurs within 45 days of the child's referral.	Record review

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			CF		The municipality contracts with evaluation providers that participate in IFSP meetings.	Description of process EIO follows to ensure contracted evaluators and county evaluators* do this; provider-specific monitoring data to determine county follow up
				The EIO ensures IFSPs are developed in a timely manner, using a team approach		
			CF		When an evaluator determines a child is eligible, the parents' and child's social security numbers are obtained by the EIO	Record review
	MR14	x	CF		When an evaluator determines a child is eligible, an initial IFSP meeting is convened within 45 days of the child's referral .	Record review
	MR15		CF		Reason(s) why initial IFSP was held after the required 45-days is documented in child's record and the reason code is recorded in the KIDs system and other data systems required by the SDOH.	Record review, KIDs system report
x	MP34		FC		IFSP meetings are conducted in settings & times convenient to parent	Interview; policies & procedures
	MR12	x	CF		Timely written notice of IFSP meetings is sent to required participants	Record review
x	MR16				Required participants attend IFSP meetings	Record review
	MR33	x	FC		Dates of 6-month IFSP reviews authorized by the EIO were timely	Record review
x	MR34	x	FC		Dates of annual IFSP evaluations authorized by the EIO were timely	Record review
	MP35		FC		Municipality ensures interim IFSPs are available when needed	Interview; policies & procedures
		x	FC	**The EIO ensures IFSPs for each eligible child and family are complete**		
	MR17		FC		IFSPs contain a statement of child's present level of functioning	Record review

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	MR18		FC		With parent consent, IFSPs contain a statement of familly's strengths, priorities and concerns	Record review
	MR19		FC		IFSPs contain a statement of major outcomes expected to be achieved, criteria and procedures used to determine progress	Record review
	MR28		FC		IFSPs contain the name of the ongoing service coordinator chosen by the parent	Record review
	MR20		FC		IFSPs contain a statement of services, including transportation, with frequency, intensity, location and method of delivery for each	Record review
x	MR26		FC		IFSPs contain projected dates for initiation and duration of services	Record review
	MR21		FC		IFSPs contain a statement of natural environments in which services will be appropriately provided	Record review
	MR22		FC		IFSP authorized by EIO contained reasons why IFSP team agreed that child will not receive services with typically developing peers	Record review
x	MR32		FC		With parent consent, IFSPs contain steps to support the potential transition of the child out of EI , and include the date EIP services end and, if applicable, the date preschool services will begin	Record review
x	MR25		FC		IFSPs contain a statement of other public programs & benefits the child/family may be eligible for	Record review
	MR27		T		IFSP services can be linked back to the eval report	Record review
	MP11	x	FC	**The EIO ensures that each eligible child has an ongoing service coordinator to coordinate and monitor implementation of the IFSP during the child's participation in the EIP**		

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			FC		Ongoing service coordinators report unresolved problems regarding delivery of IFSP services to the EIO	Interview; contract requirements; description of process EIO follows to ensure contracted OSCs and county OSCs* do this;
x	MP09		FC		Ongoing service coordinators complete required activities to monitor and implement IFSPs so that children make progress and parent concerns are appropriately addressed.	Interview; contract requirements; description of process EIO follows to ensure contracted OSCs and county OSCs* do this;
x			S	**The EIO ensures services are delivered appropriately**		
	MP73		FC		Family culture & dominent language are considered when services are authorized	Interview; policies & procedures
x	MP31	x	FC		Families are encouraged to participate in services to extent they are comfortable	Interview; policies & procedures
				The EIO ensures 'children in care' have equal access to evaluations, IFSPs and EI services, using qualified surrogate parents when appropriate		Foster care children must be included in record sample
			ADM		Written policies and procedures regarding children in care ensure they have equal and timely acces to evaluations, IFSPs and EI services, including using qualified surrogate parents when appropriate	Written policies and procedures Record review
		x	ADM		Reasonable efforts are made to discover the whereabouts of a parent before determining the need for a surrogate parent.	Record review + include in written policy
	MR37		ADM		When necessary, consent to appoint a surrogate parent is obtained from birth/adoptive parent	Record review + include in written policy
	MR38	x	ADM		Regulatory requirements are followed when appointing, removing and replacing a qualified surrogate parent	Record review + include in written policy

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	MR40		ADM		IFSP & relevant documentation is transmitted to municipality of residence for children in care, including documentation for change to code 35.	Record review + include in written policy
		x	S	**The EIO ensures parents are fully informed, in their dominant language, about the rights and entitlements afforded them under the EI Program**		
			ADM		Policy/procedures are in place to inform parents, in their dominant language, about their rights and entitlements	Written policies and procedures
	MP81	x	ADM		Parents are notified, in writing, of their right to access & amend child's record annually (per EI regulations); copies are provided at no more than the specified fee	Record review + include in written policy
	MR50	x	ADM		Written notice is sent to the parent at least 10 working days before EIO proposes or refuses to initiate or change an evaluation, service setting or services	Record review + include in written policy
	MR51		ADM		Written notices contain details regarding the action being proposed, reasons and how to pursue due process procedures should the parent disagree	Record review + include in written policy
x	MR52		ADM		Written notices use understandable and dominant language, unless not feasible	Record review + include in written policy
	MR49		ADM		If alternative to written notice is used (oral, sign, Braille, etc.), there is written evidence in the record	Record review + include in written policy
		x	ADM		Written consent from the parent is obtained prior to the provision of EI services.	Record review
x	MR45	x	ADM		Written consent is obtained so the muni can provide for the confidential exchange of information among parent and EI providers.	Record review
	MR46	x	ADM		The parent is informed of their right to refuse to sign a general release and offered the opportunity to sign a selective release.	Record review; examination of release/consent forms

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x	MR47		ADM		Parent is informed of their right to revoke a general release at any time and this information is included on the release form.	Record review; examination of release/consent forms
			ADM	**The EIO ensures disputes regarding eligibility or services are resolved timely and appropriately**		
	MP71		ADM		Procedures are in place to resolve problems raised by families and providers	Interview; policy & procedures
	MP49	x	ADM		Policy/procedures ensure that parents can access & receive mediation to settle unresolved disputes according to the procedures outlined in EI regulations	Written policy & procedures
	MR54	x	ADM		When there is an unresolved disagreement about eligibility or IFSP services or the parent requests such information, written notice is sent to parents about their right to due process through mediation & impartial hearing	Record review + include in written policy
	MR57	x	ADM		Parent consent is obtained to transmit info to community dispute resolution center	Record review + include in written policy
	MR56		ADM		Timely written notice is sent to community dispute resolution center of request for mediation from the parent or EIO	Record review + include in written policy
	MR58	x	ADM		Timely written notice is sent to the parent when county will use an attorney during mediation	Record review + include in written policy
			ADM		EIO ensures EIO & SC modified IFSP based on mediation within five working days after receipt of mediation agreement	Record review + include in written policy
	MR61		ADM		When mediation does not resolve all issues, parent isinformed, in a timely manner, of their right to and procedures for an impartial hearing	Record review + include in written policy
	MP50	x	ADM		Policy/procedures ensure that parents can access & receive an impartial hearing to settle disputes according to the procedures outlined in EI regulations	Record review + include in written policy

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	MR62		ADM		Within 5 days of receipt of the notice of impartial hearing request, written notice is sent to parent that county will use an attorney during impartial hearing	Record review + include in written policy
	MR63		ADM		IFSP is modified based on the impartial hearing decision within 5 working days after receipt of written or oral decision	Record review + include in written policy
	MR64	x	ADM		EIO ensures that during pendency of mediation or impartial hearing or appeal, either previous IFSP or sections of IFSP not in dispute are implemented	Record review + include in written policy
				The EIO ensures children are appropriately discharged from EI		
	MP39	x	T		Policy/procedures are in place to ensures steps to support children's transition to either preschool services or other ea.childhood programs when they leave the EI Program	WRITTEN POLICY
	MR39	x	T		The local commissioner of social services or designee is notified of the child's potential transition and invited to participate in all transition planning activities.	Record review + include in written policy
		x	T	`	For children thought not to be eligible for preschool services, a transition plan to other appropriate early childhood and supportive services is developed and parents are assisted to access such services	Record review + include in written policy
x		x	T		For children thought to be eligible for preschool services, a written referral is sent at least 120 days before the child is first eligible for these services to the child's school district asking the school district to evaluate the child to determine if (s)he needs special education services. The notification and the referral to the school district may be the same as long as all required information for both is included .	Record review + include in written policy
x	MR44	x	T		For children thought to be eligible for preschool services, a transition conference is arranged at least 90 days before the child is first eligible for services or the child's third birthday, whichever is first.	Record review + include in written policy

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x		x	T		The chair of the CPSE of the child's school district must be invited to the transition conference	Record review + include in written policy
x		x	T		Parents are informed regarding all aspects of transition, their rights and responsibilities regarding the EI and preschool systems. This may be done at the transition conference.	Record review + include in written policy
		x	T		Information concerning the transition procedure is reviewed with the parent and parent consent is obtained for the transfer of pertinent records per EI regulations.	Record review + include in written policy
		x	T		When requested by the parent, only children determined to be eligible for services under Section 4410 of the Education Law prior to their 3rd birthday receive EI services contained in an IFSP beyond their 3rd birthday.	Record review + include in written policy
	MP67	x		**The EIO ensures that services are delivered in a manner that protects the health and safety of eligible children.**		
			ADM		Contracted providers maintain a safe physical environment within a facility when they deliver EI services	WRITTEN POLICY + MONITOR
			ADM		Contracted providers practice in a way that protects the health and safety of children during the delivery of services	WRITTEN POLICY + MONITOR
			ADM		Contracted providers are in compliance with other applicable State and local standards that apply to their practice	WRITTEN POLICY + MONITOR

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	MP84		ADM		Municipality appropriately screens individual providers through the SCR	WRITTEN POLICY + MONITOR
			ADM		Contracted providers conduct SCR screening of their employees and contractors	WRITTEN POLICY + MONITOR
			ADM		Municipality follows up on health & safety immediate remediation by providers	WRITTEN POLICY + MONITOR
				The EIO ensures that services are delivered by trained, qualified service providers		
x			ADM		Municipality contracts with individual providers who are qualified and agency providers who use qualified personnel	Interview; policies & procedures; MONITOR
			ADM		Municipality contracts with individual and agency providers who participate in periodic training	Interview; policies & procedures; MONITOR
		x	ADM		Municipality contracts with providers that use qualified service coordinators who participate in service coordination training	Interview; policies & procedures; MONITOR
x		x	ADM		County accepts notifications from the Department of Health regarding provider disqualifications, notifies the parents of any child receiving services from the provider, and makes arrangements for provision of services by a qualified provider.	Interview; policies & procedures; MONITOR
	MP69		ADM	**no regulatory requirement. Requirement for SC to attend DOH SC training only**	Municipality promotes EI training to providers	Interview; policies & procedures; contract requirements; promotional
				The EIO ensures that EI records are maintained in a confidential manner		

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x	MP48	x	ADM		County ensures that personally identifiable data, information, or records (including electronic information), pertaining to an eligible child are not disclosed by the county , except in accordance with Title 34 of the Code of Federal Rules Part 99, Sections 300.560 through 300.576 (with the modification specified in Section 303.5(b) of Title 34 of the Code of Federal Regulations) and Part 303 of Title 34 of the Code of Federal Regulations.	Interview; policy & procedures
	MP66	x	ADM		Muni ensures that contracted providers follow confidentiality procedures	MONITOR
x				**The EIO convenes a Local Early Intervention Coordinating Council to provide input to the local EI program**		
	MP76	x	ADM		LEICC holds at least 2 meetings each year	Review minutes; policies and procedures
x	MP79	x	ADM		LEICC submits required annual report to the EIO regarding the adequacy of the EI system	Review annual reports
				The EIO fulfils his/her obligations regarding ensuring that services are authorized, delivered and billed appropriately		
	MP70	x	S		Services are only delivered to eligible children.	Record review; interview
x	MP28		S		Established criteria is used when authorizing respite services	Policy & procedures

MUNICIPAL INDICATORS

EI Adm Contract Requirement	Indicator	Art. 6 requirement	Cluster ADM=Admin & Oversite CF=Child Find FC=Family Cent'd S=SvcDeliv & NatEnv T=Transition	Main Indicator GREEN = new	Sub Indicators	REVIEW PROCESS *if county is the service provider of record on the IFSP, validation should occur thru record review
x	MP27	x	S		When necessary, transportation is provided directly, by contract, or through reimbursement of the parent per regulatory requirements.	Record review
x	MP64		ADM		There is a process to follow up implementation of provider Corrective Action Plans.	Interview; policies & procedures; MONITOR
	MP55		ADM		Muni monitors provider bills for service reimb and verifies that the service took place prior to payment	Interview; policies & procedures; MONITOR
x				**The EIO pays providers accurately and timely**		
	MP56		ADM		Providers are paid in a timely manner	Interview; policies & procedures; documentation
		x	ADM		Payment to providers for billable activities and services are made according to prescribed billing rules established in EI regulations.	Interview; policies & procedures; documentation
				The EIO ensures that only qualified and State-approved providers deliver services		
		x	ADM		Municipality only contracts with State-approved service providers to deliver EI services.	Interview; policies & procedures; documentation
			ADM		Municipality contracts with providers only for EI services the provider received State approval to deliver.	Interview; policies & procedures; documentation
			ADM	**The EIO ensures it has contracts in place with a sufficient number of qualified service providers to serve all eligible children within the municipality**		
x	MP30		S		Services begin within 2-3 weeks of the IFSP meeting.	Record review

MUNICIPAL INDICATORS

EI Adm Contract Requirement	Indicator	Art. 6 requirement	Cluster ADM=Admin & Oversite CF=Child Find FC=Family Cent'd S=SvcDeliv & NatEnv T=Transition	Main Indicator GREEN = new	Sub Indicators	REVIEW PROCESS *if county is the service provider of record on the IFSP, validation should occur thru record review
	MP32	x	S		All service models are available	Interview; policies & procedures
x				**The EIO maximizes third-party contributions to pay for EI services**		
	MP53	x	ADM		Either directly, or through a fiscal agent, municipality seeks payment from private third party insurers prior to claiming payment from Medicaid. The municipality then seeks payment from Medicaid prior to claiming to SDOH, for EI services.	Interview; policies & procedures; documentation, also may include record review
		x	ADM		Municipality is subrogated to any rights the child or parent may have or be entitled to from third party reimbursement and promptly notifies the health insurer or benefits plan administrator of the intent to exercise those subrogation rights.	Interview; policies & procedures; documentation
	MP54		ADM		MA and 3rd party insurance claiming is timely.	Interview; policies & procedures; documentation
	MP63		ADM		Providers are enrolled as non-billing MA providers and reassign benefits	Interview; policies & procedures; MONITOR
	MR67	x	ADM		Service providers maintain and forward any documentation and information necessary to support municipal billing of insurance and Medicaid.	Interview; policies & procedures; MONITOR
	MR68	x	ADM		Municipality has a process in place for insurance billing, including arrangements for co-pays & deductibles to parents	Interview; policies & procedures; documentation
		x		**The EIO ensures required data is reported to the Department**		
	MP52		ADM		The EI Data System is regularly updated & reports submitted to the Department 4x/year (beg. 10/02)	Interview; policies & procedures; documentation

HEALTH & SAFETY ATTACHMENT

Health, Safety and Sanitation Components to Include in Written Policy and to Apply When Delivering *Facility-Based* Early Intervention Services

Early Intervention Program regulations require individual and agency providers who are approved to deliver services in a facility-based setting to develop and maintain written health and safety policies and procedures applicable to their particular practice.

Providers approved to deliver services in a facility-based setting should include the following health, safety, and sanitation components in their written health and safety policies and apply them in their practices, as appropriate. This includes, but is not limited to, the following:

1. **The facility provides a safe physical environment for children, persons delivering services, and other individuals that access the premises:**
   For all providers:
   - Fire alarm and detection systems are present and documented to be in working order, as indicated by documentation of periodic testing and maintenance in accordance with manufacturer's instructions and/or applicable code and state licensing. The New York State Department of State, local municipalities, and local fire districts establish building and fire codes that early intervention facility-based providers **must** be aware of and comply with. Specifically, fire detection, alarm, and suppression equipment appropriate to the type of building construction, size, height, and occupancy must be provided and maintained in accordance with the applicable requirements of the New York State Uniform Fire Prevention and Building Code and applicable local fire safety codes.
   - Fire extinguishers are available and in working order as demonstrated by gauge showing full charge. Extinguishers with seals must have unbroken seals, and providers must have knowledge of how to operate extinguisher(s).
   - Evacuation routes are clearly posted and known to all staff.
   - Evacuation drills are conducted at least monthly.
   - Building access and egress are secure, including preventing accidental access to outside areas.
   - Hallways and exits are free from clutter and obstructions.
   - Access to building hazards is restricted, including to portable heaters, pools, ditches, wells, open or easily accessible windows, etc.
   - Stairs, walkways, ramps and porches are free of ice, snow, and other hazards.
   - Furniture is safely arranged and secure, including highchairs with safety straps.
   - Radiators and electrical outlets are properly covered and child proof.
   - Trash is covered and stored appropriately.
   - Bathroom facilities are clean, appropriately sanitized; and supplied with toilet paper, soap, and disposable towels.

- Toilets/sinks are accessible to children (special bathroom facilities, potty chairs, stepstools, etc.).
- Diapering facilities are available and include appropriate disposal containers; surfaces are sanitized after each use.
- Linens, blankets, bedding, cribs, cots, mats are clean and are changed/cleaned before use by another child.
- No evidence of insect or rodent infestation is present.
- Toxic materials, including cleaning supplies, flammable substances, prescription drugs, over-the-counter medicine, plants, lighters, and matches are stored appropriately, inaccessible to children, and stored away from food.
- Any pets on premises pose no threat to children.
- No peeling or significantly damaged paint or plaster.
- Small objects, plastic bags, Styrofoam, and other potentially harmful objects are inaccessible to children.
- No obvious dampness or odors.

2. **The provider delivers services in a way that protects the health and safety of children and other persons involved in the delivery of services, including employing a policy for adequate emergency procedures.**

   For all providers:
   - Children are supervised at all times, including during toileting.
   - Consumption of, or being under the influence of, alcohol or controlled substances is stated to be prohibited.
   - Emergency system contact numbers are readily available.
   - Provider illness, emergency, or other inability to provide services is addressed.
   - Child illnesses and emergencies are addressed, including:
     - ✓ procedures to address emergency health situations, such as administration of first aid/CPR, if certified, or contacting emergency medical personnel
     - ✓ emergency contact procedures, including notifying parents and obtaining emergency consents
     - ✓ procedures for notification to the Early Intervention Official of serious child illnesses or emergencies, when appropriate
     - ✓ procedures for addressing self-injurious behavior
     - ✓ procedures for addressing routine, non-emergency child illnesses
   - Equipment/materials/toys are developmentally appropriate, in good condition, cleaned and sanitized as needed, especially after use by children who are ill or if items come in contact with bodily fluids.
   - Universal precautions are used, as appropriate, including:
     - ✓ hand washing/sanitation before providing services to children, after diapering, handling animals, in contact with any bodily fluids, or before eating
     - ✓ availability and use of disposable gloves
     - ✓ handling of potentially infectious bodily fluids (e.g., blood), including the cleaning and disinfecting of soiled surfaces; policy and practice should include a 10% solution of bleach and water prepared fresh each day or equivalent disinfectant. 10% bleach solution is equivalent to 1 part bleach to 9 parts water
     - ✓ adequate disposal of waste in a secure leak-proof plastic bag
   - Smoking is prohibited in indoor areas, outdoor areas in use by children, and in vehicles while children are being transported.
   - Health and safety incidents are documented, including child illnesses, injuries, and signs of abuse/maltreatment.

For agency providers only:

- If applicable, prescription and over the counter medications are administered and stored in a safe manner according to the requirements of the applicable State standards. Administration of all medication (prescription and over-the-counter) is documented.
- If applicable, food sanitation and safety in preparation, serving and storage of food is addressed according to New York State Public Health Law, Section 225, Part 14. This includes use of suitable utensils and/or sanitary gloves to prepare food; use of suitable utensils, sanitary gloves, waxed paper, or napkins to serve food; frequent cleaning and appropriate sanitizing of food contact surfaces; washing, rinsing, and sanitizing of tableware after each use.

3. **The provider is in compliance with other applicable local or State standards that apply.**

For all providers:

- Copies of:
  - ✓ current Certificate of Occupancy, if applicable
  - ✓ documentation of current building inspection, if applicable
  - ✓ documentation of current fire inspection

  Please note, local code enforcement officials may be a resource in this regard.

- For day care providers, current NYS day care permit/license/registration as follows:
  - ✓ outside NYC, if operating more than 3 hours per day with 3 or more children
  - ✓ within NYC, if operating with more than 6 children, regardless of number of hours of operation

- There is a written process in place to report suspected child abuse and maltreatment, or to cause a report to be made, including notification to the New York State Central Register of Child Abuse and Maltreatment according to the New York State Social Services Law, Section 413 or Section 414, as appropriate, when there is reasonable cause to suspect that a child coming before a provider in their professional or official capacity is an abused or maltreated child.

For agency providers only:

- All new employees and contracted individuals who have the potential for regular and substantial contact with children are screened through the New York State Central Register of Child Abuse and Maltreatment, prior to unsupervised contact with children, according to the New York State Social Services Law, Section 424-a.

4. **The provider is in compliance with New York State Department of Health Early Intervention Program regulations and standards, and New York State Education Department regulations regarding Qualified Personnel.**

For all providers:

- All individuals providing early intervention services have the appropriate licensure, certification, registration, or documentation requirements in the area in which they are providing services. Please note the following particular circumstances:
  - ✓ A New York State Education Department's provisional/permanent certification in special education or initial/professional certification as a Teacher of Students with Disabilities (birth—grade 2) may provide early intervention services, as appropriate.

- ✓ Documentation identifying the licensed speech-language pathologist who provides supervision to the individual completing their nine months of supervised contact and/or Clinical Fellowship Year (CFY), as well as terms of the supervision.
- ✓ Notification of Approval or Form 6, or documentation that an individual completing their nine months of supervised experience possesses a Masters degree in speech-language pathology; is employed by the agency where s/he is completing their supervised experience; and is supervised by a licensed, registered speech-language pathologist from the same agency that employs the individual completing their nine months of supervised experience.
- ✓ A Department of Health-approved, child-specific waiver requested by the Early Intervention Official to allow a teacher of the speech and hearing handicapped to provide early intervention speech therapy services to a particular child, under certain circumstances.

For agency providers delivering facility-based services, all current and future staff receive training regarding health and safety policies and procedures, and are evaluated to ensure procedures are being followed. All contractors who deliver services on behalf of the provider are made aware of appropriate health and safety practices and are monitored to ensure appropriate health and safety practices are being followed.

Health, Safety and Sanitation Components to Apply When Delivering *Home and Community-Based* Early Intervention Services

Providers approved to deliver home and community-based early intervention services should apply the following health, safety, and sanitation components in their practices, as appropriate. This includes, but is not limited to, the following:

1. **The provider delivers services in a way that protects the health and safety of children and other persons involved in the delivery of services, including during emergencies:**
   For all providers:
   - Children are supervised at all times. Parent/caregiver is present during service delivery when services are delivered in the home.
   - Consumption of, or being under the influence of, alcohol or controlled substances is prohibited.
   - Emergency system contact numbers are available.
   - Provider illness, emergency, or other inability to provide services is addressed.
   - Child illnesses and emergencies are addressed, including:
     - ✓ procedures to address emergency health situations, such as administration of first aid/CPR, if certified, or contacting emergency medical personnel
     - ✓ procedures for notification to the Early Intervention Official of serious problems, when appropriate
     - ✓ procedures for addressing self-injurious behavior
     - ✓ procedures for addressing routine, non-emergency child illnesses

- Equipment/materials/toys are developmentally appropriate, in good condition, cleaned between uses, and sanitized weekly, after use by children who are ill or if the items come into contact with bodily fluids.
- Universal precautions are used, as appropriate, including:
  - ✓ hand washing/sanitation before providing services to children, after diapering, handling animals, in contact with any bodily fluids, or before eating
  - ✓ availability and use of disposable gloves
  - ✓ handling of potentially infectious bodily fluids (e.g., blood), including the cleaning and disinfecting of soiled surfaces; policy and practice should include a 1:10 solution of bleach and water prepared fresh each day or equivalent disinfectant
  - ✓ adequate disposal of waste in a secure leak-proof plastic bag
- Health and safety incidents are documented, including child illnesses, injuries, and signs of abuse/maltreatment.

2. **The provider is in compliance with other applicable local or State standards, as appropriate.**

   For all providers:
   - There is knowledge of a process to report suspected child abuse and maltreatment, or to cause a report to be made, including notification to the New York State Central Register of Child Abuse and Maltreatment according to the New York State Social Services Law, Section 413 or Section 414, as appropriate, when there is reasonable cause to suspect that a child coming before a provider in their professional or official capacity is an abused or maltreated child.

   For agency providers only:
   - All new employees and contracted individuals who have the potential for regular and substantial contact with children are screened through the New York State Central Register of Child Abuse and Maltreatment, prior to unsupervised contact with children, according to the New York State Social Services Law, Section 424-a.

3. **The provider is in compliance with New York State Department of Health Early Intervention Program regulations and standards, and New York State Education Department regulations regarding Qualified Personnel.**

   For all providers:
   - All individuals providing early intervention services have the appropriate licensure, certification, registration or documentation requirements in the area in which they are providing services. Please note the following particular circumstances:
     - ✓ A New York State Education Department's provisional/permanent certification in special education or initial/professional certification as a Teacher of Students with Disabilities (birth—grade 2) may provide early intervention services, as appropriate.
     - ✓ Documentation identifying the licensed speech-language pathologist who provides supervision to the individual completing their nine months of supervised contact and/or Clinical Fellowship Year (CFY), as well as terms of the supervision.
     - ✓ Notification of Approval or Form 6, or documentation that an individual completing their nine months of supervised experience possesses a Masters degree in speech-language pathology; is employed by the agency where s/he is completing their supervised experience; and is supervised by a licensed, registered speech-language pathologist from the same agency that employs the individual completing their nine months of supervised experience.

- ✓ A Department of Health approved, child-specific waiver requested by the Early Intervention Official, to allow a teacher of the speech and hearing handicapped to provide early intervention speech therapy services to a particular child, under certain circumstances.

For agency providers delivering home/community-based services, all current and future staff receive training regarding health and safety procedures and are evaluated to ensure procedures are being followed. All contractors who deliver services on behalf of the provider are made aware of appropriate health and safety practices and are monitored to ensure appropriate health and safety practices are being followed.

The following reference materials will be of assistance to early intervention service providers to develop and implement health and safety policies relevant to their unique situation:

- American Public Health Association and American Academy of Pediatrics under a grant from the U.S. Health Resources and Services Administration. *Caring for Our Children—National Health and Safety Performance Standards: Guidelines for Out-of-Home Child Care Programs*. Washington, DC: APHA & APA, 1992.

- Shapiro Kendrick, A., Kaufmann, R. and Messenger, K.P., eds. *Healthy Young Children*. Washington, DC: National Association for the Education of Young Children, 1995.

- Centers for Disease Control and Prevention Website, www.cdc.gov/ncidod.

CONFIDENTIALITY ATTACHMENT

Components to Include/Describe in Written Policy for Maintaining Provider Early Intervention Records

Early Intervention Program (EIP) records are defined in EIP regulations, Section 69-4.1(ak). A child's early intervention clinical record is considered an educational, not medical, record and is governed by the Federal Family Educational Rights and Privacy Act (FERPA). EIP billing/claiming records must also meet the requirements of the Federal Health Insurance Portability and Accountability Act (HIPAA). EI providers who are licensed, registered, or certified under New York State Education Law must retain their records in accordance with the laws and regulations that apply to their profession.

Policies and procedures for confidentiality should apply throughout the stages of collection, storage, disclosure and destruction of records, including electronic records. All providers delivering early intervention services should write a policy/procedure describing how they will meet the following confidentiality requirements:

- Agencies must designate an individual who has appropriate authority to be responsible for ensuring the confidentiality of personally identifiable information in records, including electronic records.

- Describe how the storage of records is secure. Records containing personally identifiable information must be maintained in secure locations, such as a room or file that can be locked when unattended. Records must be disposed of using an appropriate method such as shredding.

- If records that contain personally identifiable information are stored off-site, describe how the storage of these records is secure. These records must be maintained in secure locations such as in a file, room or storage unit that is locked. The method of retrieving these files must also maintain the confidentiality of these records. If a professional records management company is used for storage of records, written assurance is available from that organization (such as a contract or company policy) which ensures that confidentiality requirements are met including that records are kept locked, disposed of appropriately, and not disclosed to anyone other than the provider.

- Describe how transported records are secured and how confidentiality is maintained when not with the provider.

- Describe how the confidentiality of electronic records is maintained, as follows:

    - Describe how the confidentiality of electronic records that are stored on computer is maintained. Internal controls must be in place when information is stored on computers that limit access to authorized staff within an agency or to the individual provider. This includes, but is not limited to, password protection and secure storage of discs, CD's, DVD's and/or other removable storage devices.

    - Describe how confidentiality is maintained when email is used. Due to the potential for breach of confidentiality, child specific identifiable information may not be transmitted via e-mail unless rigorous administrative, technical and physical safeguards are in place, such as encryption, firewalls, etc. In addition, all parties involved in the sending and receipt of an electronic record must be able to maintain the confidentiality of that record.

    - Describe how confidentiality of faxed information is maintained. Safeguarding of faxed information requires, but is not limited to, the use of a fax cover sheet that includes a confidentiality statement. The provider must also ensure that the fax recipient maintains a secure site, where faxed information would not be accessible to unauthorized personnel or to the general public.

- Agencies must identify those individuals within their agency who are authorized to routinely access a child's record. Each agency must maintain a current listing of the names and positions of those employees who may have access to personally identifiable information. Only individuals who collect or use information for the

purpose of facilitating the child's/family's participation in the Early Intervention Program should be given this authorization. Describe how this is implemented.

- A record must be kept of all individuals, other than authorized individuals, who access a child's record, including the date of access and the purpose for which the record was accessed. Describe how this access is documented.

- Describe how parents are notified of the process that they must follow to inspect and review all records pertaining to their child. This notification should include a description of the process including how parents would make the request, who they must speak to, and other details. Please note, if a parent is unable to submit a request to review records in writing, a verbal request should be accepted.

- Parental access to their child's record must be ensured. Access to records includes: a review of the record by the parent or a representative on behalf of the parent unless such access is prohibited under State or federal law; an explanation and interpretation of material included in any EI record upon request; and, a copy of any record within 10 working days of the request (if the request is made as part of mediation or an impartial hearing, a copy must be provided within 5 days.) Describe how this confidentiality requirement will be met.

- Fees for copying and retrieving records must not exceed allowable rates. A fee not to exceed 10 cents per page for the first copy and 25 cents per page for additional copies may be charged to the parent to copy EI records, unless the fee prevents the parent from inspecting and reviewing the records. No fee may be charged for records related to evaluations and assessments or for the search and retrieval of records. An evaluator or service provider may charge for copies as permitted under PHL §18.

- Describe how the procedure to address amendment of their child's records protects the parent's rights. The parent has the right to request an amendment to their child's record when the parent believes the information contained in the record is inaccurate, misleading, or violates the privacy or other rights of their child.

    - If the provider decides not to amend the record as requested, the provider informs the Early Intervention Official of this decision. The Early Intervention Official is responsible for informing the parent in writing of the provider's decision not to amend the record and that the parent has the right to a hearing. The hearing will be conducted by an individual designated by the municipality, who does not have a direct interest in the outcome of the hearing.

    - If information in the record is found to be inaccurate, misleading, or to violate the privacy of the child/family, the provider will amend the information and will inform the family's service coordinator. The service coordinator will notify the parent in writing of the amendment.

- When records contain information about more than one child, information about other children receiving services must be protected. Only information pertaining to the child/family that is the subject of a request for record access or disclosure may be released. Describe how personally identifiable information about other children receiving services is protected.

- Written parental consent must be obtained before personally identifiable information is disclosed to anyone other than authorized individuals. Written parental consent for release of or obtaining information must include the name of the entity; which records will be obtained or released; the specific record(s) to be used and the purpose of such use; the date the parent signed the consent; and the parent's signature and relationship to the child. Only information appropriate to a request should be released. *

- If record review for quality assurance (or other purposes such as fiscal audit, etc.) is performed by individuals not involved in the direct provision of early intervention services, the provider must detail in his/her policy the following steps to obtaining written parental consent. The parent must be informed of the names of these individuals, the purpose for the record access, and must provide written consent for such access. If consent is given, those individuals must be informed about, and required to adhere to, all confidentiality requirements applicable to personally identifiable information within the Early Intervention Program. They must also comply with all legal requirements that protect records containing sensitive information (such as sexual or physical abuse, treatment for mental illness or mental health problems, HIV status, communicable disease status, the child's parentage, etc.) *

- Describe how records containing sensitive information are protected. Providers must adhere to the confidentiality requirements of the Early Intervention Program, including all legal requirements that protect

records containing sensitive information (such as sexual or physical abuse, treatment for mental illness or mental health problems, HIV status, communicable disease status, the child's parentage, etc.) When consent is given by a parent or guardian to release information, only information appropriate to a request should be released. Sensitive information about the child and family must be protected.

- At a minimum, records must be retained for six years from the date that care, services, or supplies were provided to the child or family. Providers who are licensed, registered, or certified under New York State Education Law must retain records in accordance with the laws and regulations that apply to their profession.

- If electronic signatures are used, electronic documentation must be maintained in a manner that demonstrates the provider's right to receive payment under the Medicaid program and ensures the confidentiality of child and family information. Records must meet the general and specific requirements of the regulation as to content. It must be possible to determine when the record was created. There must be a process to document alteration of the record and also a process to prevent alteration (i.e. 'read-only' format, PDF, etc.). The direct provider of service must be identified in the record. The provider must be able to produce a sample record for review. If electronic signatures are used, provide details of how this compliance is assured.

- Describe how provider assures adherence to requirements for maintaining the confidentiality of personally identifiable information, as follows:

    - Agency providers must assure that all employees, independent contractors, consultants, and volunteers with access to personally identifiable information are informed about, and required to adhere to, all confidentiality requirements applicable to personally identifiable information within the Early Intervention Program. Agencies must also assure knowledge of and compliance with all legal requirements that protect records containing sensitive information (such as sexual or physical abuse, treatment for mental illness or mental health problems, HIV status, communicable disease status, the child's parentage, etc.).

    - Individual providers must keep informed of all applicable confidentiality requirements as described above.

*Note: The New York State Department of Health, as lead agency responsible for oversight of the EIP, is required to monitor providers of early intervention evaluation, services, and service coordination. The department has contracted to perform on-site reviews of early intervention providers under contract with municipality(ies). FERPA authorizes the disclosure of the child/family's record, without parent consent, to specified officials (e.g., state officials/contractor) for audit or evaluation purposes of any federally or state-supported education program or in connection with the enforcement of or compliance with federal legal requirements which relate to any such program.

Attachment G

Provider Comprehensive Monitoring Report

Agency Provider:
State ID:
Review Type: Comprehensive
Applicable County Contracts:
Approved to Deliver:
Facility-based EI:
Areas Reviewed:
# of Children Currently Served:
Reported Languages:
Date(s) of Monitoring:
Monitoring Team:
Municipality Representative in Attendance:
Provider's Address:
Site Reviewed:
Approved Site(s):

Introduction

The New York State Department of Health is the lead agency for New York State's Early Intervention Program under the Individuals with Disabilities Education Act. The mission of the New York State Early Intervention Program is to identify and evaluate infants and toddlers whose healthy development is compromised and to provide for appropriate intervention to improve child and family development.

As lead agency, the Department of Health is required under federal and state law and regulation (34 CFR 303.501; Public Health Law Section 2550 (b)) to monitor municipalities responsible for local administration of the Early Intervention Program and providers of early intervention services. The Department of Health has entered into a contract with the contractor to conduct on-site monitoring reviews of municipalities and providers of early intervention services (including providers of service coordination services, evaluators, and all other early intervention services).

The primary focus of on-site reviews completed by the contractor, as the Department's designee, is to monitor compliance with New York State Public Health Law (Title II of Article 25) and regulations (10 NYCRR) governing the Early Intervention Program.

Procedures for Early Intervention Monitoring

Standardized protocols and review tools have been developed by the Department and are used by the contractor monitoring teams to complete on-site monitoring reviews for the Early Intervention Program. The review tools include a comprehensive set of indicators designed to determine the extent to which the provider's policies, procedures, and implementation of those policies and procedures adhere to New York State Public Health Law, regulations, and administrative guidance. The contractor teams are comprised of individuals with expertise in early intervention and administration.

The standardized pre-site review tools used to monitor providers include:

Municipal survey mailed to and completed by municipalities in contract with the provider to deliver early intervention services. The purpose of the municipal survey is to gather data regarding a municipality's experience with the provider for the provision of early intervention services.

Self-Assessment, mailed to and completed by the provider. The purpose of the self-assessment is to give providers an opportunity to conduct a review of their own child records, policies, and procedures prior to the onsite review, using the same indicators by which they will be monitored.

The contractor teams review information gathered through the pre-site tools, as well as information supplied by the Department, when applicable (e.g., systems complaints determinations, previous monitoring determinations and previous corrective action plans) to help focus on-site review activities.

On-site review activities include:

Interviews conducted with providers or agency staff. For providers with multiple sites, interviews will be conducted at the specific site being reviewed. The purpose of the interviews is to inform the provider of the activities that will be completed during the monitoring review; to obtain information from provider or agency staff about policies and procedures the provider has in place for the provision of early intervention services; and, to explain the preliminary findings of the monitoring review to the provider.

Child record reviews. The purpose of the child record review is to gather data regarding the provision of early intervention services that the provider renders to ensure that services are provided in accordance with New York State Early Intervention Program regulations and administrative guidance. For providers with multiple sites, child record reviews will consist of records of children who are being served at the specific site being reviewed.

Review of policies, procedures, other data and documentation and other direct observation related to

the provision of early intervention services. For providers with multiple sites, this review will include policies and procedures that are applicable across the agency, as well as those that are specific to the site being reviewed. The purpose of the review of this information is to gather data to ensure that provider or agency staff providing early intervention services are qualified and follow policy and procedures which are in accordance with Early Intervention Program regulations and administrative guidance.

Presentation of Findings

All reports present the findings of the on-site monitoring review of the provider. Reports delineate the areas of compliance and non-compliance with New York State Public Health Law, regulations, and administrative guidance as determined by the comprehensive set of indicators that comprise the review tools.

Findings are organized in clusters associated with required components of the Early Intervention Program and consistent with clusters employed by the U. S. Department of Education, Office of Special Education Programs, to monitor state implementation of the Part C Early Intervention Program under Individuals with Disabilities Education Act (IDEA). Each cluster is comprised of a set of indicators from the review tools that are related to Early Intervention Program components. Depending on the type of service(s) the provider delivers, the number of sites at which a provider delivers early intervention services, and/or their oversight responsibilities, some or all of the monitoring indicators may apply.

The clusters are as follows:

Public Awareness and Child Find

The monitoring indicators that are reviewed in this cluster include provisions related to referral, initial service coordination and evaluation. Based upon information gathered through all sources used in the review process and when applicable, determinations are made regarding the practices used by the provider in: acting as a primary referral source to the Early Intervention Program; providing initial service coordination; performing evaluations; determining eligibility and reporting eligibility determinations.

Family Centered Services

The monitoring indicators that are reviewed in this cluster include provisions related to initial and ongoing service coordination and standards for service providers. Based upon information gathered through all sources used in the review process, and, when applicable, determinations are made regarding the practices used by the provider in: developing and/or participating in the Individual Family Services Plan (IFSP) process; and, provision of IFSP services including parent's involvement in service delivery.

Service Delivery and Natural Environments

The monitoring indicators that are reviewed in this cluster include provisions related to the delivery of services in settings that are natural or normal for the child's age peers who have no disability to the extent appropriate. Based upon information gathered through all sources used in the review process, and, when applicable, determinations are made regarding the practices used by the provider in: ensuring that services are individualized and delivered in accordance with the IFSP; ensuring that a child development emphasis approach is used; consulting with parents and other service providers to ensure the effective provision of services; ensuring that all services are delivered in environments appropriate to the unique needs of the child; and, services are delivered in a timely fashion.

Transition

The monitoring indicators that are reviewed in this cluster include provisions related to the transition of the child from the Early Intervention Program. Based upon information gathered through all sources used in the review

process, and, when applicable, determinations are made regarding the practices used by the provider in: ensuring that a transition plan is developed with the family and included in the IFSP; ensuring transition steps are made timely and completely without gaps in early intervention services to preschool services; and, that referrals to appropriate programs are made.

Administration and Oversight

The monitoring indicators that are reviewed in this cluster include provisions related to the general administrative oversight of early intervention services delivered and billed. Based upon information gathered through all sources used in the review process, and, when applicable, determinations are made regarding the practices used by the provider in: staff development and supervision; individual provider caseload; confidentiality policy and procedures followed for child records; parent access to records; documentation maintained to support billing of all services; ensuring that appropriate Department of Social Services representatives are notified and included in the coordination of early intervention services when children are in foster care and ensuring that quality assurance activities are in place.

The findings of the review completed on the provider are presented in the following manner:

Exhibit A is a summary table that describes the number of indicators across all review tools that were found to be in compliance with New York State Public Health Law and regulations pertaining to the Early Intervention Program.

Exhibit B presents areas of regulatory non-compliance that will require submission of a Corrective Action Plan.

Exhibit C presents areas found to be in need of improvement. Although submission of a Corrective Action Plan will not be required, the provider is expected to correct these areas, which may be reviewed during subsequent onsite monitoring visits. In addition, health and safety-related deficiencies in these areas may be reported to municipalities in contract with the provider for immediate remediation.

If monitoring results for this review determined non-compliance with New York State regulations in one or more areas, as noted in Exhibit B, three copies of a Corrective Action Plan addressing each area ***must be submitted within forty-five (45) days*** to the following individual:

Monitoring Project Manager
Contractor
Address

The Corrective Action Plan must include: (1) a plan to develop a policy or procedure to correct the violation, (2) a timeline of activities to implement the plan of correction, (3) the person(s) responsible to carry out the plan, and (4) the manner in which the effectiveness of the plan will be measured.

Where monitoring results determined that compliance with New York State regulation was generally practiced, but improvement is suggested to ensure ongoing or complete compliance, or when monitoring results determined that a non-regulatory indicator was not practiced for all cases, "Areas Needing Improvement" are noted in Exhibit C. As stated earlier, a Corrective Action Plan is not required to be submitted for these areas, however, the areas may be monitored in the future and health and safety-related deficiencies in these areas may be reported to municipalities in contract with the provider for immediate remediation.

Additional Comments:

This section of the monitoring report is a place where additional information can be provided to DOH regarding a specific indicator that has been cited, or about an issue that was not cited as a regulatory finding but could raise a concern, for example: irregular billing practices, incorrect county practices, statements made by the provider during the monitoring review in response to a regulatory finding or needs improvement, documents provided by

the provider during or after the review.

Also, it is an area where health and safety findings are written down that cannot be cited as regulatory findings, but still need to be addressed and corrected by the provider, for example: use of universal precautions in the service area, other health and safety practices which need to be corrected, notifying the EIO in case of child illness or emergencies

Monitoring Indicators That Met Early Intervention Program Standard (Exhibit A)

Early Intervention Cluster	Report Statement	Indicators that Met Monitoring Criteria
Child Find	Based on review of policies and practices, interviews conducted with personnel, and/or review of individual child records, it was determined that the provider has maintained compliance, to the extent indicated in the next column, with New York State Early Intervention Program regulations in regard to activities related to child find, including referral practices.	14 of 14 assessed in this cluster met the standard. indicators
Family Centered Services	Based on review of policies and practices, interviews conducted with personnel, and/or review of individual child records, it was determined that the provider has maintained compliance, to the extent indicated in the next column, with New York State Early Intervention Program regulations in regard to family centered services, including IFSP meetings, family assessment, service coordination, and involving parents in service provision.	11 of 12 assessed in this cluster met the standard. indicators
Service Provision and Natural Environment	Based on review of policies and practices, interviews conducted with personnel, and/or review of individual child records, it was determined that the provider has maintained compliance, to the extent indicated in the next column, with New York State Early Intervention Program regulations in regard to service coordination, IFSP development, service provision, and supports for unique needs of eligible infants and toddlers and their families.	4 of 7 assessed in this cluster met the standard. indicators
Transition	Based on review of policies and practices, interviews conducted with personnel, and/or review of individual child records, it was determined that the provider has maintained compliance, to the extent indicated in the next column, with New York State Early Intervention Program regulations in regard to transition from Part C to preschool programs or other services.	0 of 0 assessed in this cluster met the standard. indicators
Administration and Oversight	Based on review of policies and practices, interviews conducted with personnel, and/or review of individual child records, it was determined that the provider has maintained compliance, to the extent indicated in the next column, with New York State Early Intervention Program regulations in regard to program administration and oversight, including procedural safeguards, fiscal accountability and quality improvement.	16 of 21 assessed in this cluster met the standard. indicators

Indicator, Cluster and Reference

Indicator: Provider Policy/Practice and Staff Interview Tool 40 (PP40)

Cluster: Administration and Oversight

Early Intervention Program regulations 10NYCRR 69-4.17 (c) and (d) state that "Personally identifiable data, information, or records pertaining to an eligible child shall not be disclosed by any officer or employee of the Department of Health, state early intervention service agencies, municipalities, evaluators, service providers or service coordinators, to any person other than the parent of such child, except in accordance with Title 34 of the Code of Federal Rules Part 99, sections 300.560 through 300.576 ...to preserve the confidentiality of records pertaining to children participating in the early intervention program ...Early intervention officials, all providers approved to deliver early intervention services ...shall: (i) implement and maintain policies and procedures to assure the protection of confidential personally identifiable information ...; (ii) submit assurances that all employees ...independent contractors, consultants, and volunteers with access to personally identifiable information are informed of and are required to adhere to all confidentiality requirements ...(iii) ...protect records containing sensitive information (e.g. such as sexual or physical abuse, treatment for mental illness ...HIV status, ...etc.); and (iv) identify the person or person(s) with designated responsibility for guaranteeing the confidentiality of personally identifiable information." Also, the "Early intervention officials shall ensure the confidentiality of all information maintained in an electronic format except as required or permitted by state or federal law ...and ...ensure the parent is afforded the opportunity to review and inspect all the records pertaining to the child and ...family ...used for the purposes of the Early Intervention Program, unless the parent is otherwise prohibited such access ...The opportunity to review and inspect ...includes the right to (i) understandable explanations about ...the record ...(ii) obtain a copy of the record within ten working days ...(iii) obtain a copy ...within five working days if the request is made as part of a mediation or impartial hearing, (iv) have a representative of the parent view the record." The "...early intervention official, evaluator, service provider and service coordinator shall keep a record of parties obtaining access to records ...(except access by parents and authorized employees of the municipality or approved evaluator, service provider, or service coordinator) including the name ..., date access was given, and ...purpose..."

Findings

Regulation Finding

Based on observation, interviews conducted with the provider/staff, and/or review of documents and data, it was determined that the provider did not maintain a procedure sufficient to ensure that all requirements of Title 34 of the Code of Federal Regulations and other applicable legal requirements for confidentiality were followed. Specifically, the provider's procedures and/or written policies regarding child records (written and electronic) were insufficient, including: PP40-4: Confidentiality of electronic records is maintained. Internal controls must be in place when information is stored on computers that limit access to authorized staff within an agency or to the individual provider. This includes, but is not limited to, password protection and secure storage of discs, CD's, and DVD's. Due to the potential for breach of confidentiality, child specific identifiable information may not be transmitted via e-mail unless rigorous administrative, technical and physical safeguards are in place, such as encryption, firewalls, etc. In addition, all parties involved in the sending and receipt of an electronic record must be able to maintain the confidentiality of that record. Safeguarding of faxed information requires, but is not limited to, the use of a fax cover sheet that includes a confidentiality statement. The provider must also ensure that the fax recipient maintains a secure site, which is not accessible to the general public. PP40-9: A fee not to exceed 10 cents per page for the first copy and 25 cents per page for additional copies may be charged the parent to copy EI records, unless the fee prevents the parent from inspecting and reviewing the record. No fee may be charged for records related to evaluations and assessments or for the search and retrieval of records. An evaluator or service provider may charge for copies as permitted under PHL §18. PP40-10: The procedure to address amendment of their child's record must protect the parent's rights. The parent has the right to request an amendment to their child's record when the parent believes the information contained in the record is inaccurate, misleading, or violates the privacy or other rights of their child. If the provider decides not to amend the record as requested, the provider informs the Early Intervention Official of this decision. The Early Intervention Official is responsible for informing the parent in writing of the provider's decision not to amend the record and that the

parent has the right to a hearing. The hearing will be conducted by an individual designated by the municipality, who does not have a direct interest in the outcome of the hearing. If information in the record is found to be inaccurate, misleading, or to violate the privacy of the child/family, the provider will amend the information and will inform the family's service coordinator. The service coordinator will notify the parent in writing of the amendment. PP40-14: At a minimum, records must be retained for six years from the date that care, services, or supplies were provided to the child or family. Providers who are licensed, registered, or certified under state education law must retain records in accordance with the laws and regulations that apply to their profession.

A comprehensive written confidentiality policy must be developed and maintained by all providers participating in the Early Intervention Program. The enclosed attachment, "Components to Include in Written Policy for Maintaining Provider Early Intervention Records," will assist the provider to develop confidentiality policies that are correct and appropriate for the provider's practice. Copies of the attachment will not be considered acceptable as a confidentiality policy - it must be modified to reflect the provider's specific practice. For additional information on early intervention records, please refer to: Early Intervention Program Memorandum 03-1, "Guidance on Early Intervention Records."

It is required that the provider develop, and submit for approval, a Corrective Action Plan which addresses the issues cited and ensures compliance with New York State Early Intervention Program regulations.

Monitoring Indicators That Did Not Meet Early Intervention Program Standard (Exhibit B)

Indicator, Cluster and Reference

Indicator: Provider Child Record Review Tool 55 (PR55)

Cluster: Service Provision and Natural Environment

Early Intervention Program regulation 10NYCRR 69-4.9(g)(4) states that "State early intervention agencies and early intervention officials shall make reasonable efforts to ensure that early intervention services delivered to eligible infants and toddlers: use a team approach that is multidisciplinary, interdisciplinary, or transdisciplinary, including the expertise of all appropriate qualified personnel."

Findings

Regulation Finding

Based on a review of 3 child record(s) documenting service provision and other service providers, it was determined that in 1 child record(s) there was insufficient documentation that the provider used a multidisciplinary, interdisciplinary or transdisciplinary team approach including the expertise of all appropriate qualified personnel serving the child through EI.

The provider must develop and implement procedures to utilize a team approach when delivering services in the Early Intervention Program. These procedures must include reasonable efforts to ensure a team approach that includes the expertise of all appropriate qualified personnel. Communication with other team members may be accomplished through a variety of methods. The provider must maintain documentation of these activities in the child's record. If the team approach is utilized during service delivery, it should be reflected in session notes. For additional information on documentation, please refer to: Early Intervention Program Memorandum 03-1, "Guidance on Early Intervention Records."

It is required that the provider develop, and submit for approval, a Corrective Action Plan which addresses the issues cited and ensures compliance with New York State Early Intervention Program regulations.

Indicators That Need Improvement (Exhibit C)

Indicator, Cluster and Reference

Indicator: Provider Child Record Review Tool 57 (PR57)

Cluster: Service Provision and Natural Environment

Early Intervention Program regulation 10NYCRR 69-4.11(a)(10)(ii) states that "The IFSP shall be in writing and include ... a physician's or nurse practitioner's order pertaining to early intervention services which require such an order and which includes a diagnostic statement and purpose of treatment."

Findings

Needs Improvement

Based on a review of 10 child record(s) documenting service provision, it was determined that in 2 child record(s) there was insufficient documentation that the provider obtained prescriptions/orders or recommendations for service as needed.

Under state education law, the following services may not be provided without written orders from specific medical professionals: physical therapy, occupational therapy, and nursing services. Physical therapy services and occupational therapy services require a written order from a physician, physician's assistant, or nurse practitioner. Nursing services must have a written physician's order. A written recommendation from a physician, nurse practitioner, or speech pathologist, resulting from the child's evaluation, is necessary for speech pathology services. When a physician issues a script/order for an early intervention service, it is recommended that the treating therapist (licensed/certified professional) maintain the original order as part of the provider record and the original prescription/order must be retrievable for audit/quality assurance purposes. In the event that the county seeks to maintain the original script/order, the provider should have a copy of the script/order in the child's file before delivering services (provided that the practice act that applies to the provider's profession allows the provider to maintain a copy rather than an original prescription/order). The physician's order or recommendation should be consistent with the frequency and time period during which the services are to be delivered as specified in the IFSP. New physician's orders or recommendations should be obtained any time there is a change in the period for which a service is to be delivered or a new service requiring an order or recommendation is added to the IFSP. The written order or recommendation should be dated and signed by the issuing medical professional. For additional information on written orders, please refer to: Early Intervention Program Memorandum 95-2, "Individualized Family Service Plans." For additional information on documentation, please refer to: Early Intervention Program Memorandum 03-1 "Guidance on Early Intervention Records."

Attachment G

Provider Focused Monitoring Report

Agency Provider:
State ID:
Review Type: Focused
Applicable County Contracts:
Approved to Deliver:
Facility-based EI:
Areas Reviewed:
# of Children Currently Served:
Reported Languages:
Date(s) of Monitoring:
Monitoring Team:
Municipality Representative in Attendance:
Provider's Address:
Site Reviewed:
Approved Site(s):

The New York State Department of Health is the lead agency for New York State's Early Intervention Program under the Individuals with Disabilities Education Act. The mission of the New York State Early Intervention Program is to identify and evaluate infants and toddlers whose healthy development is compromised, and to provide for appropriate intervention to improve child and family development.

As lead agency, the Department of Health is required under federal and state law and regulation (34 CFR 303.501; Public Health Law Section 2550 (b)) to monitor providers of early intervention services and municipalities responsible for local administration of the Early Intervention Program. The Department of Health has entered into a contract with the contractor to conduct on-site monitoring reviews of municipalities and providers of early intervention services, including providers of service coordination services, evaluators, and all other early intervention services.

The primary purpose of a focused on-site review completed by the contractor, as the Department's designee, is to ensure that initial or previously identified deficiencies have been corrected and the provider is in compliance with New York State Public Health Law (Title II of Article 25) and regulations (10 NYCRR) governing the Early Intervention Program.

Procedures for Early Intervention Focused Monitoring

The contractor monitoring teams comprised of individuals with expertise in early intervention and administration utilized customized protocols and review tools developed by the Department to complete your on-site focused monitoring review. The review tools included a set of indicators designed to determine the extent to which your policies, procedures, and practices adhered to Federal law, New York State Public Health Law and regulations.

The contractor teams examined previous monitoring reports, Corrective Action Plans (CAPs), and any municipal comments and/or information from the NYS Department of Health before conducting this review.

Federal Cluster Areas

Findings are organized in clusters associated with required components of the Early Intervention Program and consistent with clusters employed by the U.S. Department of Education, Office of Special Education Programs, to monitor state implementation of the Part C Early Intervention Program under Individuals with Disabilities Education Act (IDEA). The clusters are as follows: Public Awareness and Child Find, Family Centered Services, Service Delivery and Natural Environments, Transition, and Administration and Oversight.

Presentation of Findings

This report presents the findings of an on-site focused monitoring review. It delineates the areas of non-compliance with State law and regulations, as determined by the review tools.

The findings of the focused review are presented in the following manner:

Exhibit A presents areas of initial or continued regulatory non-compliance that require immediate corrective action and immediate submission of a written Corrective Action Plan.

Exhibit B presents areas found to be in need of improvement. Although submission of a Corrective Action Plan will not be required, the provider is expected to correct these areas, which may be reviewed during subsequent onsite monitoring visits. In addition, health and safety-related deficiencies in these areas may be reported to

municipalities in contract with the provider for immediate remediation.

Details of review findings may also be included in the "Additional Comments" section that follows the report introduction.

If monitoring results for this focused review determine non-compliance with New York State regulations in one or more areas, as noted in Exhibit A, three copies of a Corrective Action Plan addressing each deficiency ***must be submitted within forty-five (45) calendar days*** of receipt of this report to the following individual:

Monitoring Project Manager
Contractor
Address

Corrective Action Required

When Exhibit A presents areas of regulatory non-compliance, there must be immediate corrective action and submission of a written Corrective Action Plan. The written Corrective Action Plan for this focused review must address any new or repeat deficiencies even if the action steps for a repeat deficiency were accepted in your previous Corrective Action Plan. A recommended sample Corrective Action Plan format is enclosed.

The Corrective Action Plan must include:

(1) Action steps, including:

a. Steps the provider has already taken, or will take, to ensure the deficiency will not recur in the future.
b. In-service training the provider (and employees/contractors) will attend, or training materials and resources the provider will acquire and use, in the area of the deficiency, to remedy the deficiency. THE ENCLOSED LIST OF "EARLY INTERVENTION STATEWIDE TRAINING" (ATTACHMENT A-3) PROVIDES INFORMATION ON TRAINING COURSES THAT COULD BE INCLUDED IN YOUR CAP.

For agencies, the in-service training must include:
i. Training opportunities for current and future employees/contractors,
ii. Distribution of agency policies and procedures to current and future employees.
c. Supervision of the practices of employees.
d. Monitoring of the practices of contractors delivering services on behalf of the provider.

(2) A timeline for each action step to correct each deficiency (terms such as "frequently," "periodically" or "ongoing" are <u>not</u> acceptable). The timeline to correct each deficiency must be as short a time as possible.
(3) The person(s) responsible to carry out each action step. For agency providers, the individuals must be direct employees of the agency and have appropriate authority to carry out policy changes (titles must be identified).
(4) A description of how each action step will be evaluated to see if it is successful.

Where monitoring results determined that compliance with New York State regulation was generally practiced, but improvement is suggested to ensure ongoing or complete compliance, or when monitoring results determined that a non-regulatory indicator was not practiced for all cases, "Areas Needing Improvement" are noted in Exhibit B. As stated earlier, a Corrective Action Plan is not required to be submitted for these areas, however, the areas may be monitored in the future and health and safety-related deficiencies in these areas may be reported to municipalities in contract with the provider for immediate remediation.

Additional Comments:

This section of the monitoring report is a place where additional information can be provided to DOH regarding a specific indicator that has been cited, or about an issue that was not cited as a regulatory finding but could raise a concern, for example: irregular billing practices, incorrect county practices, statements made by the provider during the monitoring review in response to a regulatory finding or needs improvement, documents provided by the provider during or after the review.

Also, it is an area where health and safety findings are written down that cannot be cited as regulatory findings, but still need to be addressed and corrected by the provider, for example: use of universal precautions in the service area, other health and safety practices which need to be corrected, notifying the EIO in case of child illness or emergencies

Monitoring Indicators That Did Not Meet Early Intervention Program Standard Indicator, Cluster and Reference (Exhibit A)

Indicator: Provider Policy/Practice and Staff Interview Tool 54 (PP54)

Cluster: Administration and Oversight

Early Intervention Program regulation 10NYCRR 69-4.9(c) states that "All providers of early intervention services shall maintain a physical plant that ensures a safe environment for eligible children and their families." Early Intervention Program regulation 10NYCRR 69-4.9(e) states that "Providers of early intervention services who are approved by the Department of Health or other State early intervention service agencies to deliver services in a facility-based setting shall employ a policy for addressing health, safety, and sanitation issues which is submitted to the approving agency as part of the application process and monitored by that agency." Early Intervention Program regulation 10NYCRR 69-4.9(f) states that "Individual providers of early intervention services who deliver such services in their own home or private office shall maintain a physical plant which meets all applicable health and safety codes (including local health and safety codes) and physical plant standards."

Findings

Regulation Finding

Based on observation, interviews conducted with provider/staff and/or review of policies, practices and documents, it was determined the provider did not always deliver services in a way that protects the health and safety of children and other persons involved in the delivery of services.

● PP54-29: Practice observed or described was not adequate to ensure use of universal precautions when handling potentially infectious bodily fluids (e.g. blood), including cleaning and disinfection of soiled surfaces and adequate disposal of waste.

Additionally, written policies for the issues stated above are not adequate, or are not followed, to ensure services are delivered in a way that protects the health and safety of children and other persons involved in the delivery of services.

Providers that deliver services in a facility they own/lease are responsible for developing and maintaining comprehensive written health and safety policies. The Department will be establishing health, safety and sanitation requirements for all providers in the future. Until that time, information in the enclosed attachment, "Health, Safety and Sanitation Components," will assist providers to develop correct health and safety policies appropriate for their practice. Copies of the attachment will not be considered acceptable as a health and safety policy - it must be modified to reflect the provider's specific practice and facility. Early Intervention Officials are responsible for the health and safety of children participating in the Early Intervention Program. The Department will report serious deficiencies in this area to municipalities in contract with the provider for immediate

remediation.

It is required that the provider develop, and submit for approval, a Corrective Action Plan which addresses the issues cited and ensures compliance with New York State Early Intervention Program regulations.

Indicators That Need Improvement
Indicator, Cluster and Reference (Exhibit B)

Indicator: Provider Policy/Practice and Staff Interview Tool 52 (PP52)

Cluster: Administration and Oversight

The 1997 amendment to the NYS Social Services Law Section 424-a includes early intervention services established under Section 2540 of the Public Health Law to improve "the assessment and evaluation of persons who will have the potential for regular and substantial contact with children being cared for by child-care agencies, programs, or facilities, through increased access to screening persons with the State Central Register of Child Abuse and Maltreatment." Early Intervention Program regulation 10NYCRR 69-4.9(e) states that "Providers of early intervention services who are approved by the Department of Health or other State early intervention service agencies to deliver services in a facility-based setting shall employ a policy for addressing health, safety, and sanitation issues which is submitted to the approving agency as part of the application process and monitored by that agency."

Findings

Needs Improvement

Based on observation, interviews conducted with the staff, and/or review of policies, practices and documents, it was determined that the provider did not always maintain a sufficient established procedure to ensure that all new employees are screened through the New York State Central Register of Child Abuse and Maltreatment, prior to unsupervised contact with children. Specifically, although all current staff have completed the New York State Central Register of Child Abuse and Maltreatment (SCR) screening process, the provider did not have a process for supervising staff prior to receipt of clearance. Requires immediate remediation.

Additionally, written policies for the issues stated above are not adequate, or are not followed, to ensure that all new employees are screened through the New York State Central Register of Child Abuse and Maltreatment, prior to unsupervised contact with children.

Under NYS Social Services Law, all early intervention providers are required to screen their newly hired or contracted individuals who will have regular and substantial contact with children through the NYS Central Register of Child Abuse and Maltreatment (SCR). At least 30 days should be allowed for the SCR to respond to a database check request; if no response has been received after that amount of time a call should be made to the SCR to follow up on the status. If notice is received from the SCR that a person is the subject of an indicated report of child abuse or maltreatment, it is advisable that the provider seek appropriate counsel in making a determination to hire an applicant for employment or hire a consultant who will have the potential for regular and substantial contact with children receiving early intervention services. Please note that employees/contractors who will have substantial contact with children may not deliver services without supervision of the responsible provider before results of the screen are received. Early Intervention Officials are responsible for the health and safety of children participating in the Early Intervention Program. The Department will report serious deficiencies in this area to municipalities in contract with the provider for immediate remediation.

For additional information regarding implementation of this requirement, please refer to Early Intervention Program Memorandum 2001-1 "Guidelines on Database Check for Providers of Early Intervention Services through the State Central Register of Child Abuse and Maltreatment."

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ATTACHMENT H
Clinical Practice Review for Early Intervention Program Autism Services

Objective of Clinical Practice Review

CONTRACTOR will review clinical practices utilized in evaluation and service delivery for young children with a diagnosis of Autism or Pervasive Developmental Disorder, who are receiving, or who have received services through the New York State Department of Health Early Intervention Program. The objective of the review is to detail specific aspects of the services delivered for quality of care. Additionally, the review will measure whether service practices include access to intensive applied behavioral analysis treatment methods.

Procedures

The clinical practice review process will encompass assessment of a statewide sample of child records over the course of 2 years of the monitoring contract, with a total of up to 65 records reviewed annually. Each individual review will consist of examination of an inclusive set of that child's records and completion of the review tool developed by the Department (Attachment I). Additionally, a parent survey, developed by the Department, will be mailed to the parent of each child sampled, with phone follow-up to complete the survey as needed (Attachment I). CONTRACTOR will work with the Department to further develop and define the protocols to be utilized.

The annual reviews will begin upon the Department's finalization of review protocols, and notifications necessary to ensure receipt of the first child records from municipalities.

A summary report with detailed analysis of results will be completed after all child records have been reviewed. A final report will be submitted following that, to coincide with the end of each annual contract period.

Sampling Methodology

The sample of child records will include between 50 and 65 records to be reviewed each year, over a period of two years (the precise number of child records reviewed will be at least 50, or ten percent of all infants/toddlers identified with the diagnosis of Autism/Pervasive Developmental Disorder).

The Department will provide the names of children for the sample to the CONTRACTOR. Sample records will include eligible children with a diagnosis of Autism/PDD who have been served within the Early Intervention Program since the Clinical Practice Guidelines for Autism/PDD were disseminated statewide (Spring 1999).

Current data shows that the sample would consist of fifty-two (52) children located in 37 counties with over 50% in NYC. Eleven of the 37 counties would have multiple child records in the sample.

Compilation of Child Records

The Department will notify municipalities of residence of each child sampled, requesting that they assemble copies of all Early Intervention Program records for the child, and send them to the CONTRACTOR's office in a pre-defined manner.

Autism Clinical Practice Reviewers

The CONTRACTOR will engage up to two persons to review all child records. These reviewers will be selected due to their demonstrated competence and expertise in evaluating and delivering services to very young children with Autism/PDD. The reviewers will also have knowledge and background on the content of the Department's Clinical Practice Guidelines for Autism/PDD.

Confidentiality of all child records sampled will be prioritized and ensured. Reviewers will agree to and sign a comprehensive confidentiality policy approved by the Department, and will adhere to a standard of practice that ensures confidentiality. All confidentiality procedures will comply with the Federal Educational Rights and Privacy Act, as well as the Health Insurance Portability and Accountability Act. The reviewer(s) will examine the child records either at a CONTRACTOR office or at their own facility.

Ongoing program management will be accomplished by the Monitoring Coordinator for the Early Intervention Program Quality Improvement Monitoring Initiative. The Project Manager will provide ongoing oversight of the clinical practice reviews.

Data Collection and Management of Child Records

All data will be entered electronically into an individual tool as each review is completed. Data from each review will be kept at the CONTRACTOR office within an Excel or Access database.

A tracking system will be put into place to ensure that child records are accounted for at all times. The tracking system will be located in a file shared by the CONTRACTOR main office and the reviewer. All incidences of child record transfer or inspection will be recorded in terms of date, time, and location. CONTRACTOR will take all necessary precautions to ensure appropriate delivery and return of all child records.

Reporting

Quarterly reports on the progress of the contract deliverables will be submitted to the Department of Health, Early Intervention Program. Additionally, an Annual report on all related events and results will be submitted.

A final report will be submitted upon completion of the contract requirements. This report will compile global results of all indicators, as well as specifics as required such as mean, median, regional practices, municipality practices, and other analysis as decided upon by the Department and CONTRACTOR.

ATTACHMENT I

EI Clinical Record Review

Child Identification Number:					
Provider Number:					
Reviewer's Name:					
Date of Review:					
I. Evaluation	**Agree**	**Somewhat Agree**	**Somewhat Disagree**	**Disagree**	**Can't Judge**
A. The evaluation confirms a diagnosis of autism/pdd.	☐	☐	☐	☐	☐
B. The evaluation instruments are appropriate.	☐	☐	☐	☐	☐
C. The professionals comprising the evaluation team were appropriate for this child.	☐	☐	☐	☐	☐
D. Interventions are linked to the assessment of the child.	☐	☐	☐	☐	☐
II. Ongoing Assessment					
A. When an assessment of an intervention is shown to not be effective appropriate changes are made.	☐	☐	☐	☐	☐
B. An intervention can be modified when it no longer meets the needs of the child or if there are changes in the child's health, behavior, family dynamics or in the intervention setting	☐	☐	☐	☐	☐
C. Periodic in-depth reassessment of the child's progress and developmental status is done at least once every six to twelve months.	☐	☐	☐	☐	☐
III. IFSP					
A. The child's age was considered in developing the IFSP.	☐	☐	☐	☐	☐
B. The severity of autistic symptoms was considered in developing the IFSP.	☐	☐	☐	☐	☐
C. The evaluation results are reflected in the IFSP.	☐	☐	☐	☐	☐
D. The family's needs/concerns are addressed in the IFSP.	☐	☐	☐	☐	☐
E. The outcomes/goals are stated in the IFSP.	☐	☐	☐	☐	☐

COMMENTS:

_____

_____

_____

Child Identification Number:					
Provider Number:					
IV. Intervention/Services Provided	**Agree**	**Somewhat Agree**	**Somewhat Disagree**	**Disagree**	**Can't Judge**
A. Policies/Procedures					
1. The provider has no customs, policies or practices, formal or otherwise, that would result in inadequate or inappropriate services or the limiting or withholding of behavior modification therapy.	☐	☐	☐	☐	☐
2. The municipality has no customs, policies or practices, formal or otherwise, that would result in inadequate or inappropriate services or the limiting or withholding of behavior modification therapy.	☐	☐	☐	☐	☐
B. General Approach					
1. Services focused on					
a. increasing the child's attention to social stimuli	☐	☐	☐	☐	☐
b. developing imitation skills	☐	☐	☐	☐	☐
c. communication and language skills	☐	☐	☐	☐	☐
d. symbolic play skills	☐	☐	☐	☐	☐
e. developing social relationships	☐	☐	☐	☐	☐
2. Services include					
a. a functional approach to dealing with problem behaviors	☐	☐	☐	☐	☐
b. a highly structured and supportive teaching environment	☐	☐	☐	☐	☐
c. a high degree of predictability and routine	☐	☐	☐	☐	☐
d. strategies for generalization of skills to less restrictive settings	☐	☐	☐	☐	☐
e. strategies for transition between daily activities	☐	☐	☐	☐	☐
f. long-term strategies for transitions between intervention settings	☐	☐	☐	☐	☐
g. opportunities for family involvement	☐	☐	☐	☐	☐

COMMENTS:

_____

_____

_____

Child Identification Number:					
Provider Number:					
IV. Intervention/Services Provided (cont'd)	**Agree**	**Somewhat Agree**	**Somewhat Disagree**	**Disagree**	**Can't Judge**
C. Behavioral Interventions					
1. An option for an intervention approach is a behavioral or Applied Behavioral Analysis (ABA) model.	☐	☐	☐	☐	☐
a. If this approach was used please complete the following:					
1. The principles of applied behavior analysis intervention strategies are included as an important element of the program.	☐	☐	☐	☐	☐
2. The number of hours per week of individualized i.e. one-to-one, behavioral intervention using ABA (not including the time spent by parents) is appropriate.	☐	☐	☐	☐	☐
3. The following were considered when determining the precise number of hours of behavioral intervention:					
a. age	☐	☐	☐	☐	☐
b. severity of autistic symptoms	☐	☐	☐	☐	☐
c. rate of progress	☐	☐	☐	☐	☐
d. other health considerations	☐	☐	☐	☐	☐
e. the expertise and training of the therapist.	☐	☐	☐	☐	☐
4. The number of hours of intensive behavioral intervention are periodically reviewed and revised.	☐	☐	☐	☐	☐
5. All professionals and paraprofessionals that function as therapists in an intensive behavioral intervention program receive regular supervision from a qualified professional with specific training and expertise in applied behavior analysis.	☐	☐	☐	☐	☐
6. Parents are trained in behavioral techniques in order to be able to provide additional instruction to the child or to help the child generalize skills.	☐	☐	☐	☐	☐
7. The parent has the opportunity to access extensive and extensive and ongoing training that includes regular consultation with a qualified professional.	☐	☐	☐	☐	☐
8. When using behavioral interventions:					
a. the child's strengths and learning styles are identified	☐	☐	☐	☐	☐
b. the target behaviors are clearly identified defined with measurable criteria for mastery.	☐	☐	☐	☐	☐
9. Data collection is regular, ongoing and objectively measurable and is reviewed regularly by persons ready and able to exercise that role.	☐	☐	☐	☐	☐

ATTACHMENT I

Child Identification Number:
Provider Number:

D. Check all of the following services the child is receiving/has received.

___ special education

___ occupational therapy

___ physical therapy

___assistive technology

___ audiology

___ ABA

___ behavioral interventions using approaches other than ABA

___ interventions using The Developmental, Individual Difference, Relationship (DIR) model

___ interventions using sensory integration therapy

These services are/were appropriate for the child:

___agree ___disagree ___can't judge

Additional Comments:

_____

_____

_____

_____

I certify that these findings are based on a complete review of the early intervention records of the child identified by the number above.

_____ _____

Print Name **Date**

_____ _____

Signature **Profession/Title**

Parent Questionnaire

Child's Number: _____
Interviewer: _____ Date: _____

	Agree	Somewhat Agree	Somewhat Disagree	Disagree
1. Your desired outcomes, priorities and needs were considered when developing the IFSP.	☐	☐	☐	☐
2. You were offered an opportunity for meaningful involvement in your child's intervention program.	☐	☐	☐	☐
3. You were offered the opportunity to access training about your child's intervention program.	☐	☐	☐	☐
4. You were informed of the advantages and disadvantages of the intervention approaches proposed or used.	☐	☐	☐	☐
4. Your child's progress is monitored on an ongoing basis.	☐	☐	☐	☐
6. Interventions are modified or changed based on your child's progress.	☐	☐	☐	☐
7. A behavioral or Applied Behavior Analysis (ABA) model was discussed and raised as an option for an intervention approach.	☐	☐	☐	☐
8. Check all of the following your child is receiving: **__special education __ speech/language pathology** **__occupational thera __ social work services** **__ physical therapy __ psychological services** **__ assistive technology __ family training, counseling and support groups** **__ audiology** **___ behavioral interventions using ABA** **___ behavioral interventions using approaches other than ABA** **___interventions using The Developmental, Individual difference, Relationship (DIR) model** **___interventions using sensory integration therapy**				
a. The services checked are/were appropriate for my child.	☐	☐	☐	☐
b. The services checked are/were beneficial to my child.	☐	☐	☐	☐

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ATTACHMENT J

Application for Approval of Individual Evaluators, Service Providers and Service Coordinators

New York State Department of Health, Early Intervention Program

Application for the Approval of Individuals

As Early Intervention Evaluators, Service Providers & Service Coordinators

This application is to be used to apply for approval of individuals as early intervention evaluators, service providers and service coordinators for the statewide Early Intervention Program under Title II-A of Article 25 of the Public Health Law.

Who May Apply: Individuals recognized as qualified personnel by the Early Intervention Program, as defined in 10 NYCRR Section 69-4.1(aj) and with the requisite experience, will be considered for approval as Early Intervention Program Individual Providers.

Minimum Requirements: Applicants must be currently licensed and registered or certified in a profession recognized by the Early Intervention Program as qualified Personnel.

Applicants must have a minimum of 1600 clock hours of experience within the past five years in a clinical pediatric, early intervention or early childhood program delivering services to children ages birth to five years that includes children with special needs. Supervised experience required for licensure or certification may be counted toward this requirement when clinical experience has been in a clinical pediatric, early intervention or early childhood program delivering services to children aged birth to five years that includes children with special needs.

1. Applicants must have developed a Program Standards Plan and must give assurances to maintain the plan. The Program Standards Plan must include policies and/or procedures which ensure:
    - services are delivered in accordance with federal and state laws and regulations related to Early Intervention;
    - provision of services on a twelve month basis and flexibility in the hours of service delivery including evening and weekend hours;
    - provision of services that are family-centered;
    - teaming and communication with other professionals providing early intervention services to the same children;
    - case conferencing and consultation;
    - participation in continuing education and in-service training on policies and procedures related to the Early Intervention Program and Early Intervention Program core competencies.
    - participation in State Department of Health-sponsored EI training, depending on the professional's role (e.g., service coordinator, evaluator, service provider);
    - resolution of questions, concerns, and problems involving parents, county personnel, and other service providers;
    - continuous assessment to improve the quality of service delivery.

How to Apply for Approval as an Individual Early Intervention Provider: To obtain approval, the applicant must submit a completed application, including all required schedules and attachments to New York State. The applicant must also submit a copy of the completed application and all attachments to each county in which the applicant proposes to provide early intervention services. The copy of the application must be sent to the county at the same time as the application is submitted to New York State. The county will review your application and may provide comments to the State regarding your qualifications as an Early Intervention provider.

The following references may be of assistance when completing this application:

- Individuals with Disabilities Education Act (IDEA) Part C (Title 20 USC Sec. 1431 et. seq.) and Title 34 Code of Federal Regulations Part 303 (http://www.ed.gov/about/offices/list/osers/osep/index.html)

- Title II-A of Article 25 of the Public Health Law and Title 10 NYCRR Subpart 69-4 (Early Intervention Program State Program Regulations) (www.health.state.ny.us/nysdoh/eip)

Submit the original signed application to:

Early Intervention Program
NYS Department of Health
Corning Tower, Room 287
Empire State Plaza
Albany, New York 12237-0618
(518) 473-7016
eip@health.state.ny.us

Inquiries concerning this application can be directed to the New York State Department of Health, Early Intervention Program, at the above address or telephone number.

Incomplete applications will be returned. The applicant will receive written notification of approval or disapproval upon completion of the review process.

Social Security Number
__ __ __-__ __-__ __ __ __

Early Intervention Program
NYS Department of Health
Corning Tower, Room 287
Empire State Plaza
Albany, New York 12237-0618

Application for the Approval of Individuals as Evaluators, Service Providers & Service Coordinators

- THIS APPLICATION IS FOR APPROVAL OF **INDIVIDUALS ONLY** (USE FORM # DOH3736 FOR AGENCIES OR GROUPS OF INCORPORATED PROFESSIONALS)
- ALL ATTACHMENTS MUST BE NUMBERED AND REFERENCED TO THIS APPLICATION WHERE INDICATED
- ONLY APPLICATIONS WITH ORIGINAL SIGNATURES WILL BE ACCEPTED

SCHEDULE 1 – Background Information

A. Applicant Identification

Enter your name and social security number. Enter your mailing address. If using a P.O. Box, you must include a street address.

Name (Mr., Mrs., Ms, Miss, Dr.) (Last) (First)				
Social Security No.				
Mailing Address				
Street				
City	County	State	Zip	Telephone # ( )
E-mail:			Fax # ( )	

B. Credentials

Enter information regarding professional license(s)/certificate(s). The last name on the license and registration **MUST** match the name on the application.

Name of Profession:	NYS License/Certification No:
Dates of Registration/Certification From: _____/_____/_____ To: _____/_____/_____ Permananent: _____	
Name of Profession:	NYS License/Certification No:
Dates of Registration/Certification From: _____/_____/_____ To: _____/_____/_____ Permananent: _____	

C. Employment History

The following experience requirements apply to all individuals seeking approval to provide early intervention services as a professional individual provider:

- A minimum of 1600 clock hours of experience within the past five years in a clinical pediatric, early intervention or early childhood program delivering services to children under five years old that includes children with special needs.

- Supervised experience required for licensure or certification may be counted toward this requirement when clinical experience has been in a clinical pediatric, early intervention or early childhood program delivering services to children aged birth to five years that includes children with special needs.

- Individuals who do not meet the experience requirements may apply for a waiver of these requirements. Contact your municipal early intervention program for information on obtaining a waiver.

Using the chart below, describe all clinical experience within **the past five years** (listing the most recent experience first) in which you provided services in your discipline to infants and young children (**age birth to 5 years**) and their families in the settings described above. This may include supervised clinical experience required for licensure or certification.

Dates (From/To)	**Employer Name & Address Telephone number Supervisor's Name**	**Approved EI Provider?**	**Total Hours By Age Group**
From __/__/__ To __/__/__		No ❑ Yes ❑	Birth-2 years No. of Hours ____ 2 yrs – 5 yrs No. of Hours ____
From __/__/__ To __/__/__		No ❑ Yes ❑	Birth-2 years No. of Hours ____ 2 yrs – 5 yrs No. of Hours ____
From			

Dates (From/To)	**Employer Name & Address Telephone number Supervisor's Name**	**Approved EI Provider?**	**Total Hours By Age Group**
__/__/__ To __/__/__		No ❑ Yes ❑	Birth-2 years No. of Hours ____ 2 yrs – 5 yrs No. of Hours ____
From __/__/__ To __/__/__		No ❑ Yes ❑	Birth-2 years No. of Hours ____ 2 yrs – 5 yrs No. of Hours ____
From __/__/__ To __/__/__		No ❑ Yes ❑	Birth-2 years No. of Hours ____ 2 yrs – 5 yrs No. of Hours ____

D. Affiliations

1. Are you an approved Medicaid Provider?

   No ❑ Yes ❑

If yes: Please provide your Medicaid Provider number: _____

2. Are you recognized by any managed care plans as a participating or in-network provider?

   No ❑ Yes ❑

If yes: Please attach a list of all managed care plans with which you are a participating or in-network provider. (Attachment # ____)

SCHEDULE 2 – DISCLOSURE INFORMATION

A. Offices Held in Health or Human Service Agencies/Facilities

Enter information regarding any offices you held in any health or human service agencies or facilities, including early intervention or special education preschool programs, within the past ten (10) years. Attach additional sheets if necessary (Attachment #_____)

Check here if ❒ Not applicable

Name of Facility/Agency	Title of Office Held: From: _____/_____/_____ To: _____/_____/_____
Address:	
Name of Facility/Agency	Title of Office Held: From: _____/_____/_____ To:_____/_____/_____
Address:	

B. Ownership/Interest in any other entity

Enter the name, address and other data of any health or human services agencies or facilities you have or had a fiscal or operating interest in within the past ten (10) years. Include all entities that were approved to provide early intervention or childhood education services.

Check here if ❒ Not applicable

Name of entity	Type of entity
Address	Date of Ownership From (date) _____/_____/_____ To (date) _____/_____/_____ Type of Ownership/Interest:
Current status of entity (check one) ❒ Open ❒ Closed ❒ Proposed	

State Agency Approval of entity listed above (check one)

❑ Department of Health
❒ State Education Department
❒ Office of Mental Health
❒ Office of Mental Retardation and Developmental Disabilities
❒ Office of Alcohol and Substance Abuse Services

Attach additional sheets if necessary (Attachment #_____)

C. Record of Legal Actions

1. Except for minor traffic violations, were you ever convicted of any violation of the law (e.g., criminal, civil, or administrative charges)?

   ❑ No ❑ Yes

2. Have you ever been sanctioned by any Federal, State or local agency in relation to the operation of an agency that provides health and human services?

   ❑ No ❑ Yes

3. Have you ever been restricted, suspended or excluded from participation as a Medicaid provider?

   ❑ No ❑ Yes

4. Are there any criminal, civil or administrative charges pending against you?

   ❑ No ❑ Yes

5. If the answer to any of these questions is "yes", complete the following for <u>each</u> action. Attach additional sheet(s) as necessary. If criminal or civil action has been taken against you, attach documents from the court describing the disposition of the action. (Attachment #_____)

Date of Action: _____ Type of Action: _____

Location: _____

Explanation of Violation:

_____
_____
_____
_____
_____

D. Professional Record

1. Has your professional license, registration or certificate ever been suspended or revoked, or have you ever been the subject of any other enforcement actions (e.g., fines, sanctions, etc.)?

   ☐ Yes ☐ No

2. If "yes" to (1) above, attach a separate sheet providing the following information:

   a. Date(s) of action(s)

   b. Reason(s) for action(s)

   c. Resolution of action(s) (include corrective action that was taken and whether approval has been reinstated)

   d. Date of reinstatement

   e. Corrective action(s) that facilitated reinstatement.

   (Attachment #_____)

SCHEDULE 3 – Availability

A. Available FTEs

Complete the chart below, indicating your availability to provide early intervention services for each category /categories for which you are seeking approval. To calculate the full-time equivalents (FTE), divide the number of hours you want to work each week by 40 (e.g., 40 hours equals one FTE, 20 hours equals .5 FTEs, etc.).

Discipline	Available FTE
Audiology:	
Audiologist	
Medical/Nursing:	
Pediatrician	
Physician other than Pediatrician	
Physician Assistant*	
Nurse Practitioner	
Registered Nurse	
Licensed Practical Nurse*	
Nutrition:	
Certified Dietitian/Nutritionist	
Registered Dietitian	
Occupational Therapy:	
Occupational Therapist	
Occupational Therapy Assistant*	
Physical Therapy:	
Physical Therapist	
Physical Therapist Assistant*	
Psychology:	
Licensed Psychologist	
School Psychologist**	
Social Work:	
Licensed Master Social Worker	
Licensed Clinical Social Worker	
Speech Pathology:	
Speech-Language Pathologist	

Discipline	Available FTE
Special Education:	
Teacher of Special Education	
Teacher of Students with Disabilities	
Teacher of Blind and Partially Sighted	
Teacher of the Blind and Visually Impaired	
Teacher of Deaf and Hearing Impaired	
Teacher of the Deaf and Hard of Hearing	
Teacher of Speech and Hearing Handicapped	
Teacher of Speech and Language Disabilities	
Vision Services:	
Certified Orientation and Mobility Specialist	
Certified Low Vision Specialist	
Fellows of the College of Optometrists in Vision Development (FCOVD)	

*These professionals can only provide early intervention services in an employment setting with appropriate supervision, with the exception of service coordination services

** Per Article 153, Section 7605, of the State Education Law, certified school psychologists may only provide services when directly employed by a federal, state, county or municipal government, or employed by providers approved under section 4410 of education law.

SCHEDULE 4 – SERVICE PROGRAM

A. Services

Check the early intervention services types for which you are seeking approval (see Definitions). *Please check all that apply*.

❑ Individual Provider (Contract directly with county)

❑ Subcontractor (Contract with an approved agency)

1. ❑ Supplemental Evaluations
2. ❑ Service Coordination Services
3. ❑ Early Intervention Service Model Options (Check all that apply)

   a. Home/community-based individual/collateral visits ❑

   b. Facility-based individual/collateral visits * ❑

   c. Group Services* ❑

   Check all applicable site locations in addition to service model.

   1. Parent – Child groups
      - On-site in facility operated by you ❑
      - Off-site ❑
      - Both ❑

   2. Group developmental intervention ❑
      - On-site in facility operated by you ❑
      - Off site in community settings ❑
      - Both ❑

   3. Family/caregiver support group
      - On-site in facility operated by you ❑
      - Off site in community settings ❑
      - Both ❑

***** Complete **Schedule 5 – Facility Sites** if you intend to provide early intervention services using any of the above model options at a site you own and/or operate.

B. Languages and Other Forms of Communication

Indicate the languages (other than English) and other forms of communication with which you are fluent, if any.

Spanish	☐ Yes	Russian	☐ Yes
Chinese Mandarin	☐ Yes	Arabic	☐ Yes
HaitianCreole	☐ Yes	Hebrew	☐ Yes
Bengali	☐ Yes	French	☐ Yes
Urdu	☐ Yes	Vietnamese	☐ Yes
Sign Language	☐ Yes	Yiddish	☐ Yes

Other (please specify) _____

_____

C. Specialized Services

Can you provide specialized services for specific populations of infants and toddlers?

☐ No ☐ Yes

If yes, please specify service method (e.g., behavioral interventions) and population. Attach additional sheets if necessary. (Attachment# ____)

_____ _____
Service Method Population

_____ _____
Service Method Population

D. Child Care Licensing Requirements

<u>All Individuals Providing Services</u>

1. Do you now or do you intend to provide care, which may include group developmental interventions, to three or more children together for more than three hours per day per child in a facility owned and/or operated by you?

   ☐ No Yes

2. If yes, are you registered or licensed by the Office of Children and Family Services (OCFS) to deliver child care services?

   No ❑ Yes ❑ (please provide type and registration license number below)

   Type: _____ License #_____

*If you **<u>are not</u>** a licensed child care provider but answered yes to (1) above, you should contact the Office of Children and Family Services regarding obtaining licensure as a child care provider*

3. If "yes" to (2) above, provide the date of the most current site visit, program review or audit by the Office of Children and Family Services:

   Date of Review: ___/_____/_____

4. Have you ever been the subject of any child-care related enforcement actions (e.g., fines, sanctions, etc.) or operated a daycare center that had its registration or license restricted, revoked or suspended by OCFS?

   No ❑ Yes ❑

   If "yes" attach separate sheet providing the following information:

   a. Dates of action

   b. Reason(s) for action

   c. Resolution of action (include corrective action that was taken and whether approval has been reinstated) (Attachment #_____)

<u>Individuals Providing Services in New York City</u>

5. Do you now, or do you intend to provide care, which may include group developmental interventions, to seven or more children together for five or more hours per week?

   No ❑ Yes ❑

   If yes, are you licensed by the New York City Department of Health and Mental Hygiene to deliver day care services?
   No ❑ Yes ❑

6. If yes, please provide your permit number below and append a copy of your permit:

   Permit #_____

If you are not a licensed day care provider but answered yes to (6) above, you should contact the New York City Department of Health and Mental Hygiene regarding obtaining licensure as a day care provider.

7. If "yes" to (7) above, provide the date of the most current site visit, program review or audit by the New York City Department of Health and Mental Hygiene:

   Date of Review: ___/_____/_____

8. Have you ever been the subject of any child-care related enforcement actions (e.g., fines, sanctions, etc.) or operated a daycare center that had its permit restricted, revoked or suspended by the New York City Department of Health & Mental Hygiene?

No ❑ Yes ❑

If "yes" attach separate sheet providing the following information*:*

a. Dates of action

b. Reason(s) for action

c. Resolution of action (include corrective action that was taken and whether approval has been reinstated) (Attachment #_____)

E. Service Catchment Area

Check all counties for which you are seeking to provide early intervention services. If you check counties that are not in proximity to your address or to each other, please provide an explanation as to how you will be able to deliver services in these counties. (Attachment # _____)

- ❑ Albany
- ❑ Allegany
- ❑ Broome
- ❑ Cattaraugus
- ❑ Cayuga
- ❑ Chautauqua
- ❑ Chemung
- ❑ Chenango
- ❑ Clinton
- ❑ Columbia
- ❑ Cortland
- ❑ Delaware
- ❑ Dutchess
- ❑ Erie
- ❑ Essex
- ❑ Franklin
- ❑ Fulton
- ❑ Genesee
- ❑ Greene
- ❑ Hamilton
- ❑ Herkimer
- ❑ Jefferson
- ❑ Lewis
- ❑ Livingston
- ❑ Madison
- ❑ Monroe
- ❑ Montgomery
- ❑ Nassau
- ❑ Niagara
- ❑ Oneida
- ❑ Onondaga
- ❑ Ontario
- ❑ Orange
- ❑ Orleans
- ❑ Oswego
- ❑ Otsego
- ❑ Putnam
- ❑ Rensselaer
- ❑ Rockland
- ❑ St. Lawrence
- ❑ Saratoga
- ❑ Schenectady
- ❑ Schoharie
- ❑ Schuyler
- ❑ Seneca
- ❑ Steuben
- ❑ Suffolk
- ❑ Sullivan
- ❑ Tioga
- ❑ Tompkins
- ❑ Ulster
- ❑ Warren
- ❑ Washington
- ❑ Wayne
- ❑ Westchester
- ❑ Wyoming
- ❑ Yates

New York City Area

- ❑ Bronx
- ❑ Kings
- ❑ Queens
- ❑ New York
- ❑ Richmond

SCHEDULE 5 - FACILITY SITES
Complete this schedule for each and every facility site operated by the applicant.

A. Name/Address of Site

Street Address		
City	(County)	Zip
Telephone: ( )		

B. Early Intervention Service Model Options

Check the early intervention service model options that you will provide at this site:

- ❑ Facility based individual/collateral visits
- ❑ Parent-child groups
- ❑ Group developmental intervention
- ❑ Family/caregiver support group

C. Safety Policy

1. Attach a copy of the Certificate of Occupancy. (Attachment # ___)

2. Attach a fire evacuation plan and site diagram or a fire inspection report from the last 12 months for each site. (Attachment #____)

3. Attach assurances of the ability to administer cardiopulmonary resuscitation and first aid. (Attachment # ____)

D. Compliance with American with Disabilities Act

4. Is the site compliant with the Americans with Disabilities Act?

❑ Yes ❑ No

Social Security Number
__ __ __-__ __-__ __ __ __

SCHEDULE 6 - STATEMENT OF REASSIGNMENT

_____
Name of Applicant:

By this reassignment, the above-named provider of early intervention services agrees:

1. To reassign all Medicaid reimbursement for early intervention services to the municipal early intervention agency (county) that you contract with to provide early intervention services.

2. To accept as payment in full from the municipal early intervention agency (county) the State Department of Health promulgated payment levels for covered early intervention services.

3. To not bill Medicaid for eligible early intervention services which are specified in a child's individualized family services plan (IFSP). These services will be directly billed to and reimbursed by the municipal early intervention agency (county).

4. To comply with all the rules and policies as described in your contract(s) with the municipal early intervention agency(ies) (county).

_____
Signature **Date**

_____
Address

_____
City **State** **Zip**

NOTE: NOTHING IN THIS STATEMENT OF REASSIGNMENT PROHIBITS A MEDICAID PROVIDER FROM CLAIMING REIMBURSEMENT FOR MEDICAID ELIGIBLE SERVICES RENDERED **OUTSIDE** THE SCOPE OF THE EARLY INTERVENTION PROGRAM.

Social Security Number
__ __ __-__ __-__ __ __ __

SCHEDULE 7 - Provider Agreement Form

PROVIDER AGREEMENT
BETWEEN THE NEW YORK STATE DEPARTMENT OF HEALTH AND SERVICE PROVIDERS IN THE NEW YORK STATE EARLY INTERVENTION PROGRAM

Contingent upon approval by the New York State Department of Health to participate in the New York State Early Intervention Program, and the satisfactory completion of a Medicaid provider agreement and statement of reassignment for the purpose of establishing eligibility to participate in the New York State Medicaid Program under title XIX of the Social Security act, _____(Applicant's Name), hereafter called the Provider, agrees as follows to:

A. (1) Keep any records necessary to disclose the extent of services the Provider furnishes to recipients receiving assistance under the New York State Plan for Medical Assistance.
(2) On request, furnish the New York State Department of Health, or its designee, and the Secretary of the United States Department of Health and Human Services, and the New York State Medicaid Fraud Control Unit any information maintained under paragraph (A) (1), and any information regarding any Medicaid claims reassigned by the Provider to the local early intervention agency.
(3) Comply with the disclosure requirements specified in 42 CFR Part 455, Subpart B.

B. Comply with Title VI of the Civil Rights Act of 1964, Section 504 of the Federal Rehabilitation Act of 1973, and all other State and Federal statutory and constitutional non-discrimination provisions which prohibit discrimination on the basis of race, color, national origin, handicap, age, sex, sexual orientation, religion, HIV and marital status.

C. Abide by all applicable Federal and State laws and regulations, including the Social Security Act, New York State Social Services Law, Part 42 of the Code of Federal Regulations and Title 18 of the Codes and Regulations of the State of New York.

D. Provide services in accordance with Title II-A of Article 25 of the Public Health Law and Subpart 69-4 of Title 10 of the Codes Rules and Regulations of the State of New York (Early Intervention Program).

Authorized Signature: _____

Address: _____

City: _____**State:** _____**Zip:** _____

Telephone No.: _____**Date Signed:** _____

SCHEDULE 8 – ASSURANCES

The applicant assures the Commissioner of Health of compliance with all requirements under Title II-A of Article 25 of the Public Health Law; 10 NYCRR: Subpart 69-4; Part C of the Federal Individuals with Disabilities Education Act and 34 CFR Part 303.

- The applicant assures the maintenance of current state licensure and/or certification and demonstrated proficiency in early childhood development, e.g., previous experience in the delivery of services to infants and toddlers with developmental delay or disability.

- The applicant assures that s/he will notify the Department within two working days of suspension, expiration, or revocation of licensure, certification or registration.

- The applicant assures that s/he has the ability to and will provide services to children in accordance with IFSPs and in natural settings to the maximum extent appropriate.

- The applicant assures that s/he will immediately notify the Early Intervention Official if s/he becomes aware of any health or safety hazard posed by community-based settings where s/he is providing parent-child groups, family support groups, or group developmental interventions.

- The applicant assures that s/he will participate in in-service training in the delivery of early intervention services.

- The applicant agrees to enter into an approved Medicaid Provider Agreement and to reassign Medicaid benefits to the local county early intervention program or City of New York early intervention program.

- The applicant assures s/he has the ability to act as a member of a multidisciplinary team, including demonstration of prior experience in collaborating with other professionals in the design and delivery of services.

- The applicant assures s/he has the capacity to deliver services on a twelve-month basis and provide flexibility in hours of service delivery, including weekend and evening hours.

- The applicant assures s/he will comply with the confidentiality requirements set forth in federal and state statute and regulation.

- The applicant assures that s/he will conform with health, safety and sanitation standards established by the Department;

- Where applicable, the applicant assures that any sites s/he operates and will use for the purposes of early intervention service delivery are compliant with all local fire, health and safety codes, and with the Americans with Disabilities Act.

- The applicant assures that s/he will request, in writing, approval from the State Agency granting approval, if s/he wishes to modify any of the information contained in this application, including catchment area, target population or qualifications to deliver services.

- The applicant assures that the agency will abide by department policies as stated in the Department of Health's Early Intervention Program Memorandums and other forms of guidance.

Acknowledgement

I, the undersigned, hereby certify under penalty of perjury, that I am duly authorized to subscribe and submit this application and that the information contained herein and attached hereto, is accurate, true and complete in all material aspects. I further acknowledge that the application will be processed pursuant to the provisions of Title II-A of Article 25 of the Public Health Law, and the pertinent regulations adopted thereto.

_____	_____
Print Name (Mr. Mrs., Miss, Dr)	Title
_____	_____
Signature	Date

Definitions

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Term	Definition
Catchment Area	Counties for which the applicant is seeking approval to provide early intervention services.
Facility site	A site operated by an applicant seeking early intervention approval where children receive early intervention services.
Natural Environment	Settings that are natural or normal for the child's age peers who have no disability, including the home, a relative's home when care is delivered by the relative, childcare setting, or other community settings in which children without disabilities participate.
Qualified Personnel	Individuals with the appropriate licensure, certification or registration in the area in which they are providing services. A list of such personnel can be found in early intervention regulations 10NYCRR 69-4.1(aj).
Employed	Refers to personnel directly employed by an agency.
Available by Contract	Refers to individual qualified personnel and agencies available to the applicant through a contractual agreement. An individual under contract is not employed by the applicant.
Multidisciplinary Evaluation	The procedures used by appropriate qualified personnel to determine a child's initial and continuing eligibility for the Early Intervention Program, including determining the status of the child in each of the following areas of development: cognitive, physical, communication, social or emotional, and adaptive development. Multidisciplinary evaluations can be comprised of: *Core Evaluations*: must include a developmental assessment; a review of pertinent records and a parent interview as specified in regulations and may include a family assessment. *Supplemental Evaluations:* Include physician and non-physician evaluations provided upon the recommendation of the multi-disciplinary team conducting the core evaluation and with the agreement of the parent. A supplemental evaluation may also be provided in conjunction with the core evaluation by a specialist trained in the area of the child's suspected delay or disability.
Home and community-based visits	The provision by appropriate qualified personnel of early intervention services to the child and/or parent or other designated agency at the child's home or other natural environment.
Facility-based individual collateral visits	The provision by appropriate qualified personnel of early intervention services to the child and/or parent or other designated caregiver at an approved early intervention provider's site.
Parent-child groups	A group comprised of parents or caregivers, children, and a minimum of one appropriately qualified provider of early intervention services at an

Term	Definition
	early intervention provider's site or community based setting (e.g., day care center, family day care, or other community settings).
Group developmental intervention	The provision of early intervention services by appropriately qualified personnel to a group of eligible children at an approved provider's site or in a community-based setting where children under three years of age are typically found (this group may also include children without disabilities).
Family/caregiver support group	The provision of early intervention services to a group of parents, caregivers (foster parents, day care staff) and/or siblings of eligible children for the purposes of: (a) enhancing their capacity to care for and/or enhance the development of the eligible child; and (b) providing support, education, and guidance to such individuals relative to the child's unique developmental needs.
Service Coordination	Includes assistance and services provided by a service coordinator to enable an eligible child and the child's family to receive the rights, procedural safeguards and services that are authorized under the Early Intervention Program.
Specialized services	Expertise providing services to a specific population of children and/or families**.**

APPLICATION CHECKLIST

- ❑ You have kept a copy of this application and have sent a copy of the application to each county in which you propose to provide services. Send original to DOH.
- ❑ Employment section is completed and experience is related to infants and toddlers with developmental delay or disabilities.
- ❑ A summary/description of the proposed program standards plan is attached.
- ❑ Copies of your license and current registration or teaching certification is attached for all disciplines checked in Schedule 3A.
- ❑ FTEs in Schedule 3A are specified in appropriate column and do not exceed 1.0 FTE.
- ❑ Verify that **ALL** counties (Schedule 4F) checked for which you are seeking approval to provide early intervention services are within an appropriate geographical area.
- ❑ If you are seeking to provide facility-based services, copies of health, safety and fire evacuation policies; Certificate of Occupancy and assurance of ADA compliance (Schedule 5) must be enclosed for each site. Facility-based means services are being provided in a place operated by the applicant.
- ❑ The Statement of Reassignment and Provider Agreement are signed, dated and attached.
- ❑ Complete and notarize the **Acknowledgement**. (Schedule 8)

Failure to submit all required attachments and a fully completed application will result in the application being returned to the applicant for resubmission.

ATTACHMENT K

Application for Approval of Agencies or Incorporated Groups of Individuals as Evaluators, Service Providers and Service Coordinators

New York State Department of Health, Early Intervention Program

Application for the Approval of Agencies

As Early Intervention Evaluators, Service Coordinators & Service Providers

This application is to be used to apply for approval of agencies as early intervention evaluators, service providers and service coordinators for the statewide Early Intervention Program under Title II-A of Article 25 of the Public Health Law.

Who May Apply for Approval as an Early Intervention Agency: The following organizations will be considered for approval as Early Intervention Program Agencies: incorporated entities, sole proprietorships, partnerships and state-operated facilities with an organizational structure **t**hat complys with all federal and state statutes and regulations, including practice acts established by the State Education Department Office of Professions.

Minimum Agency Requirements: Agencies must designate an Early Intervention (EI) Program Director with a minimum of two years full time or equivalent of experience in an early intervention, clinical pediatric or early childhood education program that includes children with special needs. This individual must be available a sufficient amount of time to develop and ensure implementation of a Program Standards Plan and to ensure that the provider is in compliance with federal and state requirements.

Agencies must also have a minimum of two individuals (excluding the program director), recognized as qualified personnel by the Early Intervention Program, as defined in 10 NYCRR Section 69-4.1(aj), each available to provide a minimum of 20 hours per week early intervention services.

A Program Standards Plan which includes policies and/or procedures to:

- ensure services are delivered in accordance with federal and state laws and regulations related to Early Intervention ;
- ensure provision of services on a twelve month basis and flexibility in the hours of service delivery including evening and weekend hours;
- ensure provision of services that are family-centered;
- assist with teaming and communication with parents and other service providers ;
- assist with clinical mentorship opportunities;
- assist with case conferencing and consultation;
- assure availability of continuing education and in-service training on policies and procedures related to the Early Intervention Program and Early Intervention Program core competencies.
- assist with participation in State Department of Health sponsored EI training depending on the professional's role (e.g., service coordinator, evaluator, service provider);

- ensure resolution of questions, concerns, and problems involving parents, county personnel, and other service providers; and,
- routinely assess and improve the quality of service delivery.

How to apply for Approval as an Early Intervention Agency: To obtain approval, the applicant must submit a completed application, including all required schedules and attachments to New York State. The applicant must also submit a copy of the completed application and all attachments to each county in which the applicant proposes to provide early intervention services. The copy of the application must be sent to the county at the same time as the application is submitted to New York State. The county will review your application and may provide comments to the State regarding your qualifications as an Early Intervention provider.

The following references may be of assistance when completing this application:

- Individuals with Disabilities Education Act (IDEA) Part C (Title 20 USC Sec. 1431 et. seq.) and Title 34 Code of Federal Regulations Part 303 (http://www.ed.gov/about/offices/list/osers/osep/index.html)

- Title II-A of Article 25 of the Public Health Law and Title 10 NYCRR Subpart 69-4 (Early Intervention Program State Program Regulations) (www.health.state.ny.us/nysdoh/eip)

Submit the original signed and notarized application to:

Early Intervention Program
NYS Department of Health
Corning Tower, Room 287
Empire State Plaza
Albany, New York 12237-0618

Inquiries concerning this application can be directed to the New York State Department of Health, Early Intervention Program, at the above address; by telephone at (518) 473-7016, or by e-mail at eip@health.state.ny.us .

An agency that is an approved program under Section 4410 of the Education Law may apply to either the Department of Health at the above address or the State Education Department at the following address:

New York State Education Department
Office of VESID
One Commerce Plaza, Rm. 1624
Albany, NY 12234
(518) 486-7584

Incomplete applications will be returned. The applicant will receive written notification of approval or disapproval upon completion of the review process.

NYS Department of Health
Early Intervention Program
Corning Tower, Room 287
Empire State Plaza
Albany, New York 12237

Application for the Approval of Agencies as Evaluators, Service Coordinators & Service Providers

SCHEDULE 1 – Background Information

A. Applicant Identification

Enter the agency's legal name and federal employer identification number. If conducting business under an assumed name (d/b/a), also provide the d/b/a. Enter the mailing address of the agency. Enter the main telephone number for the agency and a fax number, if available. If the address of the main office is different than the mailing address or if files and records are located at a different address than the mailing address, enter that address under office address. Enter e-mail address if available.

AGENCY NAME			***Federal Employer Identification Number*** __ __ - __ __ __ __ __ __	
d/b/a (Where applicable)				
Mailing Address (Street)				
City	County	State	Zip	Telephone # ( ) Fax # ( )
Office Address (location of files and records)				
E-mail Address				

1. Has the agency named above r been previously approved by the Department of Health other state agency, to deliver early intervention evaluations, service coordination or services under a different name or organizational structure?

   ☐ Yes ☐ No

If yes, please complete all information requested below pertaining to that agency.

Name of entity	Type of entity
Address (include county)	Date of Ownership From (date) _____/_____/_____ To (date) _____/_____/_____ Type of Ownership/Interest:
Current status of entity (check one) ❒ Open ❒ Closed	
State agency approval of entity (Check all that apply) ❑ Department of Health ❑ State Education Department ❑ Office of Mental Health ❑ Office of Mental Retardation and Developmental Disabilities	

B. Designated EI Program Director

Enter the name, title, telephone number and e-mail address of the EI Program Director for the agency.

Name (Mr., Mrs., Ms, Miss, Dr.)	
Title E-mail Address:	Office Telephone # ( )

C. Board Resolution

Corporate applicants must attach a copy of a board resolution authorizing the agency to submit this application. Public applicants must attach a resolution from the local legislature, board of supervisors or other governing body having jurisdiction over the applicant agency authorizing an individual to submit this application.
(Attachment # _____)

SCHEDULE 2 – Corporate Structure/Disclosure Requirements

A. Type of Ownership

Check the box that indicates the Type of Ownership of the applicant agency. If applicable, attach a certified copy of the Assumed Name Certificate (d/b/a). Where certified copies are required, such documents can be obtained by the issuing agency, either the New York State Department of State, Division of Corporations, 41 State Street, Albany, New York 12231 or the county clerk's office in which the business is located.

1. ❑ Sole Proprietor

a. The sole proprietor must complete Schedule 3 - Disclosure Information.
b. The EI Program Director must complete Schedule 3 and attach a resume detailing experience in early intervention, clinical pediatric or early childhood education programs that include children with special needs.
c. Attach a certified copy of the Assumed Name Certificate (Attachment #_____).

2. ❑ Partnership

a. Each partner must complete Schedule 3 - Disclosure Information.
b. The EI Program Director must complete Schedule 3 and attach a resume detailing experience in early intervention, clinical pediatric or early childhood education programs that include children with special needs.
c. Attach a photocopy of the applicant's fully executed Partnership Agreement. (Attachment #_____)
d. Attach a certified copy of the Assumed Name Certificate (Attachment #_____)

3. ❑ Professional Limited Liability Company (PLLC)

a. Each officer of the applicant PLLC must complete Schedule 3 -Disclosure Information.
b. The EI Program Director must complete Schedule 3 and attach a resume detailing experience in early intervention, clinical pediatric or early childhood education programs that include children with special needs.
c. Attach a photocopy of the applicant's fully executed Articles of Organization, and filing receipt. (Attachment #_____)

4. ❑ Limited Liability Partnership (LLP)

a. Each partner must complete Schedule 3 - Disclosure Information.
b. The EI Program Director must complete Schedule 3 and attach a resume detailing experience in early intervention, clinical pediatric or early childhood education programs that include children with special needs.
c. Attach a photocopy of the applicant's fully executed Partnership Agreement. (Attachment #_____)
d. Attach a photocopy of the applicant's fully executed Certificate of Limited Partnership, and filing receipt. (Attachment #_____)

5. ❑ Not-For-Profit Corporation

a. Each officer must complete Schedule 3 - Disclosure Information.
b. The EI Program Director must complete Schedule 3 and attach a resume detailing experience in early intervention, clinical pediatric or early childhood education programs that include children with special needs.
c. Attach a certified copy of the Certificate of Incorporation, and filing receipt. (Attachment #_____)

6. ❑ Business Corporation

a. Each officermust complete Schedule 3 - Disclosure Information.
b. The EI Program Director must complete Schedule 3 and attach a resume detailing experience in early intervention, clinical pediatric or early childhood education programs that include children with special needs.
c. Attach a certified copy of the Certificate of Incorporation, and filing receipt, (Attachment #_____)

7. ❑ Professional Corporation (PC)

a. Each officer of the corporation must complete Schedule 3 - Disclosure Information.
b. The EI Program Director must complete Schedule 3 and attach a resume detailing experience in early intervention, clinical pediatric or early childhood education programs that include children with special needs.
c. Attach a certified copy of the Certificate of Incorporation, and filing receipt, (Attachment #_____)

8. ❑ Government Subdivision

a. Authorized individual must complete Schedule 3 – Disclosure Information
b. The EI Program Director must complete Schedule 3 and attach a resume detailing nt experience in early intervention, clinical pediatric or early childhood education programs that include children with special needs.

9. ❑ Limited Liability Company (LLC)

a. Each officer of the applicant LLC must complete Schedule 3 - Disclosure Information.
b. The EI Program Director must complete Schedule 3 and attach a resume detailing experience in early intervention, clinical pediatric or early childhood education programs that include children with special needs.
c. Attach a photocopy of the applicant's fully executed Articles of Organization, and filing receipt. (Attachment #_____)

B. Foreign Entities

Foreign entities are those already formed in another state that may apply for authority to conduct business in New York State. In addition to the documentation required in Section A, foreign entities must provide:

a. Schedule 3 - Disclosure Information as required for the type of organizational structure noted above (e.g., sole proprietorship, partnership, PLLC, LLP, Not-For-Profit Corporation, Business Corporation, PC, LLC, Government Subdivision).

b. The EI Program Director must complete Schedule 3 and attach a resume detailing experience in early intervention, clinical pediatric or early childhood education programs that include children with special needs.

c. Attach a copy of the Application for Authority to Do Business in New York, and the Department of State filing receipt (Attachment # _____)

C. Parent Organization Information

For all organizations with a parent organization, complete related organization information as indicated. A parent organization is any entity that wholly owns or has a majority interest in the applicant entity.

1. List the full legal name and address of the principal office and place of doing business of any parent organization. (Attachment #_____)

2. For each parent organization identified in C (1):

   a. List the full name and title of each member of the Board of Directors, board officers, principal stockholders or sponsors of such parent organization. (Attachment #_____)

   b. List the full legal name and the address of the principal office and place of doing business of any agencies or facilities owned or operated by the parent organization or subsidiary corporation that are certified or licensed for the provision of health or human services or educational services, including preschool programs for children with disabilities,

   c. Describe in detail the relationship between the applicant agency and any parent organization, including the method or mechanism by which control over the applicant agency is or will be effectuated (e.g. stock ownership, membership arrangement, common officers, directors or stockholders or other arrangement) (Attachment # _____)

***SCHEDULE 3 – DISCLOSURE INFORMATION** – all three pages must be completed by each individual identified in Schedule 2. This form may be duplicated as necessary.*

A. Personal Qualifying Information

Name (Mr., Mrs., Ms, Miss. Dr.)		Title	
Social Security Number			
Address			
City	County	Zip	Telephone #: ( )

B. Licenses/Certificates Held

1. Enter information regarding professional license(s) or teacher certification.

   NONE: _____

Name of Profession:	NYS License/Certification No:
Dates of Registration/Certification: From:_____/_____/_____ To: _____/_____/_____	
Name of Profession:	NYS License/Certification No:
Dates of Registration/Certification: From:_____/_____/_____ To: _____/_____/_____	

2. Has your professional license, registration or certification ever been suspended or revoked?

   ☐ Yes ☐ No

3. If "yes" to (1) above, attach a separate sheet providing the following information:

   a. Date(s) of action(s)

   b. Reason(s) for action(s)

   c. Resolution of action(s) (include corrective action that was taken and whether approval has been reinstated)

   d. Date of reinstatement

C. Offices/Positions Held in Health or Human Service Agencies/Facilities

Enter information regarding any offices/positions held in other health or human service agencies or facilities, including early intervention and/or special education preschool programs, over the past ten (10) years. *Attach additional sheets if necessary* (Attachment #_____)

None:_____

Name of Facility/Agency	Office/position held: From: / / to: / /
Address:	
Name of Facility/Agency	Office/position held: From: / / to: / /
Address:	

D. Record of Legal Actions

1. Except for minor traffic violations, have you ever been convicted of any violation of the law (e.g., criminal, civil, or administrative charges)?

   ❑ No ❑ Yes

2. Has any agency that provides health and human services in which you held an office or position ever been sanctioned by any Federal, State or local agency?

   ❑ No ❑ Yes

3. Have you ever been restricted, suspended or excluded from participation as a Medicaid provider?

   ❑ No ❑ Yes

4. Are there any criminal, civil or administrative charges pending against you?

   ❑ No ❑ Yes

If the answer to any of these questions is "yes", complete the following for <u>each</u> action. Attach additional sheet(s) as necessary (Attachment #_____)

Date of Action: _____ Type of Action: _____

Location: _____

Explanation of Violation:
_____

_____

E. Ownership/Interest in any other entity

Enter the name, address and other data indicating other health or human service agencies or facilities you have or had an interest in over the past ten (10) years. Include all entities that were approved to provide early intervention or early childhood services. Attach additional sheets, if necessary (Attachment #_____)

None:_____

Name of entity	Type of entity
Address	Date of Ownership From (date) _____/_____/_____ To (date) _____/_____/_____ Type of Ownership/Interest:
Current status of entity (check one) ❒ Open ❒ Closed ❒ Proposed	
State agency approval of entity (Check all that apply) ❑ Department of Health ❑ State Education Department ❑ Office of Mental Health ❑ Office of Mental Retardation and Developmental Disabilities ❑ Office of Children and Family Services ❑ Office of Alcohol and Substance Abuse Services	

F. Certification

The Certification must contain the signature of the individual named in Schedule 3 A.

The undersigned hereby certifies under penalty of perjury that the information contained in Schedule 3, and all attachments to Schedule 3 herein is accurate, true and complete in all material respects.

_____ Title_____

Print Name

_____ Date_____

Signature

SCHEDULE 4 – APPLICANT AGENCY AFFILIATION

A. Health, Education, Developmental Disabilities, and Mental Hygiene Agencies

Please complete the following questions regarding the applicant agency's affiliation with other government entities. Please answer all questions.

1. Is the applicant agency currently approved, certified or licensed by any of the following state agencies for services other than early intervention? Check below to indicate status and if yes, provide the license or certification number, if any.

1) **New York State Department of Health** ❑ No ❑ Yes

[ ] Article 28 PHL Diagnostic and Treatment Center #_____
[ ] Article 28 PHL Hospital Based Outpatient Clinic #_____
[ ] Article 36 CHHA (Certified Home Health Agency) #_____
[ ] Article 36 LHCSA (Licensed Home Care Service Agency) #_____
[ ] Approved Medicaid Provider #_____
If more than one Medicaid Provider number, provide all numbers.
(Attachment # ____)

2) State Education Department ❑ No ❑ Yes

[ ] Section 4410 Education Law #_____
[ ] BOCES/School District #_____
[ ] VESID #_____

3) Office of Mental Retardation and Developmental Disabilities ❑ No ❑ Yes

[ ] Article 16 OMRDD Clinics #_____
[ ] Comprehensive Medicaid Case Management #_____

4) Office of Mental Health ❑ No ❑ Yes

[ ] Article 31 MHL Clinics #_____

5) Office of Alcohol and Substance Abuse Services ❑ No ❑ Yes

[ ] Residential Service Provider # _____
[} Outpatient Service Provider # _____

6) Office of Children and Family Services ❑ No ❑ Yes

[ ] Day Care Center #_____

2. If "yes" to any of the above, provide the date of the most current site visit, program review or audit by the relevant government agency(ies). Attach additional sheets if necessary (Attachment #___)

State Agency _____ Date of Review: ___/__/____

State Agency _____ Date of Review ___/__/____

3. Has the applicant agency ever been the subject of any enforcement actions (e.g., fines, sanctions, etc) or had its approval, certification, or licensure restricted, revoked or suspended by any of the above State agencies?

   No ❑ Yes ❑

   If "yes" attach separate sheet providing the following information:

   a. Dates of action

   b. Reason(s) for action

   c. Resolution of action (include corrective action that was taken and whether approval has been reinstated) (Attachment #_____)

B. Child Care Licensing Agencies

Please check the relevant box below to indicate your status as a current or potential provider of childcare services:

<u>Agencies Providing Services</u>

1. Does the applicant agency now or does the applicant agency intend to provide care, which may include group developmental interventions, to three or more children together for more than three hours per day per child in a facility owned and/or operated by the agency?

   No ❑ Yes ❑

If the applicant agency is not a licensed child care provider but answered yes to the above question, the applicant agency should contact the Office of Children and Family Services for information regarding obtaining licensure as a child care provider.

<u>Agencies Providing Services In New York City</u>

1. Does the agency now, or does the agency intend to provide care, which may include group developmental interventions, to seven or more children together for five or more hours per week?

   No ❑ Yes ❑

2. If yes, are you licensed by the New York City Department of Health and Mental Hygiene to deliver day care services?

   No ❑ Yes ❑

   If yes, please provide your permit number below and append a copy of your permit:

   Permit #_____

If the agency applicant is not a licensed day care provider but answered yes to question (1), the applicant agency should contact the New York City Department of Health and Mental Hygiene to obtain licensure as a day care provider.

3. If "yes" to (2) above, provide the date of the most current site visit, program review or audit by the New York City Department of Health and Mental Hygiene:

   Date of Review: ___/_____/_____

4. Has the applicant agency ever been the subject of any childcare enforcement actions (e.g., fines, sanctions, etc) or had its approval, certification, or licensure restricted, revoked or suspended by the New York City Department of Health & Mental Hygiene?

   No ❑ Yes ❑

   If "yes" attach separate sheet providing the following information*:*

   a. Dates of action

   b. Reason(s) for action

   c. Resolution of action (include corrective action that was taken and whether approval has been reinstated) (Attachment #_____)

C. Managed Care Plan Affiliations

List all managed care plans that recognize you as an approved or in-network provider. (Attachment #____)

SCHEDULE 5 –PERSONNEL

A. Available FTEs

Complete the chart below, indicating the personnel that the agency intends to use to provide early intervention services based on a 40-hour week (e.g., 40 hours equals one FTE, 20 hours equals .5 FTEs, etc). For example, if two half-time personnel were employed, they would equal one full-time equivalent. Only include the proportion of time personnel will be available to deliver early intervention services.

Profession	**FTE Directly Employed**	**FTE Available by Contract (state approved only)**
Audiology:		
Audiologist		
Medical/Nursing:		
Pediatrician		
Physician other than Pediatrician		
Physician Assistant*		Cannot be contracted for professional services
Nurse Practitioner		
Registered Nurse		
Licensed Practical Nurse*		Cannot be contracted for professional services
Nutrition:		
Certified Dietitian/Nutritionist		
Registered Dietitian		
Occupational Therapy:		
Occupational Therapist		
Occupational Therapy Assistant*		Cannot be contracted for professional services
Physical Therapy:		
Physical Therapist		
Physical Therapist Assistant*		Cannot be contracted for professional services
Psychology:		
Licensed Psychologist		
School Psychologist**		Cannot be contracted for professional services

Profession	**FTE Directly Employed**	**FTE Available by Contract (state approved only)**
Social Work:		
Certified Social Worker		
Licensed Master Social Worker		
Licensed Clinical Social Worker		
Speech Pathology:		
Speech-Language Pathologist		
Special Education:		
Teacher of Special Education		
Teacher of Students with Disabilities		
Teacher of Blind and Partially Sighted		
Teacher of Blind and Visually Impaired		
Teacher of Deaf and Hearing Impaired		
Teacher of Deaf and Hard of Hearing		
Teacher of Speech and Hearing Handicapped		
Teacher of Speech and Language Disabilities		
Vision Services:		
Certified Orientation and Mobility Specialist		
Certified Low Vision Specialist		
Fellows of the College of Optometrists in Vision Development (FCOVD)		
Service Coordination Services		
Service Coordinators		
Paraprofessional		
1:1 Aide – Group Developmental Interventions		
Behavioral Aides		

*These professionals can only provide early intervention services in an employment setting with appropriate supervision, with the exception of service coordination services

** Per Article 153 of Section 7605 of the State Education Law, certified school psychologists may only provide services when directly employed by a federal, state, county or municipal government, or by providers approved under section 4410 of education law.

B. Personnel Information

For each of the following personnel categories, attach a list that includes, as applicable: name profession license/certification number and Department of Health early intervention provider approval ID (contracted agencies and individuals). All contracted individuals (with the exception of physicians) and all contracted agencies **MUST** be approved by the New York State Department of Health Early Intervention Program to deliver early intervention services. All names listed on this form, as "Available by Contract" will be verified for DOH approval to provide early intervention services.

- Directly employed individuals that deliver early intervention services (include name, profession and license/certification number) (Attachment # _____)

- Contracted individuals that deliver early intervention services (name, profession, license/certification number) (Attachment # _____)

- Contracted Agencies that are available by contract to deliver early intervention services (name) (Attachment # _____)

SCHEDULE 6 – SERVICE AVAILABILITY

A. Services

Check the early intervention service types for which the applicant agency is seeking approval (see Definitions). *Please check all that apply*.

1. ❑ Core Evaluations *

2. ❑ Supplemental Evaluations *

3. ❑ Service Coordination Services

4. ❑ Early Intervention Service Model Options (Check all that apply)

   a. Home/community-based individual/collateral visits ❑

   b. Facility-based individual/collateral visits * ❑

   c. Group Services* ❑

   Check all applicable site locations in addition to service model.

   1. Parent – Child groups ❑

      On-site in facility owned/operated by the agency ❑
      Off-site ❑
      Both ❑

   2. Group developmental intervention ❑

      On-site in facility owned/operated by the agency ❑
      Off site in community settings ❑
      Both ❑

   3. Family/caregiver support group ❑

      On-site in facility owned/operated by the agency ❑
      Off site in community settings ❑
      Both ❑

***** Complete **Schedule 7 – Facility Sites** for each site operated by the agency

B. Languages and Other Forms of Communication

Indicate the languages (other than English) and other forms of communication that can be used by agency staff that provide early intervention services.

	Evaluations	Service Coordination	Service Provision
Spanish	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Russian	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Chinese Mandarin	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Arabic	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
HaitianCreole	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Hebrew	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Bengali	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
French	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Urdu	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Vietnamese	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Sign Language	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Yiddish	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Other (please specify) _____

_____

C. Specialized Services (see Definitions)

Can you provide specialized services for specific populations of infants and toddlers?

☐ Yes ☐ No

If yes, please specify service method (e.g., behavioral interventions) and population. Attach additional sheets if necessary. (Attachment# ____)

_____ _____
Service Method Population

_____ _____
Service Method Population

E. Service Catchment Area

Check all counties for which the agency is seeking to provide early intervention services at time of application.

- ❑ Albany
- ❑ Allegany
- ❑ Broome
- ❑ Cattaraugus
- ❑ Cayuga
- ❑ Chautauqua
- ❑ Chemung
- ❑ Chenango
- ❑ Clinton
- ❑ Columbia
- ❑ Cortland
- ❑ Delaware
- ❑ Dutchess
- ❑ Erie
- ❑ Essex
- ❑ Franklin
- ❑ Fulton
- ❑ Genesee
- ❑ Greene
- ❑ Hamilton
- ❑ Herkimer
- ❑ Jefferson
- ❑ Lewis
- ❑ Livingston
- ❑ Madison
- ❑ Monroe
- ❑ Montgomery
- ❑ Nassau
- ❑ Niagara
- ❑ Oneida
- ❑ Onondaga
- ❑ Ontario
- ❑ Orange
- ❑ Orleans
- ❑ Oswego
- ❑ Otsego
- ❑ Putnam
- ❑ Rensselaer
- ❑ Rockland
- ❑ St. Lawrence
- ❑ Saratoga
- ❑ Schenectady
- ❑ Schoharie
- ❑ Schuyler
- ❑ Seneca
- ❑ Steuben
- ❑ Suffolk
- ❑ Sullivan
- ❑ Tioga
- ❑ Tompkins
- ❑ Ulster
- ❑ Warren
- ❑ Washington
- ❑ Wayne
- ❑ Westchester
- ❑ Wyoming
- ❑ Yates

New York City Area

- ❑ Bronx
- ❑ Kings
- ❑ Queens
- ❑ New York
- ❑ Richmond

If counties are not in proximity to the main site or additional sites, please explain how the agency will be able to deliver services to this area. (Attachment # _____)

SCHEDULE 7 – FACILITY SITES

Complete a copy of this schedule for each facility site operated by the applicant agency.

Name/Address of Site

Name			
Site Address			
City	County	Zip	Telephone ( )

Early Intervention Service Model Options

Check the early intervention service model options that you are seeking to provide at this site:

- ❑ Evaluations
- ❑ Facility based individual/collateral visits
- ❑ Parent-child groups
- ❑ Group developmental intervention
- ❑ Family/caregiver support group

Safety Policy

1. Attach a copy of the Certificate of Occupancy. (Attachment # ___)

2. Attach a fire evacuation plan and site diagram or a fire inspection report from the last 12 months for each site. (Attachment #____)

3. Attach procedures to ensure the availability of staff to administer cardiopulmonary resuscitation and first aid. (Attachment # ____)

Compliance with American with Disabilities Act

4. Is the site compliant with the Americans with Disabilities Act?

   ❑ Yes ❑ No

SCHEDULE 8 – STATEMENT OF REASSIGNMENT

Applicant Name:

By this reassignment, the above-named agency provider of early intervention services agrees:

1. To reassign all Medicaid reimbursement for early intervention services to the municipal early intervention agency (county) that you contract with to provide early intervention services.

2. To accept as payment in full from the municipal early intervention agency (county) the State Department of Health promulgated payment levels for covered early intervention services.

3. To not bill Medicaid for eligible early intervention services which are specified in a child's individualized family services plan (IFSP). These services will be directly billed to and reimbursed by the municipal early intervention agency (county).

4. To comply with all the rules and policies as described in your contract(s) with the municipal early intervention agency (county).

Signature Date

Address

City State Zip

NOTE: NOTHING IN THIS STATEMENT OF REASSIGNMENT PROHIBITS A MEDICAID PROVIDER FROM CLAIMING REIMBURSEMENT FOR MEDICAID ELIGIBLE SERVICES RENDERED **OUTSIDE** THE SCOPE OF THE EARLY INTERVENTION PROGRAM.

SCHEDULE 9 - Provider Agreement Form

PROVIDER AGREEMENT
BETWEEN THE NEW YORK STATE DEPARTMENT OF HEALTH
AND SERVICE PROVIDERS IN NEW YORK STATE EARLY INTERVENTION PROGRAM

Contingent upon approval by the New York State Department of Health to participate in the New York State Early Intervention Program, and the satisfactory completion of a Medicaid provider agreement and statement of reassignment for the purpose of establishing eligibility to participate in the New York State Medicaid Program under title XIX of the Social Security act, _____(Agency's Name), hereafter called the Provider, agrees as follows to:

A. (1) Keep any records necessary to disclose the extent of services the Provider furnishes to recipients receiving assistance under the New York State Plan for Medical Assistance.
(2) On request, furnish the New York State Department of Health, or its designee, and the Secretary of the United States Department of Health and Human Services, and the New York State Medicaid Fraud Control Unit any information maintained under paragraph (A) (1), and any information regarding any Medicaid claims reassigned by the Provider to the local early intervention agency.
(3) Comply with the disclosure requirements specified in 42 CFR Part 455, Subpart B.

B. Comply with Title VI of the Civil Rights Act of 1964, Section 504 of the Federal Rehabilitation Act of 1973, and all other State and Federal statutory and constitutional non-discrimination provisions which prohibit discrimination on the basis of race, color, national origin, handicap, age, sex, sexual orientation, religion, HIV and marital status.

C. Abide by all applicable Federal and State laws and regulations, including the Social Security Act, New York State Social Services Law, Part 42 of the Code of Federal Regulations and Title 18 of the Codes and Regulations of the State of New York.

D. Provide services in accordance with Title II-A of Article 25 of the Public Health Law and Subpart 69-4 of Title 10 of the Codes Rules and Regulations of the State of New York (Early Intervention Program).

Authorized Signature: _____

Address: _____

City: _____**State:** _____**Zip:** _____

Telephone No.: _____**Date Signed:** _____

SCHEDULE 10 - ASSURANCES

The applicant assures the Commissioner of Health and, if applicable, the Commissioner of Education, of compliance with all requirements under Title II-A of Article 25 of the Public Health Law; 10 NYCRR: Subpart 69-4; Part C of the Federal Individuals with Disabilities Education Act and 34 CFR Part 303.

- The applicant assures that the agency is appropriately staffed with qualified personnel with state licensure or certification as appropriate, and maintains a copy of current registration or certification for those personnel;

- The applicant assures that the agency will contract only with state-approved individual or agency early intervention providers;

- The applicant assures that the agency has the capacity to deliver services on a twelve-month basis and to provide flexibility in hours of service delivery, including weekend and evening hours;

- The applicant assures that agency personnel will immediately notify the Early Intervention Official if s/he becomes aware of any health or safety hazard posed in community-based settings where s/he is providing parent-child groups, family support groups, or group developmental interventions.

- The applicant assures that the agency has the capacity to deliver early intervention services in natural environments, to the maximum extent appropriate;

- The applicant assures that agency personnel have access to and participate in ongoing in-service training on the delivery of early intervention services;

- The applicant assures that the agency is in compliance with all local fire, health and safety codes; that the agency employs a policy for addressing health, safety and sanitation issues that conforms with standards established by the Department; and, where applicable, is in compliance with the American with Disabilities Act;

- The applicant assures that it will comply with the confidentiality requirements as set forth in federal and state statute and regulation;

- The applicant assures that the agency will request, in writing, approval from the State Agency granting approval, if the agency wishes to modify any of the information contained in this application, including catchment area, target population, qualified personnel available to deliver services or service models provided;

- The applicant assures that the agency has the capacity to deliver all approved service model options applied for in this application to the catchment area, in its entirety.

- The applicant assures that the agency will abide by department policies as stated in the Department of Health's Early Intervention Program Memorandums and other forms of guidance.

ACKNOWLEDGMENT

I, the undersigned, hereby certify under penalty of perjury, that I am duly authorized to subscribe and submit this application and that the information contained herein and attached hereto, with the exception of those schedules pertaining to personal and disclosure information which must be individually certified, is accurate, true and complete in all material aspects. I further acknowledge that the application will be processed pursuant to the provisions of Title II-A of Article 25 of the Public Health Law, and the pertinent regulations adopted thereto.

_____ _____
Print Name (Mr. Mrs., Miss, Ms., Dr) Title

_____ _____
Signature Date

Notarization

State of New York)
) SS:
County of)

On this _____day of _____, 20____, before me personally appeared _____ residing at
(Name)
_____ to me known and know by me to be_____
(Street, City, State, Zip) *(Title)*

of_____ and the person who executed this Agency Application in the name of said
(Corporation/Agency)
_____ and (s)he duly acknowledged to me that (s)he executed the same as and for the
(Corporation/Agency)
act and deed of said _____.
(Corporation/Agency)

_____
NOTARY STAMP Notary Public Signature

Definitions

.

Term	Definition
Catchment Area	Counties for which the agency is seeking approval to provide early intervention services.
Facility site	A site operated by an agency seeking early intervention approval where children receive early intervention evaluations or services.
Natural Environments	Settings that are natural or normal for the child's age peers who have no disability, including the home, a relative's home when care is delivered by the relative, childcare setting, or other community settings in which children without disabilities participate.
Qualified Personnel	Individuals with the appropriate licensure, certification or registration in the area in which they are providing services. A list of such personnel can be found in early intervention regulations 10NYCRR 69-4.1(aj).
Employed	Refers to personnel directly employed by an agency.
Available by Contract	Refers to individual qualified personnel and agencies available to the applicant through a contractual agreement. An individual under contract is not employed by the applicant.
Multidisciplinary Evaluation	The procedures used by appropriate qualified personnel to determine a child's initial and continuing eligibility for the Early Intervention Program, including determining the status of the child in each of the following areas of development: cognitive, physical, communication, social or emotional, and adaptive development. Multidisciplinary evaluations can be comprised of: *Core Evaluations*: must include a developmental assessment; a review of pertinent records and a parent interview as specified in regulations and may include a family assessment. *Supplemental Evaluations:* Include physician and non-physician evaluations provided upon the recommendation of the multi-disciplinary team conducting the core evaluation and with the agreement of the parent. A supplemental evaluation may also be provided in conjunction with the core evaluation by a specialist trained in the area of the child's suspected delay or disability.
Home and community-based visits	The provision by appropriate qualified personnel of early intervention services to the child and/or parent or other designated agency at the child's home or other natural environment.
Facility-based Individual collateral visits	The provision by appropriate qualified personnel of early intervention services to the child and/or parent or other designated caregiver at an approved early intervention provider's site.
Parent-child groups	A group comprised of parents or caregivers, children, and a minimum of one appropriate qualified provider of early intervention services at an early intervention provider's site or community based setting (e.g.,

Term	Definition
	day care center, family day care, or other community settings).
Group developmental intervention	The provision of early intervention services by appropriate qualified personnel to a group of eligible children at an approved provider's site or in a community-based setting where children under three years of age and typically found (this group may also include children without disabilities).
Family/caregiver support group	The provision of early intervention services to a group of parents, caregivers (foster parents, day care staff) and/or siblings of eligible children for the purposes of: (a) enhancing their capacity to care for and/or enhance the development of the eligible child; and (b) providing support, education, and guidance to such individuals relative to the child's unique developmental needs.
Service Coordination	Includes assistance and services provided by a service coordinator to enable an eligible child and the child's family to receive the rights, procedural safeguards and services that are authorized under the Early Intervention Program.
Specialized services	Expertise providing particular types of intervention methods (e.g., behavioral interventions) to a specific population of children and/or families (e.g., children with autism)**.**

APPLICATION CHECKLIST

- ❑ Make a copy of this application for your records and send a copy of the application to each county in the service catchment area.
- ❑ Federal employer (tax) identification number must appear on each page of the application.
- ❑ A summary/description of the proposed program standards plan.
- ❑ Copies of all organizational documents, such as partnership agreements or certificates of incorporation, and filing receipts (Schedule 2) must be enclosed with this application.
- ❑ Verify that all Qualified Personnel (Schedule 5) providing services under contract have current state approval to provide early intervention services.
- ❑ Provide a list of all contracted individuals and employees, including their name, profession, license and/or certification number and New York state Provider ID number.
- ❑ If "**CORE**" Evaluation Services (Schedule 6 A) is checked a letter from a NYS licensed and registered physician on their letterhead must be enclosed.
- ❑ Verify that all counties (Schedule 6 E) checked for which the agency is seeking approval to provide early intervention services are within an appropriate geographical area.
- ❑ If you are seeking to provide facility-based services, Schedule 7 must be completed for each site and copies of health, safety and fire evacuation policies; Certificate of Occupancy and assurance of ADA compliance must be enclosed for each site.
- ❑ All Schedule 3, Schedule 8, Schedule 9 and Schedule 10 forms have original signatures.
- ❑ ***Statement of Reassignment and Provider Agreement Form*** (Schedule 8 and 9) must be signed, dated and returned with this application.

Failure to submit all required attachments and a fully completed application will result in the application being returned to the applicant for resubmission. All required Schedule 3 Disclosure Information forms must be submitted by the applicant with the application submission.

ATTACHMENT L

Provider Application Review Protocols

A. Pre-Review Provider Application Activities

1. Each month, the Contractor produces the provider reapproval list that identifies currently approved providers who will be notified of the requirement to submit an application for reapproval within ninety days of notification. The monthly list will include 150 individual providers and 30 agency providers. The list is developed according to criteria developed by the Department. The Department will review and approve the list of providers to receive notification.
2. The Contractor will provide notification to each provider listed no later than five days after the first of each month. Notification must be in writing, must provide the statutory authority and standards for reapproval and be in a format approved by the Department. Notification to the provider must include the provider application form, instructions for completing the form and information regarding submission of the form. Notification must also include a telephone contact and an e-mail address to which questions may be sent.
3. The Contractor will provide provider application forms, instructions for completing the form and information for submission of the form to all individuals and entities that request an application.
4. The Contractor will send the monthly list of providers to be reapproved to each municipality within 10 days of the first of each month. Municipalities will be instructed to review the copy of the provider application that is submitted to them by new applicants for approval or by providers applying for reapproval. The Contractor will advise municipalities that objective, verifiable information about any applicant may be submitted for consideration during the review process.
5. The Contractor will provide technical assistance to all applicants requesting assistance with completing the provider application form or requesting information regarding approval standards for individual or agency providers. Technical assistance in response to telephone calls or e-mails must be provided within two business days of receipt of the request.

B. Preliminary Review Activities

1. Upon receipt of the provider application, the Contractor will check the Provider database to verify if the application is a new application or an application for reapproval. Information from the application is entered into the Provider database as either a new record for new applications or an update if the application is for reapproval.

2. The application is reviewed to determine if the application is complete and all necessary supporting documentation has been submitted. If the application is not complete or there is missing documentation, an application deficiency checklist is attached to the application and it is returned to the applicant, with contact information if the applicant requires assistance in completing the application. The deficiency checklist details the specific missing information and/or documentation. The database is updated to reflect the return status of the application.
3. Any information received from municipalities regarding applicants is attached to completed applications.

C. Individual Provider Application Review

1. Initial Application Professional Credentials Review

Individual provider applications are initially reviewed to determine if the applicant has sufficient credentials as a professional recognized as qualified personnel by Early Intervention regulations. The credentials are checked on databases maintained by the appropriate licensing or certifying agency as follows:

Qualified personnel licensed as professionals:	State Education Department Office of Professions
Qualified personnel certified as teachers:	State Education Department Office of Teaching
Registered Dietitians:	Commission on Dietetic Registration
Orientation and Mobility Specialists:	Academy for Certification of Vision and Rehabilitation Educational Professionals

Each applicant's credentials are checked to verify that the applicant has appropriate licensure or certification in the profession listed on the application, that the applicant's registration is current and that there have been no disciplinary actions taken against the license or certification.

2. Reapproval Professional Credentials Review

Individual providers' registration or certification will be checked to verify that the registration or certification is still in good standing and that there have been no disciplinary actions against the license or certification. If there has been action taken against the individual's license or certification, the Contractor will contact the licensing or certifying agency to obtain documentation of the action taken.

3. Initial Application Character Review

The second step of review is the determination of the applicant's character. The following databases are checked for all individual providers:

Department of Corrections Inmate Population Information Search

Department of Criminal Justice Systems Sex Abuse Registry

Other searches are conducted depending on the applicant's credentials and affiliations.

Professionals:	SED Office of Professional Discipline Actions Malpractice Actions
Teachers:	SED Office of Teaching Malpractice Actions
Preschool Special Education Programs (approved under §4410):	SED Office of Vocational and Education Services for Individuals with Disabilities
Physicians/ physician's assistants:	Department of Health (DOH) Office of Professional Medical Conduct DOH Bureau of Controlled Substances
Hospitals: Management	DOH Office of Health Systems
Diagnostic and Treatment Centers: Management	DOH Office of Health Systems
Medicaid Providers:	DOH Office of Medicaid Management
Home Health Agencies:	DOH Office of Health Systems Management
Day Care Centers:	Office of Children and Family Services

If any check identifies any administrative action, sanction or exclusion against the applicant, the Contractor obtains additional information from the agency that generated the action. This information should include any investigative findings, administrative proceedings and final disposition of the action.

The review also includes the applicant's response to questions regarding legal actions and professional standing. If the applicant has indicated affirmatively to any questions on the Record of Legal Actions or Professional Record, the explanation of violation is reviewed. If the nature of the violation is relevant to the individual's character as a provider of services, the Contractor will ask the applicant to provide documentation from the courts or governing body that sanctioned the applicant. If the disposition of the charges is pending, the Contractor advises the applicant that the review will be pended until resolution of charges.

The applicant's response on the application is compared to the database checks. If a database check confirms any sanction, exclusion or conviction that is not listed on the application, the provider may be denied approval based on falsification of application.

The Contractor will obtain all documentation regarding any administrative, civil or criminal actions taken against the applicant and submit the documentation to the Department. The Early Intervention Program Director, in consultation with the Division of Legal Affairs, will make the determination for denial or approval based on established criteria and in accordance with Article 23-A of Correction Law that specifies the factors to be considered concerning previous criminal convictions.

4. Reapproval Character Review

The same criteria for approval as outlined above will be considered for reapproval of providers. In addition, the Contractor will verify that:

- all monitoring, complaint investigation and/or due process findings from the Department, a municipality in contract with the provider or an agent of either entity have been resolved to the satisfaction of the agency issuing the findings;

- all corrective action plans that the provider was required to submit in response to any findings of monitoring or complaint investigations conducted by the Department, a municipality in contract with the provider or an agent of either entity have been deemed acceptable;

- all audit findings from the Department, a municipality in contract with the provider or an agent of either entity and all responses that the provider was required to submit have been accepted, and,

- All recoupments, fines and penalties assessed against the provider have been paid.

5. Initial Application Provider Experience and Training

Individuals must have a minimum of 1600 hours of experience within the last five years providing professional services to children less than five years of age with special needs. The Contractor will be required to telephone or correspond with employers listed on the application to verify the following information regarding the applicant:

- age of children served
- the professional services provided
- the actual number of hours of experience obtained.

Individuals lacking experience may qualify for a waiver of experience if the catchment area requested has a demonstrated shortage of approved providers in the applicants' discipline. The Contractor will provide the applicant with information prepared by the Department regarding the availability of a waiver of experience.

6. Reapproval Provider Experience and Training

Individual providers must have a minimum of 1600 hours of experience within the last 3 years providing professional services to children less than 5 years of age with special needs. A waiver of experience is not available for reapproval. The Contractor will verify through telephone calls or correspondence that the applicant has obtained the minimum number of hours of experience.

Individual providers must document a minimum of 30 clock hours of continuing education. At least 10 hours must be related to the delivery of services to children with special needs.

Individuals initially approved for service coordination must submit documentation of participation in an introductory service coordination training session.

D. Agency Provider Review

1. Initial Application Professional Credentials Review

Agency applications are initially reviewed to determine if the applicant has sufficient professional staff available to qualify as an early intervention agency. Agencies must have a minimum staff of an Early Intervention Program director and at least two individuals recognized as qualified personnel.

The program director must have a minimum of two years full time equivalent experience in an early intervention, clinical pediatric or childhood education program that includes children with special needs. The Contractor will review the program director's resume and Schedule 3- Disclosure Information form to verify

that the program director has the requisite experience. The Contractor will conduct telephone or send correspondence to verify the program director's experience in the settings listed above.

Schedule 5 is checked to determine that there are at least two qualified professionals, each with a minimum of twenty hours per week (each with at least a .5 full time equivalency).

2. Reapproval Professional Credentials Review

The same review criteria apply to reapproval of agency providers.

3. Initial Application Character Review

Agency applications are initially reviewed to verify that the entity has authority to provide early intervention services. The organizational documents submitted are reviewed to verify that the purposes of the agency permit provision of the services requested. The status of corporations is checked against the Department of State's Division of Corporations to ensure that the applicant exists as an active corporation. Professional corporations are checked against the SED Office of Professions database.

Agency applicants must submit disclosure information forms (Schedule 3) for the program director and the principals of the agency. The character review that is described in the Individual Provider review (item 2) must be conducted for the agency, the program director and each of the following individuals:

Sole Proprietorship	Sole proprietor
Partnership or Limited Liability Partnership	All partners
Limited Liability Company or Professional Limited Liability Company	All officers
Business Corporation or Professional Corporation	All officers
Not- for Profit Corporation	All officers
Government subdivision	Authorized operator

If the agency or any individual is identified as having enforcement action against them, the Contractor obtains supporting documentation from the agency that took the action. Applicants with enforcement actions against them are referred to the Early Intervention Program Director for further review.

The Contractor obtains all documentation regarding any administrative, civil or criminal actions taken against any individual completing a disclosure information form and sends the documentation, with the application, to the Department. The Early Intervention Program Director, in consultation with the Division of Legal Affairs, will make the determination for approval or denial based on all information and documentation obtained, using established criteria in accordance with Article 23-A of Correction Law that specifies the factors to be considered concerning previous criminal convictions.

4. Reapproval Character Review

The same information as reviewed for initial approval and the following additional information will be reviewed for reapproval of providers:

- all monitoring, investigation and/or due process findings from the Department, a municipality in contract with the provider or an agent of either entity that indicate continued and substantial non-compliance with one or more regulations;
- all corrective action plans that the provider was required to submit in response to any findings of monitoring or investigations conducted by the Department, a municipality in contract with the provider or an agent of either entity;
- all audit findings from the Department, a municipality in contract with the provider or an agent of either entity and all responses that the provider was required to submit; and,
- the contract history with any municipality.

5. Initial Application Qualified Personnel Review

The Contractor reviews Schedule 5 – Personnel to verify that the personnel listed to provide services are appropriately licensed and/or certified. Each employee's status should be verified against the appropriate database (Individual Provider review, item 1). Individuals available by contract are checked against the Early Intervention Program's provider database to verify individual provider approval.

6. Reapproval Qualified Personnel Review

The same review criteria will be used for reapproval.

E. Recommendation of Approval or Reapproval

1. Following review of the application, the Provider Approval Review Recommendation form is completed. Any negative responses must be explained in the comments section. The reviewer's name must be provided and the date the review was completed. If the

recommendation is denial of approval or reapproval, the application, review tools and all supporting documentation must be attached to the recommendation form.

2. If the recommendation is approval or reapproval of the provider, the Contractor drafts an approval letter for the state Early Intervention Program Director's signature. The letter is sent with the application form and review tools to the Department. The recommendation is reviewed by the Department and the signed approval letter is returned to the Contractor.

3. The Contractor will update the approval status in the Provider database and transmit the approval letter to the applicant and all municipalities within the provider's catchment area.

4. The Department will review applications submitted with a recommendation for denial. If the Department concurs with the recommendation, the Contractor is notified. The Contractor will draft a denial letter for the state Early Intervention Program Director's signature.

5. The signed denial letter is returned to the Contractor for mailing to the applicant and all municipalities within the provider's catchment area. The Provider database is updated to reflect the denial status.

ATTACHMENT M

Individual Provider Application Deficiency Checklist

Applicant Name: _____

Date of Return: _____

The attached application has been reviewed and was found to be incomplete. If you still wish to receive state approval as an early intervention service provider, please correct the items checked below by:
1) Entering any missing/incomplete information on the application.
2) Changing any incorrect information and initialing changes.
3) Signing and dating the attached Schedule 5 and having it notarized by a notary public.
4) Returning this checklist, the completed application and the completed, notarized attachment with all required attachments to:

( )

If you have any questions, call ( ) at ( )

Schedule 1 Background Information

A. Applicant Identification

☐ Name on registration must match name on application.
If your name or address on your registration has changed, you must report the change in writing, within thirty days to:

New York State Education Department
Office of the Professions – Records and Archives Unit
89 Washington Avenue
Albany, New York 12234
(518) 474-3817 extension 380

You will be sent a computer-generated card to attach to your registration certificate. A copy of this card needs to be submitted with this application.

B. Credentials

☐ Provide a copy of your current NYS Education Department registration (not your license) (Last name on registration must match last name on application).

☐ Provide a copy of your current NYS Education Department teaching certificate.

C. Employment History

- ☐ Specify any/all employment working in your profession with children under 5 years old in the past five years. Include exact dates of employment, employer name, and ages of population you work(ed) with.

Schedule 2 Disclosure Information

C. Record of Legal Actions

- ☐ Check Yes or No for questions 1 through 4.
- ☐ Complete number 5.
- ☐ Attach documentation of disposition from the court.

Schedule 3 Availability

- ☐ This must be completed in full time equivalents (FTEs) (i.e. 40 hours = 1FTE; 20 hours = .5FTE).
- ☐ FTE total cannot exceed 1.0 (40 hours a week).

Schedule 4 Service Program

A. Services

- ☐ Complete Schedule 5 Facility Sites since you intend to provide services at a site you own and/or operate.

E. Service Catchment Area

- ☐ Some counties checked on the application are a significant distance from your listed address. Please explain your ability to provide timely and appropriate services over this large geographic area.

Schedule 6 Statement of Reassignment

- ☐ Statement of Reassignment form must be signed.

Schedule 7 Provider Agreement

☐ Provider Agreement form must be signed.

Schedule 8 Assurances

☐ New Acknowledgment must be completed each time an application is re-submitted. A blank copy is enclosed.

Note:

Your application is missing some pages. Complete the attached pages.

Other:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Agency Provider Application Deficiency Checklist

NAME OF AGENCY: _____

AGENCY CONTACT: _____

DATE: _____

The attached application has been reviewed and was found to be incomplete. If your agency still wishes to receive state approval as an early intervention service provider, please correct as indicated below by:
1) Entering any missing/incomplete information directly on the application.
2) Changing any incorrect information and initialing those changes.
3) Signing and dating the enclosed Certification/Corporate Acknowledgment each time the application is returned. The EI Program Director must sign the Certification and have it notarized by a notary public.
4) Returning this information sheet with the corrected application and all necessary attachments to:

( )

(If you have any questions, call ( )

Schedule 1 - Background Information

A. Applicant Identification

- ☐ Tax Identification number is missing--must be 9 digits.
- ☐ Address is incomplete.
- ☐ Telephone number / area code is missing.
- ☐ Agency name on application does not match name on business papers.

Schedule 3 – Disclosure Information

- ☐ This must be completed by each individual identified in Schedule 2.

Schedule 4 Applicant Agency Affiliation

A. Health, Education, Developmental Disabilities and Mental Hygiene Agencies

- ☐ If "yes" is checked for any questions 1 through 6, provide the license or certificate number.

Schedule 5 Personnel

- ☐ The **number** of FTEs must be completed for each discipline that will be available.

- ☐ You must indicate that more than one qualified personnel is available to provide services. List each provider's name and profession.

- ☐ A _____ Assistant requires supervison by a licensed _____ and will only be approved to provide services if a licensed _____ who will provide supervision is also listed.

- ☐ A certified school psychologist may only provide services when directly employed by a federal, state, county or municipal government agency, a chartered elementary/secondary school or degree-granting education or an approved 4410 institution. Your agency is not a federal, state, county or municipal government agency, or an approved 4410 institution; therefore, a Certified School Psychologist cannot be approved.

- ☐ Other:
  _____
  _____
  _____

Schedule 6 Service Availability

A. Services

- ☐ Schedule 7 Facility Sites must be completed since you indicated that your agency will provide services at a site that the agency operates.

E. Service Catchment Area

- ☐ Some counties checked on the Application are a significant distance from the main agency site, or other service delivery sites listed on the Application. On a separate sheet, explain the ability of agency staff to provide timely and appropriate services and of administration to provide oversight of staff over this large geographical area.

Schedule 8 Statement of Reassignment

- ☐ Statement of Reassignment form must be completed and signed by the EI Program Director of the agency.

Schedule 9 Provider Agreement

- ☐ Provider Agreement form must be completed and signed by the EI Program Director of the agency.

Schedule 10 Assurances

- ☐ The Acknowledgment must be signed by the EI Program Director of the agency and must be notarized.

Other:

_____

_____

_____

_____

_____

ATTACHMENT N

New York State Department of Health, Early Intervention Program

Recommendation for Approval of Individual Providers

As Early Intervention Evaluators,
Service Coordinators & Service Providers

Applicant Name: _____ **APPROVED**

Reviewer Name & Date: _____ **DENIED**

Circle a response to all questions. If any answers are "no", provide an explanation in the comments section and attach supporting documentation. Any negative answers may be grounds for denial. Circle "APPROVED " or "DENIED" above.

Review Criteria

Professional Credentials Review:		
Applicant is licensed/ certified in a discipline recognized as qualified personnel.	YES	NO
Applicant's registration/certification is current and active.	YES	NO
Applicant Character Review:		
Applicant has no disciplinary action against license/certification.	YES	NO
Applicant has not been incarcerated in a NYS correctional facility.	YES	NO
Applicant does not appear on Sex Abuser Registry.	YES	NO
Applicant has not had enforcement actions taken against him/her by any other agency.	YES	NO
Applicant has not been affiliated with any agency which has had enforcement action taken against it.	YES	NO
Applicant has had no criminal convictions.	YES	NO
Applicant has no charges pending against him/her.	YES	NO
Applicant self reported any enforcement actions against licensure, criminal or civil actions.	YES	NO N/A

Professional Experience Review:		
Applicant has provided at least 1600 clock hours of professional service to children under the age of 5 years.	YES	NO
Provider History Review:		
Applicant has complied with all requests for corrective action plans.	YES	NO N/A
Applicant has not committed repeat violations.	YES	NO
Applicant has not had violations regarding health and safety issues.	YES	NO
Municipalities have not provided substantive objections to the applicant.	Yes	No

Comments:

ATTACHMENT N

New York State Department of Health, Early Intervention Program

Recommendation for Approval of Agencies

As Early Intervention Evaluators,
Service Coordinators & Service Providers

Applicant Name: _____ **APPROVED**

Reviewer Name & Date: _____ **DENIED**

Circle a response to all questions. If any answers are "no", provide an explanation in the comments section and attach supporting documentation. Any negative answers may be grounds for denial.

Review Criteria

Professional Credentials Review:		
The agency has submitted sufficient organizational documents and if applicable, is "active" on Dept. of State's database and on SED's website.	Yes	No
The EI Program Director has at least 2 years experience in an early intervention, clinical pediatric or childhood education program.	Yes	No
Applicant has at least 2 individuals other than the program director who are appropriately licensed and/or certified as qualified personnel.	Yes	No
At least 2 qualified personnel will provide services for at least .5 FTE each.	Yes	No
Applicant Character Review:		
The EI Program director has had no administrative, civil or criminal enforcement action taken against him/her.	Yes	No
No individuals (other than the program director) required to submit a Schedule 3 have had administrative, civil or criminal enforcement action taken against him/her.	Yes	No

Provider History Review:		
The applicant has provided corrective action plans as required in response to local or state monitoring or due process proceeding.	Yes	No
The applicant has not had violations regarding health and safety issues.	Yes	No N/A
The applicant has not had three or more violations of the same regulation within three years.	Yes	No
Municipalities have not provided substantive objections to the applicant.	Yes	No

Comments:

ATTACHMENT O

LETTER OF INTENT TO BID AND
INTENT TO ATTEND BIDDERS' CONFERENCE

This letter of Intent to Bid and Intent to Attend the Bidder's Conference should be mailed to the address below and received by September 19, 2007 or submitted via Fax to (518) 486-1090 by September 19, 2007.

New York State Department of Health
Division of Family Health Room 287
Corning Tower, Empire State Plaza
Albany, New York 12237-0657
Attn: Margaret Dennin

Dear Ms. Dennin:

_____ has received the Division of Family Health's Request for Proposals to Conduct Monitoring Activities for Early Intervention and Other Department of Health Programs and To Review Provider Applications.

____ We intend to submit a proposal to the New York State Department of Health Division of Family Health not later than 4:00pm on October 24, 2007.

____ We intend to participate in the Bidder's Conference call on , September 24, 2007 from 1:00 PM to 4:00 PM, regarding the Request for Proposals To Conduct Monitoring Activities for Early Intervention and Other Department of Health Programs and to Review Provider Applications.

Sincerely,

_____	_____ _____
Signature *Date*	*Signature* *Date*
_____	_____
Title	*Title*
_____	_____
Name of Official Representative (if different from above)	*Name of Official Representative (if different from above)*
_____	_____
_____	_____
Address	*Address*
_____ _____	_____ _____
Telephone Number *Fax Number*	*Telephone Number* *Fax Number*

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MISCELLANEOUS / CONSULTANT SERVICES

ATTACHMENT P

STATE AGENCY (Name and Address):

NYS COMPTROLLER'S NUMBER:

ORIGINATING AGENCY CODE:12000

CONTRACTOR (Name and Address):

TYPE OF PROGRAM(S):

CHARITIES REGISTRATION NUMBER:

FEDERAL TAX IDENTIFICATION NUMBER:

MUNICIPALITY NO. (if applicable):

CONTRACT TERM
FROM:
TO:

FUNDING AMOUNT FOR CONTRACT TERM:

STATUS:
CONTRACTOR IS ( ) IS NOT ( ) A SECTARIAN ENTITY

CONTRACTOR IS ( ) IS NOT ( ) A NOT-FOR-PROFIT ORGANIZATION

CONTRACTOR IS ( ) IS NOT ( ) A N Y STATE BUSINESS ENTERPRISE

( ) IF MARKED HERE, THIS CONTRACT'S RENEWABLE FOR ___ ADDITIONAL ONE-YEAR PERIOD(S) AT THE SOLE OPTION OF THE STATE AND SUBJECT TO APPROVAL OF THE OFFICE OF THE STATE COMPTROLLER.

BID OPENING DATE:

APPENDICES ATTACHED AND PART OF THIS AGREEMENT
Precedence shall be given to these documents in the order listed below.

X	APPENDIX A	Standard Clauses as required by the Attorney General for all State Contracts.
X	APPENDIX X	Modification Agreement Form (to accompany modified appendices for changes in term or consideration on an existing period or for renewal periods)
__	APPENDIX Q	Modification of Standard Department of Health Contract Language
X	STATE OF NEW YORK AGREEMENT	
X	APPENDIX D	General Specifications
X	APPENDIX B	Request For Proposal (RFP)
X	APPENDIX C	Proposal
X	APPENDIX E-1	Proof of Workers' Compensation Coverage
X	APPENDIX E-2	Proof of Disability Insurance Coverage
___	APPENDIX H	Federal Health Insurance Portability and Accountability Act Business Associate Agreement
X_	APPENDIX _B-1_:	
___	APPENDIX __:	

IN WITNESS THEREOF, the parties hereto have executed or approved this AGREEMENT on the dates below their signatures.

_____	_____
CONTRACTOR	STATE AGENCY
_____	_____
By:_____	By: _____
_____	_____
Printed Name	Printed Name
Title:_____	Title: _____
Date:_____	Date:_____
	State Agency Certification: "In addition to the acceptance of this contract, I also certify that original copies of this signature page will be attached to all other exact copies of this contract."
_____	_____

STATE OF NEW YORK)
)SS.:
County of _____)

On the ___ day of _____ in the year _____ before me, the undersigned, personally appeared _____, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) is(are) subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their/ capacity(ies), and that by his/her/their signature(s) on the instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument.

_____
(Signature and office of the individual taking acknowledgement)

ATTORNEY GENERAL'S SIGNATURE	STATE COMPTROLLER'S SIGNATURE
_____	_____
Title:_____	Title:_____
Date: _____	Date: _____

STATE OF NEW YORK
AGREEMENT

This AGREEMENT is hereby made by and between the State of New York agency (STATE) and the public or private agency (CONTRACTOR) identified on the face page hereof.

WITNESSETH:

WHEREAS, the STATE has formally requested contractors to submit bid proposals for the project described in Appendix B for which bids were opened on the date noted on the face pages of this AGREEMENT; and

WHEREAS, the STATE has determined that the CONTRACTOR is the successful bidder, and the CONTRACTOR covenants that it is willing and able to undertake the services and provide the necessary materials, labor and equipment in connection therewith;

NOW THEREFORE, in consideration of the terms hereinafter mentioned and also the covenants and obligations moving to each party hereto from the other, the parties hereto do hereby agree as follows:

I. Conditions of Agreement

A. This AGREEMENT incorporates the face pages attached and all of the marked appendices identified on the face page hereof.

B. The maximum compensation for the contract term of this AGREEMENT shall not exceed the amount specified on the face page hereof.

C. This AGREEMENT may be renewed for additional periods (PERIOD), as specified on the face page hereof.

D. To exercise any renewal option of this AGREEMENT, the parties shall prepare new appendices, to the extent that any require modification, and a Modification Agreement (the attached Appendix X is the blank form to be used). Any terms of this AGREEMENT not modified shall remain in effect for each PERIOD of the AGREEMENT. The modification agreement is subject to the approval of the Office of the State Comptroller.

E. Appendix A (Standard Clauses as required by the Attorney General for all State contracts) takes precedence over all other parts of the AGREEMENT.

F. For the purposes of this AGREEMENT, the terms "Request For Proposal" and "RFP" include all Appendix B documents as marked on the face page hereof.

G. For the purposes of this AGREEMENT, the term "Proposal" includes all Appendix C documents as marked on the face page hereof.

II. Payment and Reporting

A. The CONTRACTOR shall submit invoices to the STATE's designated payment office:

.
.

B. Payment of such invoices by the State (NYS Department of Health) shall be made in accordance with Article XI-A of the New York State Finance Law.

III. Term of Contract

A. This agreement shall be effective upon approval of the NYS Office of the State Comptroller.

<or insert other time period, and reference renewal option, if required>

<Note: The contract period must agree with that stated in the Contract Reporter notice.>

B. This Agreement may be terminated by mutual written agreement of the contracting parties.

C. This Agreement may be terminated by the Department for cause upon the failure of the Contractor to comply with the terms and conditions of this Agreement, including the attachments hereto, provided that the Department shall give the contractor written notice via registered or certified mail, return receipt requested, or shall deliver same by hand-receiving Contractor's receipt therefor, such written notice to specify the Contractor's failure and the termination of this Agreement. Termination shall be effective ten (10) business days from receipt of such notice, established by the receipt returned to the Department. The Contractor agrees to incur no new obligations nor to claim for any expenses made after receipt of the notification of termination.

D. This Agreement may be deemed terminated immediately at the option of the Department upon the filing of a petition in bankruptcy or insolvency, by or against the Contractor. Such termination shall be immediate and complete, without termination costs or further obligations by the Department to the Contractor.

E. This agreement may be canceled at any time by the Department of Health giving to the contractor not less than thirty (30) days written notice that on or after a date therein specified this agreement shall be deemed terminated and canceled.

IV. Proof of Coverage

Unless the CONTRACTOR is a political sub-division of New York State, the CONTRACTOR shall provide proof, completed by the CONTRACTOR's insurance carrier and/or the Workers' Compensation Board, of coverage for:

A. Workers' Compensation, for which one of the following is incorporated into this contract as Appendix E-1:

1. WC/DB-100, Affidavit For New York Entities And Any Out-Of-State Entities With No Employees, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage Is Not Required; OR

2. WC/DB-101, Affidavit That An OUT-OF-STATE Or FOREIGN EMPLOYER Working In New York State Does Not Require Specific New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage; OR

3. C-105.2 – Certificate of Workers' Compensation Insurance. PLEASE NOTE: The State Insurance Fund provides its own version of this form, the U-26.3; OR

4. SI-12 – Certificate of Workers' Compensation Self-Insurance, OR GSI-105.2 – Certificate of Participation in Workers' Compensation Group Self-Insurance.

B. Disability Benefits coverage, for which one of the following is incorporated into this contract as Appendix E-2:

1. WC/DB-100, Affidavit For New York Entities And Any Out-Of-State Entities With No Employees, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage Is Not Required; OR

2. WC/DB-101, Affidavit That An OUT-OF-STATE Or FOREIGN EMPLOYER Working In New York State Does Not Require Specific New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage; OR

3. DB-120.1 – Certificate of Disability Benefits Insurance OR the DB-820/829 Certificate/Cancellation of Insurance; OR

4. DB-155 – Certificate of Disability Benefits Self-Insurance

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STATE OF NEW YORK
OFFICE OF THE STATE COMPTROLLER - BUREAU OF CONTRACTS
VENDOR RESPONSIBILITY QUESTIONNAIRE

Attachment Q

1. VENDOR IS: ☐ **PRIME CONTRACTOR** ☐ **SUB-CONTRACTOR**		
2. VENDOR'S LEGAL BUSINESS NAME	**3. IDENTIFICATION NUMBERS** **a) FEIN #** **b) DUNS #**	
4. D/B/A – Doing Business As (if applicable**) & COUNTY FILED:**	**5. WEBSITE ADDRESS** (if applicable)	
6. ADDRESS OF PRIMARY PLACE OF BUSINESS/EXECUTIVE OFFICE	**7. TELEPHONE NUMBER**	**8. FAX NUMBER**
9. ADDRESS OF PRIMARY PLACE OF BUSINESS/EXECUTIVE OFFICE ***IN NEW YORK STATE***, if different from above	**10. TELEPHONE NUMBER**	**11. FAX NUMBER**
12. PRIMARY PLACE OF BUSINESS IN NEW YORK STATE IS: ☐ **Owned** ☐ **Rented** If rented, please provide landlord's name, address, and telephone number below:	**13. AUTHORIZED CONTACT FOR THIS QUESTIONNAIRE** **Name** **Title** **Telephone Number** **Fax Number** **e-mail**	

14. VENDOR'S BUSINESS ENTITY IS (please check appropriate box and provide additional information):

a) ☐ **Business Corporation**	**Date of Incorporation**	**State of Incorporation***
b) ☐ **Sole Proprietor**	**Date Established**	
c) ☐ **General Partnership**	**Date Established**	
d) ☐ **Not-for-Profit Corporation**	**Date of Incorporation**	**State of Incorporation*** **Charities Registration Number**
e) ☐ **Limited Liability Company (LLC)**	**Date Established**	
f) ☐ **Limited Liability Partnership**	**Date Established**	
g) ☐ **Other – Specify:**	**Date Established**	**Jurisdiction Filed (if applicable)**

* If not incorporated in New York State, please provide a copy of authorization to do business in New York.

15. PRIMARY BUSINESS ACTIVITY - (Please identify the primary business categories, products or services provided by your business)

16. NAME OF WORKERS' COMPENSATION INSURANCE CARRIER:

17. LIST ALL OF THE VENDOR'S PRINCIPAL OWNERS AND THE THREE OFFICERS WHO DIRECT THE DAILY OPERATIONS OF THE VENDOR (Attach additional pages if necessary):

a) NAME (print)	**TITLE**	**b) NAME** (print)	**TITLE**
c) NAME (print)	**TITLE**	**d) NAME** (print)	**TITLE**

A DETAILED EXPLANATION IS REQUIRED FOR EACH QUESTION ANSWERED WITH A "YES," AND MUST BE PROVIDED AS AN ATTACHMENT TO THE COMPLETED QUESTIONNAIRE. YOU MUST PROVIDE ADEQUATE DETAILS OR DOCUMENTS TO AID THE CONTRACTING AGENCY IN MAKING A DETERMINATION OF VENDOR RESPONSIBILITY. PLEASE NUMBER EACH RESPONSE TO MATCH THE QUESTION NUMBER.

18.	Is the vendor certified in New York State as a (check please): ☐ Minority Business Enterprise (MBE) ☐ Women's Business Enterprise (WBE) ☐ Disadvantaged Business Enterprise (DBE)? ***Please provide a copy of any of the above certifications that apply.***	☐ **Yes**	☐ **No**
19.	Does the vendor use, or has it used in the past ten (10) years, any other Business Name, FEIN, or D/B/A other than those listed in items 2-4 above? ***List all other business name(s), Federal Employer Identification Number(s) or any D/B/A names and the dates that these names or numbers were/are in use. Explain the relationship to the vendor.***	☐ **Yes**	☐ **No**
20.	Are there any individuals now serving in a managerial or consulting capacity to the vendor, including principal owners and officers, who now serve or in the past three (3) years have served as:		
a)	An elected or appointed public official or officer? ***List each individual's name, business title, the name of the organization and position elected or appointed to, and dates of service.***	☐ **Yes**	☐ **No**
b)	A full or part-time employee in a New York State agency or as a consultant, in their individual capacity, to any New York State agency? ***List each individual's name, business title or consulting capacity and the New York State agency name, and employment position with applicable service dates.***	☐ **Yes**	☐ **No**
c)	If yes to item #20b, did this individual perform services related to the solicitation, negotiation, operation and/or administration of public contracts for the contracting agency? ***List each individual's name, business title or consulting capacity and the New York State agency name, and consulting/advisory position with applicable service dates. List each contract name and assigned NYS number.***	☐ **Yes**	☐ **No**
d)	An officer of any political party organization in New York State, whether paid or unpaid? ***List each individual's name, business title or consulting capacity and the official political party position held with applicable service dates.***	☐ **Yes**	☐ **No**

21.	Within the past five (5) years, has the vendor, any individuals serving in managerial or consulting capacity, principal owners, officers, major stockholder(s) (10% or more of the voting shares for publicly traded companies, 25% or more of the shares for all other companies), affiliate[1] or any person involved in the bidding or contracting process: **a)** 1. been suspended, debarred or terminated by a local, state or federal authority in connection with a contract or contracting process; 2. been disqualified for cause as a bidder on any permit, license, concession franchise or lease; 3. entered into an agreement to a voluntary exclusion from bidding/contracting; 4. had a bid rejected on a New York State contract for failure to comply with the MacBride Fair Employment Principles; 5. had a low bid rejected on a local, state or federal contract for failure to meet statutory affirmative action or M/WBE requirements on a previously held contract; 6. had status as a Women's Business Enterprise, Minority Business Enterprise or Disadvantaged Business Enterprise denied, de-certified, revoked or forfeited; 7. been subject to an administrative proceeding or civil action seeking specific performance or restitution in connection with any local, state or federal government contract; 8. been denied an award of a local, state or federal government contract, had a contract suspended or had a contract terminated for non-responsibility; or 9. had a local, state or federal government contract suspended or terminated for cause prior to the completion of the term of the contract?	☐ **Yes** ☐ **No**
	b) been indicted, convicted, received a judgment against them or a grant of immunity for any business-related conduct constituting a crime under local, state or federal law including but not limited to, fraud, extortion, bribery, racketeering, price-fixing, bid collusion or any crime related to truthfulness and/or business conduct?	☐ **Yes** ☐ **No**
	c) been issued a citation, notice, violation order, or are pending an administrative hearing or proceeding or determination for violations of: 1. federal, state or local health laws, rules or regulations, including but not limited to Occupational Safety & Health Administration (OSHA) or New York State labor law; 2. state or federal environmental laws; 3. unemployment insurance or workers' compensation coverage or claim requirements; 4. Employee Retirement Income Security Act (ERISA); 5. federal, state or local human rights laws; 6. civil rights laws; 7. federal or state security laws; 8. federal Immigration and Naturalization Services (INS) and Alienage	☐ **Yes** ☐ **No**

	laws; 9. state or federal anti-trust laws; or 10. charity or consumer laws? ***For any of the above, detail the situation(s), the date(s), the name(s), title(s), address(es) of any individuals involved and, if applicable, any contracting agency, specific details related to the situation(s) and any corrective action(s) taken by the vendor.***		
22.	In the past three (3) years, has the vendor or its affiliates[1] had any claims, judgments, injunctions, liens, fines or penalties secured by any governmental agency? ***Indicate if this is applicable to the submitting vendor or affiliate. State whether the situation(s) was a claim, judgment, injunction, lien or other with an explanation. Provide the name(s) and address(es) of the agency, the amount of the original obligation and outstanding balance. If any of these items are open, unsatisfied, indicate the status of each item as "open" or "unsatisfied."***	☐ **Yes**	☐ **No**
23.	Has the vendor (for profit and not-for profit corporations) or its affiliates[1], in the past three (3) years, had any governmental audits that revealed material weaknesses in its system of internal controls, compliance with contractual agreements and/or laws and regulations or any material disallowances? ***Indicate if this is applicable to the submitting vendor or affiliate. Detail the type of material weakness found or the situation(s) that gave rise to the disallowance, any corrective action taken by the vendor and the name of the auditing agency.***	☐ **Yes**	☐ **No**
24.	Is the vendor exempt from income taxes under the Internal Revenue Code? ***Indicate the reason for the exemption and provide a copy of any supporting information.***	☐ **Yes**	☐ **No**
25.	During the past three (3) years, has the vendor failed to:		
	a) file returns or pay any applicable federal, state or city taxes? ***Identify the taxing jurisdiction, type of tax, liability year(s), and tax liability amount the vendor failed to file/pay and the current status of the liability.***	☐ **Yes**	☐ **No**
	b) file returns or pay New York State unemployment insurance? ***Indicate the years the vendor failed to file/pay the insurance and the current status of the liability.***	☐ **Yes**	☐ **No**
26.	Have any bankruptcy proceedings been initiated by or against the vendor or its affiliates[1] within the past seven (7) years (whether or not closed) or is any bankruptcy proceeding pending by or against the vendor or its affiliates regardless of the date of filing? ***Indicate if this is applicable to the submitting vendor or affiliate. If it is an affiliate, include the affiliate's name and FEIN. Provide the court name, address and docket number. Indicate if the proceedings have been initiated, remain pending or have been closed. If closed, provide the date closed.***	☐ **Yes**	☐ **No**

27.	Is the vendor currently insolvent, or does vendor currently have reason to believe that an involuntary bankruptcy proceeding may be brought against it? ***Provide financial information to support the vendor's current position, for example, Current Ratio, Debt Ratio, Age of Accounts Payable, Cash Flow and any documents that will provide the agency with an understanding of the vendor's situation.***	☐ **Yes**	☐ **No**
28.	Has the vendor been a contractor or subcontractor on any contract with any New York State agency in the past five (5) years? ***List the agency name, address, and contract effective dates. Also provide state contract identification number, if known.***	☐ **Yes**	☐ **No**
29.	In the past five (5) years, has the vendor or any affiliates[1]: **a)** defaulted or been terminated on, or had its surety called upon to complete, any contract (public or private) awarded; **b)** received an overall unsatisfactory performance assessment from any government agency on any contract; or **c)** had any liens or claims over $25,000 filed against the firm which remain undischarged or were unsatisfied for more than 90 days ? ***Indicate if this is applicable to the submitting vendor or affiliate. Detail the situation(s) that gave rise to the negative action, any corrective action taken by the vendor and the name of the contracting agency.***	☐ **Yes**	☐ **No**

[1] "Affiliate" meaning: (a) any entity in which the vendor owns more than 50% of the voting stock; (b) any individual, entity or group of principal owners or officers who own more than 50% of the voting stock of the vendor; or (c) any entity whose voting stock is more than 50% owned by the same individual, entity or group described in clause (b). In addition, if a vendor owns less than 50% of the voting stock of another entity, but directs or has the right to direct such entity's daily operations, that entity will be an "affiliate" for purposes of this questionnaire.

State of:)
) ss:
County of:)

CERTIFICATION:

The undersigned: recognizes that this questionnaire is submitted for the express purpose of assisting the State of New York or its agencies or political subdivisions in making a determination regarding an award of contract or approval of a subcontract; acknowledges that the State or its agencies and political subdivisions may in its discretion, by means which it may choose, verify the truth and accuracy of all statements made herein; acknowledges that intentional submission of false or misleading information may constitute a felony under Penal Law Section 210.40 or a misdemeanor under Penal Law Section 210.35 or Section 210.45, and may also be punishable by a fine and/or imprisonment of up to five years under 18 USC Section 1001 and may result in contract termination; and states that the information submitted in this questionnaire and any attached pages is true, accurate and complete.

The undersigned certifies that he/she:

- has not altered the content of the questions in the questionnaire in any manner;
- has read and understands all of the items contained in the questionnaire and any pages attached by the submitting vendor;
- has supplied full and complete responses to each item therein to the best of his/her knowledge, information and belief;
- is knowledgeable about the submitting vendor's business and operations;
- understands that New York State will rely on the information supplied in this questionnaire when entering into a contract with the vendor; and
- is under duty to notify the procuring State Agency of any material changes to the vendor's responses herein prior to the State Comptroller's approval of the contract.

Name of Business

Address

City, State, Zip

Signature of Owner/Officer_____

Printed Name of Signatory

Title

Sworn to before me this _____ day of _____, 20____;

_____
Notary Public

_____
Print Name

_____
Signature

_____

ATTACHMENT R

CHECKLIST TO DETERMINE "REASONABLE" EFFORT

BY APPLICANTS/CONTRACTORS FOR CONTRACTS OF $1 MILLION OR MORE

A copy of this form should be completed and retained on file by the Contractor. The completed form should be available for review for the duration of the contract.

The contractor:

- has a copy of the NYS Directory of Certified Minority and Women-Owned Business Enterprises? Y ____ N ____
- has solicited quotes from firms listed in the Directory? Y ____ N ____
- has contacted the NYS Department of Economic Development to obtain listings of NYS subcontractors and suppliers for products and services currently purchased from out-of-state/foreign firms? Y ____ N ____
- has utilized other sources to identify NYS subcontractors and suppliers (such as Thomas Register, in-house vendor list)? Y ____ N ____
  (If Yes, source: _____)
- has placed advertisements in NYS newspapers? Y _____ N ____
- has participated in vendor outreach conferences? Y ____ N ____
- has provided New York State residents notice of new employment opportunities resulting from this contract through listing any such positions with the Job Service Division of the NYS Department of Labor, or providing such notification by another method? Y ____ N ____

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ATTACHMENT S

PRENATAL CARE ASSISTANCE PROGRAM
BUREAU OF WOMEN'S HEALTH
GUIDELINES FOR CONDUCTING SITE VISIT SURVEY

Prior to site visit:

1. Contact PCAP Coordinator about four (4) weeks before the visit and discuss available dates, nature of visit, suggested participants, and agenda for the visit.

2. Send confirmation letter (form letter) and presurvey questionnaire, with a copy to Denise Hernas in CO and your Supervisor (unless your supervisor does not wish to receive this information).

3. Review Presurvey Questionnaire (PSQ) and last survey findings. In some cases, review of PCAP application may be useful.

4. Inform the facility that they must pull and have available to you on site approximately 10 charts (no more than 20) with at least 3/4 of them being recent postpartum cases and a couple of high-risk cases. *Note: Managed Care charts can be reviewed*.

5. If PCAP has multiple sites:
   1) Request charts from each additional site. Number of charts requested depends on the volume of clients;
   2) If there is a different PCAP Coordinator at additional sites, reviewer can interview them, if necessary;
   3) Review essential policies and procedures from additional sites unless provider states that policies and procedures are the same throughout all sites;
   4) Reviewer may decide to visit one or two additional sites depending on the numbers of PCAP clients served at the sites, previous survey results, distance from the main site, etc. Discuss approach with PCAP Coordinator prior to survey.

6. Determine if PCAP has signed Qualified Provider (QP) Agreement. If any questions, please contact Colleen Maloney at 486-6562.

7. Determine if PCAP has signed the HIV Primary Provider Agreement. Please contact John Schnurr at 473-3786.

At site visit:

- Tour program
- Get PCAP contact name, address and phone #, if different from presurvey information.
- Verify information on presurvey tool including updating clinic sites/days, # client enrollment, etc.
- Determine catchment area
- Ask for blank copy of medical record which includes all recording tools
- At the first meeting with PCAP staff, ask staff to review the flow of a PCAP client through their program to obtain a general idea of how the PCAP functions.
- Discuss PCAP survey process. **Note**: charts may be done prior to interviewing staff.

Part 85.40 Standards

B. **General Requirements**

1. Ask the PCAP staff to describe the process of how a client gets on Medical Assistance (MA). How is the application done? Review list of documents necessary for Medical Assistance.

2. What is the system for verifying MA application approved/denied?

3. How does the PCAP conduct presumptive eligibility (PE)?

4. Is the PCAP using Growing Up Healthy (GUH) or Access NY Health Care application for determining MA eligibility?

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Presumptive eligibility - (PE)

   a. What staff are trained for PE? List them (name, FTE)
   b. Has PCAP signed QP agreement?

2 If other medical providers are contracting with the PCAP for deliveries, laboratory services, sonograms, etc., are written agreements in place which specify that the PCAP will be billed and not a separate bill to Medicaid? Review agreements.

3. How long does the PE/MA application approval process take?

4. Any problems with local DSS or facilitated enrollers? (if yes, can refer to Colleen Maloney at 518-486-6562).

5. Are there (MA) denials? What are the reasons for denials?

C. Outreach

1. What is the time lag for a pregnancy test when a woman calls for one?

2. Explain the PCAP's linkages with other DOH programs and community agencies, e.g., CPPSNs, CHWPs, LHD, WIC, Planned Parenthood, etc.

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Does the PCAP offer pregnancy screening on-site? Is an appointment necessary or are walk-ins accepted?

2. Entry into care of women in first trimester is __%; second trimester __%; third trimester ___

3. Time lag for first medical appointment from (+) pregnancy test? If more than six weeks, determine reason.

D. **Risk Assessment**

1. When is the initial risk assessment done? Who completes the risk assessment? Does an MD review and sign the tool?

2. Explain the process for the provision of care for a high-risk woman?

3. Are risk factors linked to the care plan?

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Are policies/protocols in place for high-risk women? Criteria for determining high-risk women.

E. Care Plan and Coordination of Care

1. How is the care plan developed for each client? Is it documented in chart? Does care plan include assessment, problems/needs, follow-up?

2. How does the PCAP ensure coordination of care? How is the coordination of care documented in each patient's chart?

3. What is system for follow-up on referrals?

4. If multiple PCAP sites, how is care coordinated across all sites, and what type of oversight is provided to

ensure consistent/uniform application of standards.

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Is there a designated PCAP coordinator?

2. If there are multiple sites, is there a designated PCAP coordinator at each site?

3. Are team conferences held? Who attends? How often are they held?

4. Are there criteria for referrals for home visits in place (review policy)? Review the procedure for identification of patients who would benefit from home visits and how is that implemented?

5. What is system for follow-up of missed visits?

F. **Nutrition**

1. How does the PCAP conduct nutrition risk assessment? Does the PCAP use a special assessment form? Discuss the process for on-going re-assessment.

2. Review your process and procedure for a WIC referral? Is WIC on-site? Is there follow-up to determine if/when women are enrolled in WIC?

3. How are vitamins and supplemental iron dispensed? **Note**: the PCAP rate includes the cost of prenatal iron and vitamins; the pharmacy can not bill Medicaid for these items.

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Is there a policy in place for nutritional risk assessment?

2. Are there policies/procedures to define nutritionally at-risk woman? Criteria for determining who receives nutritional counseling.

3. Who does nutrition counseling for at-risk women (names, title, FTE)?

G. **Health Education (Risk Appropriate)**

1. Are childbirth classes provided? If so, are they documented? **Note**: childbirth classes are not required.

2. How is health education provided? Group settings? Individual? Printed material? Video?

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Who provides health education?

H. **Psychosocial Assessment**

1. Review the process for making appropriate referrals? Who are they made to and what follow-up is conducted to ensure the patient receives necessary services?

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Who conducts the psychosocial assessment and provides the psychosocial counseling?

2. Review the process for the provision of psychosocial assessments? Is a specific screening tool used? How is this documented in the medical record? **Note**: Documentation must reflect each of the areas -- social, economic, psychosocial and emotional, domestic violence.

I. **Prenatal D&T**

1. Review the process regarding what occurs during initial visits/ subsequent visits (i.e., physical exam, lab tests, type of practitioner providing clinical care,etc.).

2. What is the process for follow-up on abnormal lab values? Is there follow-up for Hepatitis B (+) women?

3. How is prebooking handled?

4. Are AFP's done? Is there a specific consent form? How is the denial or acceptance of the test documented? What is the follow-up procedure for abnormal AFPs?

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. What is the policy and procedure for standard laboratory testing (i.e. prenatal bloodwork, GBS, Hepatitis B, AFP, Sickle Cell, etc.)?

2. What are the policies and procedures for after-hours care, specialist consultation, transfer to an OB, emergency care?

J. **HIV Services**

1. Does the PCAP perform pretest counseling? How and when is it done? Is there clinical recommendation for testing? If testing acceptance rate is low, explore reasons. Does HIV pretest counseling include notifying women that newborn's blood will be tested, availability of antiretrovirals to reduce HIV transmission to the newborn?

2. How does the PCAP track their HIV C&T data? If multiple PCAP sites, how is HIV C&T data collected from other sites?

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Who conducts the HIV Counseling and testing?

2. What are the policies and procedures for HIV C&T, including posttest counseling. Note: The PCAP must offer testing on site.

3. Has the facility signed the HIV Primary Provider Agreement? (Call John Schnurr at 518- 473-3786).

K. **Records/Reports**

1. Is information readily retrievable? (Charts, P&P)

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Does the PCAP have a log system - patient name, trimester of entry, low birthweight (LBW), rate of return for postpartum visit, # teenagers, WIC enrollment? If not, how does the PCAP track patients?

L. **Internal Quality Assurance (IQA)**

1. Is quality assurance process specific to prenatal? If not, does the quality assurance process adequately address prenatal standards? Does the process include reviewing records from all PCAP sites? Who is on QA committee?

2. Is a patient satisfaction survey of PCAP services done?

3. Determine if problems/findings of prenatal care as identified in IQA are addressed with sufficient follow-up.

4. Review birth outcomes based on presurvey questionnaire such as LBW rates and discuss strategies to improve birth outcomes.

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Review the policies and procedures for Internal Quality Assurance.

2. How frequently are audits of PCAP/MOMs record conducted? Who conducts these audits? (Review chart audit tool).

3. Review last annual QA report.

4. Review policies/procedures for handling complaints, follow-up, corrective action.

5. Check reports of last year's chart audits, committee meetings.

M. **Postpartum Services**

1. How are postpartum appointments scheduled? Review the follow-up for missed postpartum visits.

2. For the interim period following delivery, does the woman have instructions if problem occurs?

3. How are postpartum teaching needs addressed? Who provides the postpartum teaching?

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Review the postpartum return rate to identify any potential issues. Missed visit P+P should be implemented.

N. **Provider Agreement – Fiscal Review**

1. Compare the "PCAP Visits completed" table with the "PCAP Visits Billed" table. Does it appear that the PCAP is billing appropriately? Discuss discrepancies, if present.

2. Confirm that NSTs, BPPs are not billed on a fee-for-service basis.

The following information is obtained from the Presurvey Questionnaire. It is not necessary to repeat these questions on-site unless there are outstanding questions.

1. Who is the fiscal officer responsible for proper billing of PCAP to Medicaid?

2. What has the facility done to ensure that practitioners and/or radiologists are not billing Medicaid for ultrasound services to PCAP patients?

3. Do they have on file a written notice to labs and referred service providers explaining about PCAP billing, i.e., vendors to bill the facility?

EXIT CONFERENCE

- To the extent possible, information about the time and place of the exit conference should be made available to key facility administrative and PCAP staff as early as possible in the site visit, so they can adjust their schedules to be at the exit conference. It is the exception that reviewers would need to return to the PCAP facility to conduct another exit conference for those who could not attend the scheduled exit conference at the conclusion of the survey.
- Review general findings, addressing strengths as well as areas of weaknesses.
- Inform the PCAP that the site visit report will be prepared and forwarded to the agency within 4-6 weeks.
- Review the process for the development of a plan of correction, including timeframes for their response - show them a sample. If serious deficiencies noted, explain that a follow-back visit may be indicated.
- Give your phone number as contact person.

NYS DEPARTMENT OF HEALTH

Perinatal Health Unit
Bureau of Women's Health

Pre-survey Questionnaire PCAP/MOMS

AGENCY SERVICES: PCAP MOMS

Date of Pre-survey questionnaire completion _____

Name of Program: _____

Address: _____
(If there is more than one site, document address of principal administrative office) _____

_____

Name & title of responsible program contact person _____

Telephone #: ( ) _____ **Fax #:** ( ) _____

Email address: _____

Name & title of person completing this questionnaire: _____

Telephone #: ( ) _____ **Fax #:** ( ) _____

Email address: _____

TO BE COMPLETED BY PCAP/MOMS PROGRAM

I. ORGANIZATION AND ADMINISTRATION

A. List counties/area which this PCAP/MOMS services:

_____

_____

B. Prenatal Site/Practitioner Profile
See Page 2

Prenatal Site/Practitioner Profile

Name and address of each Article 28/36 prenatal services site	Days and hours of service	Provider type (one or both)	If PCAP, check type of staff rendering prenatal clinical care	If MOMS, list name and address of affiliated MOMS medical practitioner(s)
		___ PCAP ___ MOMS	OB-GYN ____ Other MD ____ Licensed Midwife ____ PA ____ NP ____	
		___ PCAP ___ MOMS	OB-GYN ____ Other MD ____ Licensed Midwife ____ PA ____ NP ____	
		___ PCAP ___ MOMS	OB-GYN ____ Other MD ____ Licensed Midwife ____ PA ____ NP ____	
		___ PCAP ___ MOMS	OB-GYN ____ Other MD ____ Licensed Midwife ____ PA ____ NP ____	

ATTACH ADDITIONAL SHEETS AS NECESSARY

C. List names and titles of staff who are responsible for providing or arranging for:

Presumptive Eligibility_____

Outreach_____

Nutrition Assessment _____

Nutrition Counseling for High Risk_____

Health Education_____

Psychosocial Assessment_____

Psychosocial Counseling_____

HIV Counseling/Testing_____

PCAP/Medicaid Billing_____

Risk Assessment_____

Clinical Care_____

GENERAL STATISTICS (for Medicaid clients only) – To complete this section you must use clinic data tracked by the PCAP coordinator. Data is requested for current calendar year and previous calendar year. Please indicate the time frames used for both below:

Current calendar year _____ Previous calendar year _____

Data elements	PCAP				MOMS			
	Previous Yr		Current Yr		Previous Yr		Current Yr	
	#	%	#	%	#	%	#	%
1. Initial visits conducted to provide prenatal services.		____		____		____		____
2. PCAP/MOMS clients enrolled in WIC.								
3. Low birthweight (<2500 gms) babies born								
3. Clients with postpartum visits.								
4. Total number of PCAP visits (or HSS visits for MOMS clients) provided.								
5. Teen clients seen in the program(s)								
6. Pregnant women received HIV pre-test counseling.								
7. Pregnant women received HIV testing.								
8. Pregnant women received post-test counseling.								

Total number of PCAP or MOMS clients during previous year._____

Current number of PCAP or MOMS clients. _____

What percent enter MEDICAL (PRENATAL) CARE IN?
(PCAP & MOMS – Please note, the % must reflect when first entered prenatal care to any provider, not when the woman first entered your care.)

first trimester? _____
second trimester? _____
third trimester? _____

What percent enter HSS care in?
(For MOMS only)

first trimester? _____
second trimester? _____
third trimester? _____

III. PRESUMPTIVE ELIGIBILITY AND MEDICAL ELIGIBILITY DETERMINATION

Please complete the following table for each county that processes your PCAP/Medicaid applications.

Name of County	**Average Processing Time**	**Percent of Denials**	**Reason(s) for Denials**
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Do you contract with managed care companies? Yes _____ No _____

If yes, please list the managed care plans below:

Are there any problems with LDSS and or facilitated enrollers? If yes, please specify.

_____

_____

_____

_____

IV. OUTREACH

A. Is pregnancy screening offered on-site? _____
If yes, by: Appointment _____ Walk-in _____
If yes, what is the charge? _____

B. What is the average number of weeks it takes for the client to have her first medical examination from the date she first contacts the program for an appointment? _____

C. Check activities conducted which reflect linkage with community based resources and disseminate program information and enrollment through local media and community channels. **(Attach sample from current year.)**

Flyers distributed in community	Newspaper Ads	Radio Spots
Onsite in schools/teen linkage	Posters	Billboards
Affiliation with local Network/Outreach Contractor	TV Spots	Other: _____

V. POLICIES PROCEDURES AND DOCUMENTS

Indicate if your program has the following policies and procedures or documents. **Please append these to this presurvey questionnaire when it is returned.**

	Yes	No
Coordination of Care		
Missed visit		
After hours emergency consultation (PCAP)		
Home visits		
Nutrition ♦ Criteria for referral to RD/nutritionist		
Psychosocial		
HIV C&T including posttest counseling		
Criteria for consultation for special medical condition (PCAP)		
Transfer to higher level of care (PCAP), e.g. to care of an OB		
Fiscal policies including MMIS billing; prevention of duplicate billing; return of PCAP/MOMS revenue to program		
Current subcontracts for medical, laboratory, and radiology		
Standard laboratory procedures (Type, frequency of lab tests conducted on patients)		
Internal QA		
Last annual QA report		
Schedule of QA meetings for current year		

Internal record review audit tool (PCAP)

Risk assessment **(Attach copy of tool)**

- Criteria for determining high risk

Health education checklist

Tracking tool

VI. RISK ASSESSMENT (PCAP

Are high risk clients referred to another facility(ies)? Yes No
If yes, name of facility(ies):

_____

VII. CARE PLAN AND COORDINATION OF CARE

Please list the name of PCAP/MOMS coordinator _____

What is the profession/discipline of the coordinator? RN SW
Other _____

What is the time (in FTE) the coordinator devotes to this position? _____FTE

If multiple sites, does each site have a coordinator? Yes No

If applicable, please list their names/profession/FTE/corresponding site

1) _____

2) _____

3) _____

Describe role of PCAP/MOMS coordinator (attach position description if available)

_____

_____

_____

_____

Are team conferences held? Yes No How often? _____

Who attends team conferences?

_____

_____

_____

VIII. PRENATAL DIAGNOSTIC & TREATMENT SERVICES (PCAP)

Which clinical practitioner (OB, FP, Licensed Midwife, NP) conducts the initial medical evaluation?

_____

Who examines the client on the subsequent visits?

_____

IX. INTERNAL QUALITY ASSURANCE

Chart Audits **(Attach a copy of the chart audit tool)**:

How frequently are audits of PCAP/MOMS client records done? _____

What is the average number of records reviewed at each audit? _____

Please list the staff responsible for chart audits (names and titles).

_____

_____

_____

X. ISSUES/TECHNICAL ASSISTANCE NEEDS

List any issues and/or technical assistance needs you would like addressed by regional PCAP staff.

1) _____

2) _____

3) _____

XI. PCAP Data

A. Please have appropriate **program** staff complete the following table for the number of visits completed.

PCAP Visits		
Visit Type	**Previous Year Number**	**Current Year Number**
Initial visits		
Subsequent Visits		
Postpartum Visits		
HIV Pretest counseling with testing		
HIV Pretest counseling without testing		
HIV Posttest counseling – positive		
HIV Posttest counseling - negative		

B. Please detach this page and have appropriate **fiscal** staff complete the following table for visits billed.

Name of Fiscal Staff completing table_____

PCAP Visits Billed		
Visit Type	**Previous Year Number Billed**	**Current Year Number Billed**
Initial visits		
Subsequent Visits		
Postpartum Visits		
HIV Pretest counseling with testing		
HIV Pretest counseling without testing		
HIV Posttest counseling – positive		
HIV Posttest counseling - negative		

Prenatal Care Assistance Program
Quality Assurance Program
Client Record Review

Site: _____

Date: _____ **EDC:** _____ **IV DATE:** _____

Reviewer: _____ **GA:** _____ **GRAV/PARA:** _____
Medical Record #: _____
Legible: yes_____ no _____

INITIAL EXAM	**Present**	**Not Present**	**Comments**
A. MEDICAL EVALUATION			
1. Medical/Obstetric History	☐	☐	_____
2. Genetic History	☐	☐	_____
3. Complete Physical Exam	☐	☐	_____
B. ASSESSMENT			
1. Initial Risk Status: _____	☐	☐	_____
2. Nutrition assessment	☐	☐	_____
. assigned level of risk: _____	☐	☐	_____
. if high risk, referred to dietitian	☐	☐	_____
. written care plan	☐	☐	_____
3. Psychosocial Assessment	☐	☐	_____
4. Environmental Assessment	☐	☐	_____
C. LABORATORY TESTS			
1. Hematocrit/Hemoglobin	☐	☐	_____
2. Blood Group & Rh Determination	☐	☐	_____
3. Irregular Antibody Screen	☐	☐	_____
4. Rubella Titre	☐	☐	_____
5. Sickle Cell Screen (if indicated) Hemoglobin Electropheresis or Chromotography Method	☐	☐	_____

6. Tuberculin Testing **(if indicated)**

7. Lead Screening (if indicated)

8. Syphilis (mandatory)

9. GC Screen

10. Urine Culture

11. Urinalysis

12. Cervical-Vaginal Cytology

13. Hepatitis B Surface Antigen (mandatory)

14. Chlamydia

15. AFP

16. HIV Universal Pretest Counseling

(Consent signed)

. Testing decision documented

. Posttest counseling, if indicated

17. F/U Abnormal Lab Values

D. CARE COORDINATION

1. All appropriate referrals documented
(e.g. WIC, DSS, substance abuse, etc.)

SUBSEQUENT VISITS

A. CARE COORDINATION

1. Review of symptoms (BP and FHR each visit)
2. Update risk status as appropriate and at 26-28 weeks
3. Follow-up missed appointments including specialty medical appointments
4. Appropriate referrals made

   F/U on referrals
5. Care Plan
   - Problem list
   - Action
   - Follow-up

B. LABORATORY TESTS

1. Glucose Challenge at 28 weeks
2. Hemoglobin or Hematocrit at 36 weeks
3. Syphilis During Third Trimester
4. GC in Third Trimester
5. Group B Strep During Third Trimester
6. HIV Testing, if appropriate

C. HEALTH EDUCATION

1. Orientation to procedures at PCAP facilities and expected site of birth
2. Rights and Responsibilities
3. Signs of Pregnancy Complication
4. Avoidance of Harmful Substances
   - alcohol
   - drugs
   - nicotine
5. Risks of HIV infection

6. Signs of Labor

7. Labor & Delivery Process

8. Expanded MA Eligibility for Infants

9. Physical Acitivity and Exercise During Pregnancy

10. Sexuality During Pregnancy

11. Occupational Concerns

12. Relaxation Techniques in Labor

13. Obstetrical Anesthesia and Analgesia

14. Preparation for Parenting

15. Newborn Screening Program

16. Family Planning

POSTPARTUM VISIT

A. PHYSICAL EXAM

1. Findings Documented

2. Appropriate Labs Ordered (Hematocrit and Pap smear)

B. RE-ASSESSMENT

1. Summary of maternal/infant outcome (eg. method of delivery, birthweight, complications)

2. Incorporation of Newborn into Family

3. Infant Feeding Method Indicated

C. HEALTH EDUCATION

1. Preconception Counseling

2. Pediatric Follow-up

D. FAMILY PLANNING SERVICES

1. Method of Contraception Indicated

E. CARE COORDINATION

1. Identification of needs and appropriate referrals made ☐ ☐ _____

. Infant ☐ ☐ _____

. Maternal ☐ ☐ _____

CONCLUSION

	Yes	No	
1. Is management of this case appropriate?	☐	☐	_____
2. Is there any evidence of a major error in diagnosis, management, judgement or technique?	☐	☐	_____

PCAP Survey Report Cover Letter

Date

Name
Agency
Address
City, State, Zip

Dear Name:

The enclosed report contains the findings and recommendations resulting from the recent review of your program by PCAP staff. This report reflects current interpretations of Part 85.40 of 10NYCRR.

Any questions about this report should be directed to PCAP regional staff.

Sincerely,

Enclosure

cc: Patricia Hess, Director, Division of Nutrition
~~Betty Rice,~~ Linda LeClair, Director, Division of Consumer and Local District Relations
~~Linda Thornton~~Rudy Lewis, Director, Perinatal Health Unit
Denise Hernas, QA Coordinator, Perinatal Health Unit

PCAP Site Evaluation Report

Name of Facility: _____

This report summarizes the findings and recommendations identified by NYS Department of Health staff during the review of the Prenatal Care Assistance Program (PCAP) services at _____. This review was conducted on _____ by _____.

This report measures compliance with PCAP standards as defined in Section 85.40 of 10 NYCRR. Compliance is measured through an onsite review of process and outcome indicators and verified by a chart audit of perinatal records. The **Summary of Findings** describes minimal PCAP performance expectations. Each item identified in the column marked **NO** represents an area of non-compliance and requires a plan of correction. This plan of correction should follow a specific format (attached) but should also include any additional documentation described in the **Comments/Technical Assistance** sections of the report. The proposed timeframes for implementation cannot exceed 90 days. Your plan of correction and additional documentation, such as new or revised policies and procedures, must be mailed within 20 working days of receipt of this report. Department of Health staff will review the plan and provide you with written confirmation if acceptable. Failure to submit a corrective action plan within 20 working days could jeopardize your PCAP designation.

The **"Comments/Technical Assistance"** sections of the report may also include recommendations. The PCAP provider is encouraged to implement actions related to these recommendations when indicated. However, failure to comply will not constitute a program deficiency.

Questions about this report may be directed to the PCAP consultant listed below. Your agency's plan of correction should be forwarded to this individual by _____.

_____
_____
_____
_____
_____

BACKGROUND

SUMMARY OF FINDINGS

B. GENERAL REQUIREMENTS	YES	NO
1. Staff is trained in presumptive eligibility (PE) by LDSS.		
2. Any subcontracts between PCAP providers and other agents or agencies providing care and services are available for review and inspection by the Department of Health.		
3. PCAP assists woman to complete the application for Medicaid and the screening checklist.		

Comments/Technical Assistance

C. OUTREACH	YES	NO
1. PCAP facilitates early entry into maternity services including the provision of on-site pregnancy screening.		
2. PCAP maintains adequate/appropriate linkages with community-based referrals resources. Describe.		
3. PCAP disseminates, through local media and community channels, information concerning available services and initial enrollment procedures. Describe.		

Comments/Technical Assistance

D. RISK ASSESSMENT

	YES	NO
1. Risk assessment, including an analysis of individual characteristics affecting pregnancy, such as genetic, nutritional, psychosocial, and historical and emerging obstetrical/fetal and medical-surgical risk factors, is done at the initial visit.		
2. Risk assessment is linked to the plan of care and clearly documented in the medical record.		
3. Uniform criteria are defined and in use for determining high risk pregnancies.		

Comments/Technical Assistance

E. CARE PLAN AND COORDINATION OF CARE

	YES	NO
1. A care plan which addresses the proper implementation and coordination of all services required by the pregnant woman is developed, routinely updated and implemented jointly by the pregnant woman and her family.		
2. Care is coordinated across all members of the health team. Describe.		
3. Prenatal or postpartum home visitation is provided to enrollees with medical or psychosocial indications for such visits.		
4. Procedure is in place for follow-up of missed visits.		
5. Documentation of follow-up for missed visits is evident.		
6. Procedure is in place for follow-up of referrals.		
7. Documentation of follow-up for referrals is evident.		

Comments/Technical Assistance

F. NUTRITION SERVICES	YES	NO
1. Documented nutrition risk assessment, including screening for specific nutritional conditions, conducted at initial visit.		
2. Professional nutritional counseling, monitoring/follow-up of at-risk women, is conducted by a nutritionist or registered dietician.		
3. Documentation of nutrition risk status is evident		
4. Nutrition care plan is documented in the medical record.		
5. WIC services are arranged at initial visit.		
6. Basic nutrition education is provided and documented.		

Comments/Technical Assistance

G. HEALTH EDUCATION	YES	NO
1. Chart review demonstrates that risk-appropriate health education is provided to each client on relevant topics.		

Comments/Technical Assistance

H. PSYCHOSOCIAL ASSESSMENT

	YES	NO
1. A psychosocial assessment is conducted/documented and includes screening for social, economic, psychological and emotional problems.		
2. Referrals are made based on the needs of the woman or fetus, to the local Department of Social Services, community mental health resources, support groups or social/psychological specialists.		

Comments/Technical Assistance

I. PRENATAL DIAGNOSTIC AND TREATMENT SERVICES

	YES	NO
1. Prenatal diagnostic and treatment services are performed by a qualified practitioner.		
2. An initial comprehensive assessment including history, review of systems and physical examination is conducted on all clients.		
3. Subsequent visits include all PCAP required components of care.		
4. The medical record contains evidence of risk appropriate laboratory tests and follow-up.		
5. After hours consultation/care available without utilizing ER.		
6. Every client is pre-booked with planned site of delivery at appropriate gestational age.		
7. Arrangements are made, if indicated, for referral of women and/or neonates to alternate care sites.		
8. Policies and procedures are in place for consultation with specialist when necessitated by specific medical condition.		
9. Policies and procedures are in place for transfer of primary responsibility for patient care from primary care professional to obstetrician.		

Comments/Technical Assistance

J. HIV SERVICES	**YES**	**NO**
1. Pre-test counseling is provided to all women.		
2. Confidential HIV testing is offered to all women.		
3. Post-test counseling is given to all women tested for HIV.		
4. The HIV positive woman and her newborn infant are provided the following services or given the necessary referrals for these services: • management of HIV disease; • psychosocial support; and • case management to assist in coordination of necessary medical, social and addictive services.		
5. Medical record and prenatal summary form contain appropriate documentation.		
6. Adheres to HIV Confidentiality (NYCRR, Part 63.8):		

Comments/Technical Assistance

K. RECORDS AND REPORTS	YES	NO
1. Records and reports are maintained in a complete, legible, and retrievable manner.		
2. A comprehensive prenatal care record is maintained for each pregnant woman which documents the provision of care and PCAP required services.		
3. Program reports including financial, administrative, utilization and patient care data are maintained in such a manner as to allow the identification of expenditure, revenue, utilization and patient care data associated with health care provided to PCAP clients.		
4. Systems are in place to track trimester of entry, low birthweight and postpartum rate of return.		
5. PCAP Annual Reports are accurate and submitted on a timely basis.		

Comments/Technical Assistance

L. INTERNAL QUALITY ASSURANCE	YES	NO
1. Written policies and procedures are in place establishing an internal quality assurance program to identify, evaluate, resolve and monitor actual and potential problems in patient care.		
2. A documented and filed prenatal chart audit is performed periodically on a statistically significant number of current PCAP client records (minimum of 10% of charts reviewed if 100 or more clients annually; no less than 10 charts to be reviewed if less than 100 clients enrolled).		
3. Written summary evaluation of all audit components is performed annually.		

4. There is a system for determining patient satisfaction.

5. There is a system for resolving patient complaints.

6. There is a system for developing and recommending corrective actions to resolve identified problems including poor outcomes of pregnancy.

7. There is a follow-up process to assure that recommendations and plans of correction are implemented and are effective.

8. Safeguards are in place to prevent the inappropriate breach of patient confidentiality requirements.

Comments/Technical Assistance

M. POSTPARTUM SERVICES	**YES**	**NO**
1. Postpartum visit identifies any medical, psychosocial, nutritional, alcohol treatment and drug treatment needs of the mother or infant that are not being met.		
2. Mother or other infant caregiver is referred to resources available for meeting such needs and providing assistance in meeting such needs where appropriate.		
3. Family planning needs are assessed, and advice and services are provided or a referral is given where indicated.		
4. Preconception counseling is provided as appropriate and encouragement of a preconception visit prior to subsequent pregnancies for women who might benefit from such visit.		

5. Infants are referred to preventive and special care services appropriate to their needs.

6. Mother is advised of the availability of Medicaid eligibility for infants.

7. Postpartum visit is scheduled in a timeframe appropriate to the needs of the patient but no later than 8 weeks after delivery.

8. There is evidence that clients are given a means of contacting provider if problems or concerns arise between delivery and postpartum visit.

9. Arrangements for pediatric care are made and documented in the medical record.

Comments/Technical Assistance

PROVIDER AGREEMENT EXTRAS	**YES**	**NO**
1. Provider has evidence of appropriate billing of PCAP/MA rates.		
2. Provider has mechanisms to ensure no duplicate billing of Medicaid including:		
• Evidence of written notification to outside vendors regarding billing requirements for PCAP patients, if outside vendors used.		
• Use of a referral form which identifies PCAP as the party responsible for payment and does not contain information which would allow direct billing of Medicaid.		
• Procedures to ensure that prenatal vitamins and iron are included in the PCAP rate and not billed to Medicaid by outside pharmacies.		
3. PCAP program is adequately staffed to ensure all PCAP services are rendered.		

Comments/Technical Assistance

ATTACHMENT T

Effective Date: 05/31/2000
Title: Section **85.40** - Prenatal Care Assistance Program

85.40 Prenatal Care Assistance Program (a) Applicability. To qualify for Prenatal Care Assistance Program (PCAP) Medicaid reimbursement rates under Section 86-4.36 of this Title or PCAP Medicaid fees, providers of comprehensive ambulatory prenatal care services operating under Article 28 of the Public Health Law as general hospitals or diagnostic and treatment centers including birth centers and certified to provide prenatal, obstetric or maternity and newborn services or physicians or licensed midwives shall have an approved provider agreement with the Department of Health to provide such services in accordance with the requirements of PCAP. Such PCAP providers shall provide care and services, either directly or through subcontract with qualified agents or agencies, in accordance with generally accepted standards of practice and patient services and in accordance with the minimum requirements established in subdivisions (b) - (m) of this section.

(b) General Requirements. (1) The PCAP provider shall act as a "qualified provider" as required by the Department of Social Services (see 18 NYCRR 360-3.7(d)).

(2) Following the determination of a pregnant woman's presumptive eligibility for Medicaid benefits, the PCAP provider shall act as a pregnant woman's authorized representative in the completion of the Medicaid application process if the woman provides consent for such action.

(3) The PCAP provider shall permit on-site program review by representatives of the Department of Health at any facilities where PCAP care and services are provided.

(4) The PCAP provider shall make available to representatives of the Department of Health, upon request, any records and reports directly related to the PCAP.

(5) Any subcontracts between PCAP providers and other agents or agencies providing care and services shall:

(i) be available for review and inspection by the Department of Health;

(ii) include assurances that the Department of Health has access to agent or agency sites and records to conduct on-site program compliance reviews; and

(iii) require that the subcontractors provide contracted care and services that meet the minimum standards established in this section and are provided in accordance with generally accepted standards of practice and patient care services.

(c) Outreach. PCAP providers shall engage in community outreach activities which, as a minimum:

(1) facilitate early entry into maternity services including the provision of on-site pregnancy

screening;

(2) reflect linkages with community-based resources commonly utilized by pregnant women; and

(3) disseminate, through local media and community channels, information concerning available services and initial enrollment procedures.

(d) Risk assessment. Every pregnant woman shall receive ongoing assessment of both maternal and fetal risk throughout the prenatal period. Such risk assessment shall include, but not be limited to, an analysis of individual characteristics affecting pregnancy, such as genetic, nutritional, psychosocial, and historical and emerging obstetrical/fetal and medical-surgical risk factors. At the time of registration, a standardized written risk assessment shall be conducted using established criteria for determining high risk pregnancies, based upon generally accepted standards of practice. This risk assessment shall be:

(1) reviewed at each visit;

(2) formally repeated early in the third trimester; and

(3) linked to the plan of care and clearly documented in the medical record.

(e) Development of care plan and coordination of care.

(1) A care plan which addresses the proper implementation and coordination of all services required by the pregnant woman shall be developed, routinely updated, and implemented jointly by the pregnant woman and her family where mutually agreeable to the woman and all appropriate members of the health care team.

(2) Care shall be coordinated to:

(i) ensure that relevant information is exchanged between the prenatal care provider and other providers or sites of care including the anticipated birthing site;

(ii) ensure that the pregnant woman and her family, with her consent, have continued access to information resources and are encouraged to participate in decisions involving the scope and nature of care and services being provided;

(iii) encourage and assist the pregnant woman in obtaining necessary medical, nutritional, psychosocial, drug and substance abuse services appropriate to her identified needs and provide follow-up to ensure ongoing access to services;

(iv) provide the pregnant woman with an opportunity to receive prenatal or postpartum home visitation when the woman may derive medical or psychosocial benefit from such visits. The visit shall identify familial and environmental factors which may produce increased risk to the woman or fetus and the relevant findings shall be incorporated into the care plan; (v) provide to or refer the pregnant woman for needed services including:

(a) inpatient care, specialty physician and clinic services which are necessary to ensure a healthy delivery and recovery;

(b) genetic services;

(c) drug treatment and screening services;

(d) dental services;

(e) mental health and related social services;

(f) emergency room services;

(g) home care;

(h) pharmaceuticals; and

(i) transportation;

(vi) provide for the pregnant woman special tests and services as may be recommended or required by the Commissioner of Health, who shall require such tests and/or services when necessary to protect maternal and/or fetal health. Women shall be provided appropriate medical care, counseling and education based on test results; and

(vii) encourage continuity of care and client follow-up including rescheduling of missed visits throughout the prenatal and postpartum period.

(f) Nutrition services. The PCAP provider shall establish and implement a program of nutrition screening and counseling which includes:

(1) individual nutrition risk assessment including screening for specific nutritional risk conditions at the initial prenatal care visit and continuing reassessment as needed;

(2) professional nutrition counseling, monitoring and follow-up of all pregnant women at nutritional risk by a nutritionist or registered dietitian;

(3) documentation of nutrition assessment, risk status and nutrition care plan in the patient medical record;

(4) arrangements for services with funded nutrition programs available in the community including provision for enrollment of all eligible women and infants in the Supplemental Food Program for Women, Infants and Children (WIC), at the initial visit; and

(5) provision of basic nutrition education and counseling for each pregnant woman which includes the following topics:

(i) appropriate dietary intake and recommended dietary allowances during normal pregnancy;

(ii) appropriate weight gain; and

(iii) infant feeding choices including individualized counseling regarding the advantages and disadvantages of breastfeeding.

(g) Health education. Health and childbirth education services shall be given to each pregnant woman based on an assessment of her individual needs. Appropriate educational materials, including video and written information, shall be used, taking into account cultural and language factors including the ability of the pregnant woman to comprehend the information. Such services shall be provided by professional staff, documented in the medical record and shall include but not be limited to the following:

(1) orientation to procedures at PCAP facilities and at the expected site of birth;

(2) rights and responsibilities of the pregnant woman;

(3) signs of complications of pregnancy;

(4) physical activity and exercise during pregnancy;

(5) avoidance of harmful practices and substances including alcohol, drugs, non-prescribed medications, and nicotine;

(6) sexuality during pregnancy;

(7) occupational concerns;

(8) risks of HIV infection and risk reduction behaviors;

(9) signs of labor;

(10) labor and delivery process;

(11) relaxation techniques in labor;

(12) obstetrical anesthesia and analgesia;

(13) preparation for parenting including infant development and care and options for feeding;

(14) the newborn screening program with the distribution of newborn screening educational literature; and

(15) family planning.

(h) Psychosocial assessment. A psychosocial assessment shall be conducted and shall include:

(1) screening for social, economic, psychological and emotional problems; and

(2) referral, as appropriate to the needs of the woman or fetus, to the local Department of Social Services, community mental health resources, support groups or social/psychological specialists.

(i) Prenatal diagnostic and treatment services. Prenatal diagnostic and treatment services shall be provided by a qualified physician practicing in accordance with Article 131 of the New York State Education Law, a licensed midwife practicing in accordance with Article 140 of the New York State Education Law, a qualified nurse practitioner practicing in accordance with Article 139 of the New York State Education Law or a registered physician's assistant practicing in accordance with Part 94 of this Title, Article 37 of the New York State Public Health Law and Article 131 of the New York State Education Law. Such services shall meet generally accepted standards of professional patient care and services.

(1) Prenatal diagnostic and treatment services provided shall include but not be limited to the following: (i) an initial comprehensive assessment including history, review of systems, and physical examination;

(ii) standard laboratory tests and procedures;

(iii) needed special laboratory tests as indicated by comprehensive assessment and initial or preliminary test findings;

(iv) evaluation of risk;

(v) discussion with the woman of options for treatment, care and technological support that are expected to be available at the time of labor and delivery together with the advantages and disadvantages of each option;

(vi) obtaining from the woman her informed choice of mode of treatment, care and technological support that are expected to be necessary; and

(vii) postpartum counseling, evaluation and referral to professional care and services, as required, to include preconception counseling as appropriate.

(2) The PCAP provider shall establish arrangements for availability of after hours and emergency consultation and care for pregnant women.

(3) The PCAP provider shall develop and implement written agreements with planned sites of delivery which address, at a minimum:

(i) pre-booking of women for delivery at 34-36 weeks gestation for low risk pregnancies and 26

weeks gestation for high risk pregnancies;

(ii) arrangements for referral of women and neonates to appropriate alternate care sites for medically indicated care;

(iii) special tests and procedures which may be required;

(iv) a plan detailing how hospitalization for medical or obstetrical problems will occur;

(v) arrangements with facilities for postpartum services; and

(vi) a system for sharing medical records with the delivery site and for receiving information from referral sources and delivery sites.

(4) The PCAP provider shall develop and implement written policies and procedures designating the requirements for consultation with a qualified physician or other health care specialist when necessitated by specific medical conditions.

(5) The PCAP provider shall designate in writing those situations which require the transfer of the primary responsibility for patient care from a primary care professional who is a family practice physician, physician's assistant, licensed midwife or qualified nurse practitioner to a qualified obstetrician.

(j) HIV services. The PCAP provider shall:

(1) routinely provide the pregnant woman with HIV counseling and education;

(2) routinely offer the pregnant woman confidential HIV testing; and

(3) provide the HIV-positive woman and her newborn infant the following services or make the necessary referrals for these services:

(i) management of HIV status;

(ii) psychosocial support; and

(iii) case management to assist in coordination of necessary medical, social and drug treatment services.

(k) Records and reports. The PCAP provider shall create and maintain records and reports in accordance with this subdivision that are complete, legible, retrievable and available for review by representatives of the Commissioner of Health upon request. Such records and reports shall include the following:

(1) a comprehensive prenatal care record for each pregnant woman which documents the provision of care and services required by this section and which is maintained in a manner

consistent with medical record confidentiality requirements;

(2) special reports and data summaries necessary for the Commissioner of Health to evaluate the provider's delivery of PCAP services;

(3) program reports including financial, administrative, utilization and patient care data maintained in such a manner as to allow the identification of expenditure, revenue, utilization and patient care data associated with health care provided to PCAP clients;

(4) records of all internal quality assurance activities; and

(5) all written policies and procedures required by this section.

(l) Internal quality assurance. The PCAP provider shall develop and implement written policies and procedures establishing an internal quality assurance program to identify, evaluate, resolve and monitor actual and potential problems in patient care. Components of such program shall include but not be limited to the following:

(1) a documented and filed prenatal chart audit performed periodically on a statistically significant number of current PCAP client records;

(2) an annual written summary evaluation of all components of such audits;

(3) a system for determining patient satisfaction and for resolving patient complaints;

(4) a system for developing and recommending corrective actions to resolve identified problems;

(5) a follow-up process to assure that recommendations and plans of correction are implemented and are effective; and

(6) safeguards to prevent the inappropriate breach of patient confidentiality requirements. (m) Postpartum services. The PCAP provider shall coordinate with the neonatal care provider to arrange for the provision of pediatric care services in accordance with generally accepted standards of prac tice and patient services. A postpartum visit with a qualified health professional shall be scheduled and conducted in accordance with medical needs but no later than eight weeks after delivery. For the interim between delivery and the postpartum visit, the PCAP provider shall furnish each woman with a means of contacting the provider in case postpartum questions or concerns arise. The postpartum visit shall include but not be limited to the following:

(1) Identifying any medical, psychosocial, nutritional, alcohol treatment and drug treatment needs of the mother or infant that are not being met;

(2) referring the mother or other infant caregiver to resources available for meeting such needs and providing assistance in meeting such needs where appropriate;

(3) assessing family planning needs and providing advice and services or referral where

indicated;

(4) providing preconception counseling as appropriate and encouraging a preconception visit prior to subsequent pregnancies for women who might benefit from such visit;

(5) referring infants to preventive and special care services appropriate to their needs; and

(6) advising the mother of the availability of Medicaid eligibility for infants.

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ATTACHMENT U

FAMILY PLANNING PROGRAM
MONITORING VISIT SUMMARY

I. A. ORGANIZATIONAL STRUCTURE AND FUNCTION		
STANDARD	**YES**	**NO**
1. The organizational structure and the relationship between the governing board, management, and staff are clearly defined and comprehensive; i.e. are inclusive of all agency operations. • *10NYCRR, 751.2; Title X Guidelines, 6.5*	[ ]	[ ]
2. The agency's governing board reflects the community it serves. • *Title X Guidelines, 6.9*	[ ]	[ ]
3. The agency has written procedures that involve the board, project director, and staff in the program and budget planning process and evaluation of agency goals and objectives. • *10 NYCRR, 751.2; Title X Guidelines, 6.2*	[ ]	[ ]
4. The agency has a certificate of incorporation and a current operating certificate. • *10NYCRR, 751.2*	[ ]	[ ]
5. The agency performs periodic family planning needs assessments of the service area to adequately identify and adjust services according to high priority populations, targeted areas, and service needs. • *10NYCRR, 751.2; Contract, Appendix A-2; Title X Guidelines, 3.2; Ambulatory Health Care Standards (Appendix 9)*	[ ]	[ ]
6. If the agency subcontracts any of its responsibilities or services, there is a written negotiated contract consistent with Title X requirements and approved by NYSDOH. • *Title X Guidelines, 6.1*	[ ]	[ ]
7. The agency has written policies in place to maintain a drug free workplace. • *45CFR Part 76, Subpart F*	[ ]	[ ]
COMMENTS		

I. B. HUMAN RESOURCES MANAGEMENT

STANDARD	YES	NO
1. The agency has written personnel policies for paid and unpaid staff which include, **at a minimum**, federal and state requirements covering staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits and grievance procedures. • *10NYCRR, 751.6; Title X Guidelines, 6.5; Civil Rights Act, Title VI*	[ ]	[ ]
2. The agency hires staff without regard to religion, race, color, national origin, creed, disability, sex and age. • *10NYCRR, 751.6 (b); Title X Guidelines, 6.5; Contract (Appendix A); Civil Rights Act, Title VI; Americans with Disabilities Act (ADA)*	[ ]	[ ]
3. The agency ensures that project staff are broadly representative of all significant elements of the population to be served by the project, and that they are sensitive to and able to deal effectively with the cultural and other characteristics of the client population. • *Title X Guidelines, 6.5*	[ ]	[ ]
4. The agency has written job descriptions for all current positions that describe the positions, duties, functions, responsibilities, supervisory relationships and specific education and experience requirements. • *10NYCRR, 751.6 (i); Title X Guidelines, 6.5*	[ ]	[ ]
5. The agency ensures that all clinic physicians, clinicians, and nurses are fully licensed and registered to practice in the State of New York. • *10NYCRR, 751.6 (f) (l); Title X Guidelines, 6.5*	[ ]	[ ]
6. The agency ensures all staff is qualified and trained according to state and federal regulations and current medical practices and staff is oriented to the agency's operations. • *10NYCRR, 751.6 (f), (j), (k); 42CFR 59.5 (b) (4)*	[ ]	[ ]
7. All personnel have been oriented that they may be subject to prosecution under Federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure and there is documentation of such. • *Title X Guidelines, 5.1*	[ ]	[ ]
8. The agency ensures that staff members are given the opportunity to update their professional knowledge and skills on a regular basis, and are documenting such. • *10NYCRR, 751.6 (m), (n); 42CFR 59.5 (b) (4); Title X Guidelines, 6.6*	[ ]	[ ]

9. The agency ensures that personnel records are confidential, complete and maintained, including performance evaluation, professional licensure and registration as appropriate, results of laboratory screening and initial and annual health exams. • *10 NYCRR 751.6; Title X Guidelines, 6.5*	[ ]	[ ]
10. A qualified project director administers the project. • *Title X Guidelines, 6.5*	[ ]	[ ]
11. The agency has policies to prevent employees, consultants, or members of governing or advisory bodies from using their positions for purposes of private gain for themselves or others. • *Title X Guidelines, 5.3*	[ ]	[ ]
12. The agency complies with CPR certification requirements. • *Title X Guidelines, 7.3*	[ ]	[ ]
COMMENTS		

I. C. MANAGEMENT INFORMATION SYSTEM

STANDARD	YES	NO	
1. The agency participates in the NYS Family Planning Data System and on a regular basis provides information electronically, consistent with the data system and as required by DHHS. • *Contract; Title X Guidelines, 6.7; Data Manual*	[ ]	[ ]	
2. The agency meets financial and other reporting requirements of the New York State Department of Health and U.S. Department of Health and Human Services. • *Contract; Title X Guidelines, 6.7*	[ ]	[ ]	
3. The agency has a policy to ensure compliance with HIPAA regulations. • *Health Insurance Portability and Accountability Act of 1996 "HIPAA" Public Law 104-191; Contract*	[ ]	[ ]	
4. The agency has a process to ensure that publications (including computer software) developed under Title X does not contain information which is contrary to program requirements or to accepted clinical practice and are in accordance with Title X guidelines and NYS policy and practice. • *Title X Guidelines, 6.10; Contract*	[ ]	[ ]	

			N/A
5. The agency complies with Government-wide regulations that apply to the rights to inventions made under government grants, contracts and cooperative agreements. • *37 CFR Part 401; Title X Guidelines, 6.11; Contract*	[ ]	[ ]	[ ]
6. The agency has a process to effectively capture and verify information required for the federal Family Planning Annual Report (FPAR), including:			
a. Validating counts provided in Ahlers reports.	[ ]	[ ]	
b. Continuous tracking of cervical cancer test results.	[ ]	[ ]	
c. Calculating physician and mid-level clinician FTEs. • *FPAR Requirements*	[ ]	[ ]	
COMMENTS			

I. D. FINANCIAL MANAGEMENT

STANDARD	YES	NO
1. The agency maintains a financial management system that meets the standards specified in Subpart C of 45CFR 74 or 92, as applicable, Administration of Grants, and complies with federal standards to safeguard the use of funds. • *Title X Guidelines, 6.3; Subpart C, 45 CFR Part 74 or Subpart C, 45 CFR Part 92*	[ ]	[ ]
2. Documentation of all income and expenditures is maintained:		
a. Revenues and expenditures are adequately identified for each grant or contract.	[ ]	[ ]
b. Records of expenditures are maintained by program and budget categories, including in-kind shares. • *Title X Guidelines, 6.3; Administration of Grants, 45CFR 74, Subpart H; BCHS Accounting Manual, Chapter V; Contract*	[ ]	[ ]
3. The agency has in place effective internal controls or policies to adequately safeguard assets and assure that assets are used solely for authorized purposes. • *OMB Circulars; A-133 (Not for Profit); A-128 (Audits of State & Local Gov.); A-110 (Hospitals)*	[ ]	[ ]
4. An independent audit is completed yearly, including a Management Letter. • *Contract; OMB Circulars; A-133 (Not for Profit); A-128 (State & Local Gov.); A-110 (Hospitals)*	[ ]	[ ]

5. Policies and procedures for charging, billing, and collecting funds for the services provided by the project are implemented and should be approved by the governing authority or board of the agency. • Title X Guidelines, 6.3	[ ]	[ ]
6. The agency ensures that clients are not denied project services or subjected to any variation in quality of service because of the inability to pay.	[ ]	[ ]
a. The agency's sliding fee scale reflects current Federal Poverty Levels.	[ ]	[ ]
b. The scale is updated yearly, or more often as needed. • *Title X Guidelines, 6.3*	[ ]	[ ]
7. Billing and collection procedures have the following characteristics:		
a. Charges are based on a cost analysis of all services provided by the project.	[ ]	[ ]
b. A schedule of discounts has been developed and implemented with sufficient proportional increments so that inability to pay is not a barrier to services.	[ ]	[ ]
c. A schedule of discounts is in place for individuals with family incomes between 101% and 250% of the Federal Poverty Level.	[ ]	[ ]
d. Fees are waived for individuals with family incomes above 250%, who, as determined by the service site project director, are unable, for good cause, to pay for family planning services.	[ ]	[ ]
e. Clients whose documented income is at or below 100% of the FPL are provided services at no charge. Projects must bill third parties authorized or legally obligated to pay for services.	[ ]	[ ]
f. Individual eligibility for a discount is documented in client financial records.	[ ]	[ ]
g. The agency bills third parties to carry out the billing process effectively, including Medicaid, third party payers without discounts, and ensures that all income-eligible clients are informed of and enrolled in Medicaid benefit programs as appropriate.	[ ]	[ ]
h. The agency provides bills to clients at the time of service and shows total charges less any allowable discounts.	[ ]	[ ]
i. Eligibility for discounts for minors who receive confidential services must be based on the income of the minor.	[ ]	[ ]
j. Reasonable efforts to collect charges without jeopardizing client confidentiality.	[ ]	[ ]
k. The agency has established a method for aging out of accounts.	[ ]	[ ]
l. If the agency accepts voluntary donations from clients, it is in accordance with Title X Guidelines. Donations from clients do not waive the billing/charging requirements set out above.	[ ]	[ ]
m. Client income is re-evaluated at least annually. *Title X Guidelines, 6.3 (1-12); 42 CFR 59.5 (a) (9); PHS Policy Statement, 6-2*	[ ]	[ ]

8. The agency seeks other sources of funding for services that are not required by the statute, regulations or guidelines, before applying Title X funds to those activities. • *Title X Guidelines, 6.3*	[ ]	[ ]
9. The agency maintains liability coverage for all segments of the project funded under the grant, including all individuals providing services. • *Title X Guidelines, 5.4*	[ ]	[ ]
COMMENTS		

I. E. FACILITY		
STANDARD	**YES**	**NO**
1. The Family Planning clinic:		
a. Is accessible to public transportation;	[ ]	[ ]
b. Has parking available; and	[ ]	[ ]
c. Have hours that are convenient to those seeking services, i.e., evening and weekend hours in addition to daytime hours. • *10NYCRR, 711.3 (b) (d); Title X Guidelines, 6.4*	[ ]	[ ]
2. The clinic's physical facility can accommodate the disabled or has an alternative plan in place so that disabled patients may access services. • *10NYCRR, 711.3 (e); 763.7 (f) (3) (ii); 45CFR Part 84.12; Title X Guidelines, 6.4; ADA*	[ ]	[ ]
3. The hours of operation and emergency numbers are visible and/or provided in writing to all clients. • *10NYCRR, 751.9 (d); ACHS, IIC (4), (5), (6)*	[ ]	[ ]
4. The agency has the following documents posted in each clinic site:		
a. "Patient Bill of Rights" • *10NYCRR, 751.9*	[ ]	[ ]
b. Evacuation Plan • *10NYCRR, 702.7; 711.2*	[ ]	[ ]
c. New York State Operating Certificate • *10NYCRR, 401.2 (c)*	[ ]	[ ]
5. The agency provide services in a facility that:		
a. Is clean and ensures the safety, comfort and privacy of each client. • *10NYCRR, 751.5 (a) (13); Title X Guidelines, 6.4*	[ ]	[ ]
b. Has adequate space for storage, exam rooms with sinks, and appropriate equipment. • *10NYCRR, 751.2 (q)*	[ ]	[ ]

6. The agency has an acceptable written plan, rehearsed and updated at least twice a year for emergency and disaster preparedness. • *10NYCRR, 702.7*	[ ]	[ ]
7. The agency has written plans and procedures in place to manage emergencies, including terrorist activity. • *Title X Guidelines, 6.4; 10 NYCRR 702.7, 751.2*	[ ]	[ ]
8. The facility meets applicable standards established by Federal, State and local governments (e.g. local fire, building and licensing codes, etc.). • *Title X Guidelines, 6.4*	[ ]	[ ]
9. The agency has infection control and disposal of hazardous and infectious waste policies that are in compliance with OSHA standards and staff is trained on these policies annually. • *Title X Guidelines, 10.1*	[ ]	[ ]
10. The agency has a plan to assure the safety, adequacy and maintenance of all equipment according to a regular schedule. • *10 NYCRR 751.5; 751.2 (r)*	[ ]	[ ]
11. Federal and State regulations regarding infection control are followed by the agency. • *Title X Guidelines, 10.1*	[ ]	[ ]
COMMENTS		

I. F. COMMUNITY EDUCATION AND PUBLIC INFORMATION		
STANDARD	**YES**	**NO**
1. The agency has a written plan that includes the following components:		
a. Community needs assessment;	[ ]	[ ]
b. Goals to educate the community, and reach the target populations;	[ ]	[ ]
c. Provision of education and information to community professionals; and	[ ]	[ ]
d. Methods to evaluate achievement. • *42CFR 59.5 (b) (3); Title X Guidelines, 3.2, 6.9, 8.1*	[ ]	[ ]

2. The agency provides an opportunity for participation in the development, implementation, and evaluation of the project by persons: a. Broadly representative of all significant elements of the population to be served **and** b. In the community knowledgeable about the community's needs for family planning services. • *Title X Guidelines, 6.9; 42 CFR59.5 (b) (10)*	 [ ] [ ]	 [ ] [ ]
3. The agency's Informational and Educational Materials Committee operates in accordance with Title X Guidelines. • *Title X Guidelines, 6.8, 6.9; 42CFR 59.6*	[ ]	[ ]
4. The agency plans and implements a community education program based on an assessment of the needs of the community in order to meet identified objectives **and** the education plan contains an implementation and evaluation strategy. • *Title X Guidelines, 6.8, 6.9*	[ ]	[ ]
5. The agency conducts inreach and outreach activities to historically underserved populations including: adolescents, substance abusers in and out of treatment facilities, and the homeless, and migrants, individuals engaged in the criminal justice system, minorities, disabled individuals and males. • *Bureau of Women's Health Key Result Area 2*	[ ]	[ ]
6. The agency maintains a supply of educational materials relevant to the population they are serving. • *Title X Guidelines, 6.8*	[ ]	[ ]
7. The agency has materials available (on a web site or other resources) to meet the needs of the agency's service population and materials are available to loan. • *Title X Guidelines, 6.8; Title X, Attachment A(1005)*	[ ]	[ ]
8. The project establishes and implements planned activities whereby their services are made known to the community, including: a. Assessment of availability of existing resources and materials; b. Promotion activities and strategies are in place; and c. Promotion activities are reviewed annually. • *Title X Guidelines, 6.9*	 [ ] [ ] [ ]	 [ ] [ ] [ ]
9. The agency provides a written evaluation of the agency's educational efforts based on its goals and objectives and submits to NYSDOH annually. • *Contract; 42CFR 59.5 (b) (10); Title X Guidelines, 6.2; 6.9; 8.1*	[ ]	[ ]

COMMENTS

II. CLINICAL SERVICES MANAGEMENT

II. A. MEDICAL ADMINISTRATION

STANDARD	YES	NO
1. The agency's medical director is a licensed and qualified physician with special training or experience in family planning and responsible for the agency medical policies, protocols and procedures. • *10NYCRR, 751.4 (a), (c), (d); 42CFR 59.5 (b) (6); Title X Guidelines, 6.5, 7.1*	[ ]	[ ]
2. The agency maintains a manual consistent with Title X guidelines, which describes all medical procedures offered and includes written and standardized procedures (protocols) for clinicians, signed by the service site Medical Director. • *10NYCRR, 751.5; Title X Guidelines, 7.1, 7.3*	[ ]	[ ]
3. The agency has a professional person designated to be responsible for the direction of each program service and the service is within their scope of practice. • *10NYCRR, 752.1 (c)*	[ ]	[ ]
4. The agency has written protocols and procedures for medical emergencies in accordance with Title X, including emergencies requiring transport, after-hours management of contraceptive emergencies, and clinic emergencies. • *10 NYCRR, 751.2 (p); 751.5; Title X Guidelines, 7.3*	[ ]	[ ]
5. All project staff is trained on and familiar with medical emergency plans. • *Title X Guidelines, 7.3*	[ ]	[ ]
6. The agency has protocols in place for accidental exposure to blood for staff and clients. • *10 NYCRR, 751.5; CDC Guidelines*	[ ]	[ ]
7. The agency provides a sufficient number of available appointments to limit the patient waiting time to no more than two weeks. • *Standards of Practice; Title X Guidelines, 8.7*	[ ]	[ ]
8. The agency ensures that clients receive appointments: a. At a variety of times convenient to the client; and b. For specific providers. • *10 NYCRR 751.5; Title X Guidelines, 6.4, 7.4*	[ ] [ ]	[ ] [ ]

COMMENTS

II. B. QUALITY ASSURANCE		
STANDARD	**YES**	**NO**
1. The medical director is responsible for supervision of the quality assurance program and reporting activities to the program director. • *10NYCRR, 751.4 (f)*	[ ]	[ ]
2. The agency has a quality assurance program in place that provides for at least annual evaluation of project personnel and services.	[ ]	[ ]
The system includes the following:		
a. An established set of clinical, administrative and programmatic standards by which conformity would be maintained;	[ ]	[ ]
b. A tracking system to identify clients in need of follow-up and/or continuing care;	[ ]	[ ]
c. Ongoing medical audits to determine conformity with agency protocols;	[ ]	[ ]
d. Peer review procedures to evaluate individual clinician performance, to provide feedback to providers, and to initiate corrective action when deficiencies are noted;	[ ]	[ ]
e. Periodic review of medical protocols to insure consistency with current standards of care;	[ ]	[ ]
f. A process to elicit consumer feedback; and	[ ]	[ ]
g. Ongoing and systematic documentation of quality assurance activities. • *10NYCRR, 751.8 (a), (d), (e); Title X Guidelines, 10.4*	[ ]	[ ]
3. Quality assurance findings, conclusions, recommendations, and actions are reported to the program director, and operator, if different, and timely corrective action is taken when deficiencies are noted. • *10NYCRR, 751.8 (d), (h); Title X Guidelines, 10.4*	[ ]	[ ]
4. Quality assurance reviews are used for revision or development of policies, granting or renewing staff privileges, and providing feedback to providers and clients. • *10NYCRR, 751.8 (f); Title X Guidelines, 10.4*	[ ]	[ ]
5. The agency's Patient Care Review Committee, which includes health care professionals representing services provided, is responsible for assessing the quality of technical services. • *10NYCRR, 751.8 (g)*	[ ]	[ ]

6. The agency's Program Review Committee, which consists of representatives of the population served, health care delivery staff and administrative staff, meet at least quarterly to review program quality. • *Guidance for Internal Quality Assessment (IQA), p. 3 (1)*	[ ]	[ ]

COMMENTS

II. C. ANCILLARY SERVICES: PHARMACEUTICALS		
STANDARD	**YES**	**NO**
1. Pharmaceutical services offered by the agency are provided in accordance with professional principles and appropriate state and federal laws relating to security and record keeping for drugs and devices.	[ ]	[ ]
If this agency has a pharmacy on-site, it is registered with the NYS Education Department. • *10NYCRR, 752.5 (a); Title X Guidelines, 10.2*	[ ]	[ ]
2. If medications are distributed by agency personnel in the absence of a pharmacy, the agency consults a qualified pharmacist to develop policies and procedures related to all phases of pharmaceutical services and drug use. • *10NYCRR, 752.5 (b); Title X Guidelines, 10.2; 42CFR 59.5 (b) (1)*	[ ]	[ ]
3. The agency stocks drugs and birth control supplies in accordance with state and federal regulations, making available to clients all methods of contraception approved by the Federal Food and Drug Administration, including emergency contraception. • *10NYCRR, 753.1 (a), 752.5 (c); Title X Guidelines, 10.2, 7.0*	[ ]	[ ]
4. Emergency resuscitative drugs, supplies and equipment are kept in a location readily accessible to the examination and treatment rooms. • *10NYCRR, 751.5 (a) (14)*	[ ]	[ ]
5. The agency maintains a drug formulary that is available to all staff members authorized to prescribe medications. • *10NYCRR, 752.5 (a) (2) (ii) (l)*	[ ]	[ ]
6. The agency has written policies and procedures to monitor expired or deteriorated medications and biologicals, including procedures for disposal in accordance with professional standards of pharmacy	[ ]	[ ]

practice. • *10NYCRR, 752.5 (c)*		
7. The agency has written policies and procedures to address and document in medical records adverse drug reactions among clients. • *10NYCRR, 752.5 (d)*	[ ]	[ ]
COMMENTS		

II. D. ANCILLARY SERVICES: LABORATORY

STANDARD	YES	NO
1. The agency assesses the credentials of laboratories with which it contracts to ensure that the laboratory conforms to state licensing requirements. • *10NYCRR, 752.4; 42CFR 59.5 (b) (l)*	[ ]	[ ]
2. When laboratory testing is performed on-site:		
a. written protocols for quality control and proficiency testing are in place	[ ]	[ ]
b. the agency meets State/ CLIA laboratory requirements • *NYSDOH WCLR Laboratory Standards*	[ ]	[ ]
3. The agency provides pregnancy testing on site. • *Title X Guidelines, 8.3*	[ ]	[ ]
4. The following laboratory procedures are provided to clients as required in the provision of a contraceptive method, or for the maintenance of health status and /or diagnostic purposes on site or by referral.		
♦ Anemia assessment	[ ]	[ ]
♦ Gonorrhea and Chlamydia test	[ ]	[ ]
♦ Vaginal wetmount	[ ]	[ ]
♦ Diabetes testing	[ ]	[ ]
♦ Cholesterol and lipids	[ ]	[ ]
♦ Hepatitis B testing	[ ]	[ ]
♦ Syphilis serology (VDRL,RPR)	[ ]	[ ]
♦ Rubella titer	[ ]	[ ]
♦ Urinalysis	[ ]	[ ]
♦ HIV testing • *Title X Guidelines, 8.3*	[ ]	[ ]
5. The agency has a written procedure established, which addresses client confidentiality, to allow for and document client notification and ensure adequate follow up of abnormal laboratory results. • *10NYCRR, 751.5 (5); Title X Guidelines, 8.3*	[ ]	[ ]

COMMENTS

II. E. MEDICAL RECORDS

STANDARD	YES	NO
1. The agency establishes medical records for all clients who obtain clinical services. • *10NYCRR, 751.7; Title X Guidelines, 10.3*	[ ]	[ ]
2. Medical records are maintained in accordance with accepted medical standards and State laws with regard to record retention. Policies and procedures for medical records are developed to ensure that records are:		
♦ Complete, legible and accurate, including documentation of telephone encounters of a clinical nature;	[ ]	[ ]
♦ Signed by the clinician and other appropriately trained professionals making entries, including name, title, and date;	[ ]	[ ]
♦ Readily accessible, including a system of cross referencing for retrieval;	[ ]	[ ]
♦ Systematically organized to facilitate prompt retrieval and compilation of information;	[ ]	[ ]
♦ Confidential;	[ ]	[ ]
♦ Safeguarded against loss or use by unauthorized persons;	[ ]	[ ]
♦ Secured by lock when not in use; and	[ ]	[ ]
♦ Available upon request to the client . • *10NYCRR, 751.7; Title X Guidelines, 10.3*	[ ]	[ ]
3. Medical records contain sufficient information to identify the client, indicate where and how the client can be contacted, justify the clinical impression or diagnosis, and warrant the treatment and end results. The medical record must include:		
♦ Personal data;	[ ]	[ ]
♦ Medical history, physical exam, laboratory test orders, results and follow-up;	[ ]	[ ]
♦ Treatment and special instructions;	[ ]	[ ]
♦ Scheduled revisits;	[ ]	[ ]
♦ Informed consents;	[ ]	[ ]
♦ Refusal of services; and	[ ]	[ ]
♦ Allergies and untoward reactions to drug (s) recorded in a prominent and specific location. • *10NYCRR, 751.5 (a) (5) (7); 751.7; 753.1; Title X Guidelines, 10.3, 8.1*	[ ]	[ ]
4. The agency retains medical records for at least six years after the date of the last service rendered.	[ ]	[ ]
For minor clients, records are maintained for at least six years after the last service or three years after the client reaches majority, whichever time period is longer. • *10NYCRR, 751.7 (j)*	[ ]	[ ]

COMMENTS

II. F. CLIENT EDUCATION SERVICES		
STANDARD	**YES**	**NO**
1. The agency has written plans for client education that include goals and content outlines to ensure consistency and accuracy of information provided. • *Title X Guidelines, 8.1*	[ ]	[ ]
2. Client education is documented in the client record. • *Title X Guidelines, 8.1*	[ ]	[ ]
3. Education is provided appropriate to the client's age, level or knowledge, language, and socio-cultural background and presented in an unbiased manner.	[ ]	[ ]
There is a mechanism to determine that the information provided has been understood. • *10NYCRR, 751.9 (c) (d) (h); 753.1 (c) (d) (l); Title X Guidelines, 8.1*	[ ]	[ ]
4. Education is responsive to the identified client needs and provides clients with the information needed to: ♦ Make informed decisions about family planning; ♦ Use specific methods of contraception correctly and identify adverse effects; ♦ Discontinue the method selected along with information regarding back-up method use, including the use of certain oral contraceptives as post-coital emergency contraception; ♦ Perform breast/testicular self-examination; ♦ Reduce risk of transmission of sexually transmitted diseases and Human Immunodeficiency Virus (HIV); ♦ Understand the range of available services and the purpose and sequence of clinic procedures; ♦ Understand the importance of recommended screening tests and other procedures involved in the family planning visit. • *10NYCRR, 751.9 (g) (h); Title X Guidelines, 8.1, 8.2*	[ ]	[ ]
5. The agency offers reproductive health education services to males. • *10NYCRR, 751.9 (a)*	[ ]	[ ]
6. Education includes information on reproductive health and health promotion/disease prevention, including nutrition, exercise, smoking cessation, alcohol and drug abuse, domestic violence and sexual abuse. • *Title X Guidelines, 8.1*	[ ]	[ ]

COMMENTS		

II. G. PREGNANCY TEST COUNSELING		
STANDARD	**YES**	**NO**
1. The agency provides prompt pregnancy screening and counseling services to clients in need according to federal and state regulations.	[ ]	[ ]
Pregnant women are offered complete information and counseling regarding their pregnancies and offered the opportunity to be provided information and counseling consistent with Title X Guidelines regarding each of the following options:	[ ]	[ ]
♦ Prenatal care delivery;	[ ]	[ ]
♦ Foster care or adoption; and	[ ]	[ ]
♦ Pregnancy termination.	[ ]	[ ]
• *10NYCRR, 753.1 (d) (3); Title X Guidelines, 8.6; 42CFR 59.5 (a) (5)*		
Referrals for such services are made promptly.	[ ]	[ ]
a. Clients who are found not to be pregnant are given information about the availability of contraceptive and infertility services, as appropriate.	[ ]	[ ]
• *Title X Guidelines, 8.6*		
b. Prenatal care appointments are scheduled within two weeks.	[ ]	[ ]
• *Standards of Care*		
2. Confirmatory pregnancy testing includes a history and a physical examination is performed according to professional standards and federal regulations, or made available by referral.	[ ]	[ ]
• *Title X Guidelines, 8.6*		
COMMENTS		

II. H. SPECIAL COUNSELING		
STANDARD	**YES**	**NO**
1. Clients are offered appropriate counseling and referral as indicated regarding future planned pregnancies, management of a current pregnancy and other individual concerns (e.g. substance use and abuse, sexual abuse, domestic violence, genetic issues, nutrition, sexual concerns, etc.) as indicated. • *Title X Guidelines, 9*	[ ]	[ ]
2. The program provides counseling on effective use of contraceptive methods, including natural family planning (NFP), and the benefit and efficacy of the methods. • Title X Guidelines, 8.2	[ ]	[ ]
3. Counseling on sterilization procedures are in compliance with federal regulations and the counseling and consent process assures that the client's decision to undergo sterilization is completely voluntary and made with full knowledge of the permanence, risks and benefits associated with female and male sterilization procedures. • *43CFR B. 50.204; Title X Guidelines, 8.4*	[ ]	[ ]
4. The agency provides adolescents with skilled counseling and age appropriate information.	[ ]	[ ]
a. Adolescents seeking contraceptive services are informed of all methods of contraception.	[ ]	[ ]
b. Abstinence, as well as contraceptive and safer sex options, to reduce risks for STD/HIV and pregnancy are discussed with all adolescents.	[ ]	[ ]
c. The agency ensures that counseling encourages family participation in the decision of minors to seek family planning services.	[ ]	[ ]
d. The agency has a policy & procedure in place to ensure the provision of counseling to minors on resisting attempts to coerce them into engaging in sexual activities. • *Title X Guidelines, 8.7*	[ ]	[ ]
5. Level I Infertility services are available on-site to women and men desiring such services. • *10 NYCRR, 753.1 (a); Title X Guidelines, 8.5*	[ ]	[ ]
6. Level II and Level III infertility services are available on-site or by referral. • *Title X Guidelines, 8.5*	[ ]	[ ]
7. The agency provides counseling on individual issues (e.g. genetic, nutrition, crisis intervention) on-site or by referral. • *Title X Guidelines, 7.4, 8.2*	[ ]	[ ]

COMMENTS		

II. I. HIV COUNSELING AND TESTING AND STD SERVICES

STANDARD	**YES**	**NO**
1. Written policies and protocols are in accordance with NYS HIV Confidentiality Law. • *10NYCRR, 63.8 (a)*	[ ]	[ ]
2. The HIV counseling and testing protocol include:		
a. a requirement that all family planning clients be provided pretest counseling;	[ ]	[ ]
b. an assessment of service resources and a current dated resource list for referrals, including partner notification assistance; • *contract; Title X Guidelines, 7.4; HIV P-NAP Letter*	[ ]	[ ]
c. HIV reporting and partner notification policies are consistent with NYS regulations; • *10 NYCRR, 63.8; HIV Reporting & Partner Notification Regulations, 6/00*	[ ]	[ ]
d. HIV pretest content, in accordance with DOHM 93-26, includes a clinical recommendation for testing; • *DOHM 93-26/Provider Agreement; 10NYCRR, 63.3 (a), (l); Guide to HIV Pre-test and Post-test counseling, 5/00*	[ ]	[ ]
e. The required use of the DOH informed consent form; • *10NYCRR, 63.3 (b), (l)*	[ ]	[ ]
f. HIV post-test counseling in accordance with DOHM 93-26; • *DOHM 93-26/Provider Agreement; 10NYCRR, 63.3 (d); Guide to HIV Pre-test and Post-test counseling, 5/00*	[ ]	[ ]
g. A follow-up plan for clients who do not return for post-test counseling and documentation requirements for follow-up procedures; • *DOHM 93-26/Provider Agreement, Provision 9 (d)*	[ ]	[ ]
h. A follow-up plan for HIV-positive individuals, including procedures for referrals for HIV-related primary care services not offered by the agency; • *DOHM 93-26/Provider Agreement, Provision 9(d);10 NYCRR 63.3; 10NYCRR, 751.5 (5)*	[ ]	[ ]
i. A description of mechanisms to ensure confidentiality of HIV-related information, including annual in-service education of employees regarding legal prohibitions against unauthorized disclosures; and • *10 NYCRR 63.9; DOHM 93-26/Provider Agreement, Provision 8*	[ ]	[ ]
j. A description of mechanisms for disclosure of HIV-related information including the DOH-approved Release Information	[ ]	[ ]

form. • *10NYCRR, 63.5 and 63.6; Provider Agreement, Provision 9*		
3. The agency has a system in place for documentation of HIV counseling and testing that include the following items documented in the medical record:		
a. pre- and post-test counseling; • *DOHM 93-26; Guide to HIV Pre-test and Post-test Counseling, 5/00*	[ ]	[ ]
b. The recommendation for testing; • *Bureau of Women's Health KRA*	[ ]	[ ]
c. The reason for refusal of the antibody test, if indicated; • *DOHM 93-26*	[ ]	[ ]
d. The test result; • *DOHM 93-26; Guide to HIV Pre-test and Post-test Counseling, 5/00*	[ ]	[ ]
e. The signed and dated informed consent; and • *10 NYCRR, 63.7*	[ ]	[ ]
f. Referrals made, if indicated. • *DOHM 93-26; Guide to HIV Pre-test and Post-test Counseling, 5/00*	[ ]	[ ]
4. The agency ensures that clients receive thorough and accurate counseling on STDs, including discussion of personal risks, steps to reduce risk, if necessary, and advise whether clinical evaluation is indicated. • *Title X Guidelines, 8.2*	[ ]	[ ]
5. The project provides detection for and treatment of the more common STDs, including tests for gonorrhea, syphilis, Chlamydia, and HIV as indicated by client request or evidence of risk for infection. • *CDC Guidelines; Title X Guidelines, 9.2*	[ ]	[ ]
6. The project provides Chlamydia testing consistent with Infertility Prevention Project Guidelines, including targeted screening to all women under age 25 for initial and annual visits and for those determined to be at risk based upon their history screening.	[ ]	[ ]
Gonorrhea screening is provided to this age group, as indicated. • *CDC Guidelines; Region II IPP Guidelines*	[ ]	[ ]
7. When STD treatment is provided on-site, appropriate follow-up measures are undertaken by the agency. • *Title X Guidelines, 9.2*	[ ]	[ ]
8. The agency complies with NYS reporting requirements for Sexually Transmitted Diseases. • *NYS Sanitary Code, 10NYCRR 2.10a*	[ ]	[ ]

COMMENTS		

II. J. PATIENT RIGHTS AND INFORMED CONSENT

STANDARD	YES	NO
1. The agency distributes to each client, and posts in patient care areas, a written statement of patients' rights. • *10NYCRR, 751.9*	[ ]	[ ]
2. Patient rights are observed in accordance with state and federal law, particularly the right to:		
a. Refuse participation in medical research; • *10NYCRR, 751.9 (j)*	[ ]	[ ]
b. Have written information disclosed only with written consent, except as necessary to provide services to the individual, with appropriate safeguards for confidentiality; and • *10NYCRR, 405.7 (b) (13) (18); Title X Guidelines, 5.2*	[ ]	[ ]
c. Formulate advance directives. • *NYCRR 400.21 and 700.5*	[ ]	[ ]
3. The agency provides services without regard to religion, race, color, national origin, creed, disability, sex, number of pregnancies, marital status, sexual orientation, age or contraception preference. • *10NYCRR, 751.5 and 751.9; 42 CFR Part 59.5*	[ ]	[ ]
4. The agency provides services to individuals in a family planning program without condition of receiving any other service.	[ ]	[ ]
Family Planning clients are allowed to voluntarily participate in the program and to use or not use any particular method of family planning. • *Title X Guidelines, 5.1*	[ ]	[ ]
5. The agency has written policies that ensure procedures documenting the clients' **informed** consent to receive the project's services.	[ ]	[ ]
The agency has informed consent forms that are signed by the client prior to receipt of medical services	[ ]	[ ]
Consent forms contain a statement that the client has been counseled; read and understands the content of the document. • *10 NYCRR 751.9; 753.1 (d) 2; Title X Guidelines, 8.0*	[ ]	[ ]

6. Consent forms are updated when there is a change in patient's contraceptive method or health status. • *Title X Guidelines, 8.0*	[ ]	[ ]
7. The agency ensures written informed consent, specific to the contraceptive method, is signed before a prescription contraceptive method is provided.	[ ]	[ ]
Specific education and consent forms for the contraceptive methods are provided as part of the project's services plan and consistent with Title X Guidelines.	[ ]	[ ]
The service site Medical Director approves the informed consent forms. • *Title X Guidelines, 8.1*	[ ]	[ ]
8. The agency ensures client confidentiality. • *10NYCRR 751.7 (g); Title X Guidelines, 5.2*	[ ]	[ ]
9. The agency has policies; including advising NYSDOH Bureau of Women's Health in writing, of clinical or sociological research activities, involving Title X clients as subjects and follows appropriate procedures in accordance with DOH IRB policies.	[ ]	[ ]
The agency complies with legal requirements governing human subjects' research in 42 CFR Part 46. • *Title X Guidelines, 5.5*	[ ]	[ ]
COMMENTS		

II. K. MEDICAL SERVICES		
STANDARD	**YES**	**NO**
1. The range of acceptable and effective medically approved family planning methods and services are provided in accordance with federal and state requirements either on site or by referral. • *10NYCRR, 753.1 (e); Title X Guidelines, 7.0; Contract*	[ ]	[ ]
2. The agency ensures that at the initial comprehensive clinical visit, a completed medical and social history is obtained on all female and male clients consistent with Title X Guidelines. • *Title X Guidelines, 8.3*	[ ]	[ ]

3. Medical services are provided according to professional principles of practice and applicable regulations. • *10NYCRR, 751.5; 753.1; Title X Guidelines, 7.2, 8.3*	[ ]	[ ]
4. The agency ensures that protocols exist that provide all project personnel with guidelines for client care. • *Title X Guidelines, 6.5*	[ ]	[ ]
5. The agency provides females comprehensive physical assessments including height and weight, examination of the thyroid, heart, lungs, breasts, abdomen, extremities, genitals and rectum.	[ ]	[ ]
The clinic provides and stresses the importance of the following: blood pressure evaluation, breast exam, and pelvic exam, pap smear, colo-rectal cancer screening in individuals over 40, and STD and HIV screening as indicated. • *10NYCRR, 751.5; Title X Guidelines, 8.3*	[ ]	[ ]
6. Counseling includes information about the possible health risks associated with declining or delaying preventive screening tests or procedures. • *Title X Guidelines, 8.3*	[ ]	[ ]
7. The agency offers services to males requesting temporary methods of contraception including: physical exam, height/weight, and examination of the thyroid, heart, lungs, breasts, abdomen, extremities, genitals and rectum.	[ ]	[ ]
The exam also includes palpation of the prostate, as appropriate and instruction in testicular self-exam and does the agency stress the importance of blood pressure evaluation, colo-rectal cancer screening in individuals over 40 and STD and HIV screening as indicated. • *Title X Guidelines, 8.3*	[ ]	[ ]
COMMENTS		

II. L. REFERRALS AND FOLLOW-UP

STANDARD	YES	NO
1. The agency ensures written policies and procedures for confidential follow-up on referrals are made as a result of abnormal physical examination or laboratory test findings. • *10NYCRR, 400.9, 753.1 (b)*	[ ]	[ ]
2. The agency provides all required services either on site or by referral and has written referral arrangements with all medical and social services providers in place.	[ ]	[ ]
The agency maintains a referral directory of health care providers, local health and human services departments, hospitals, voluntary agencies, and health service projects supported by other Federal programs and review annually, updating as needed.	[ ]	[ ]
The agency's referral protocol is adequate and reflects timely follow-up activity.	[ ]	[ ]
For services determined to be necessary but beyond the scope of the project, including primary care services, the agency refers clients to other providers for care. • *Title X Guidelines, 7.4*	[ ]	[ ]
3. The agency makes arrangements for the provision of pertinent client information to the referral provider, with client consent (except as may be necessary to provide services to the patient with personal safety issues or as required by law, with appropriate safeguards for confidentiality.)	[ ]	[ ]
a. The agency advises the client of their responsibility to comply with the referral.	[ ]	[ ]
b. The agency counsels the client on the importance of such referral and the agreed upon method of follow-up.	[ ]	[ ]
The agency participates in the Healthy Women's Partnership in the region, through which the NYS Breast and Cervical screening and treatment program operates. • *BWH letter dated 6/7/02*	[ ]	[ ]
4. The agency identifies steps to determine if the agency's referral process is successful, and take steps to improve success of referrals as needed. • *Bureau of Women's Health KRA*	[ ]	[ ]
5. Revisit schedules and protocols for specific methods are clear and consistent with Title X Guidelines. • *Title X Guidelines, 8.3*	[ ]	[ ]
6. The following components of the program are offered to and documented at the return visit:		

a. Updating of personal and family medical and social history; b. Performance of physical examination and any necessary clinical procedures, as indicated; c. Performance of routine and other indicated laboratory tests; and d. Follow-up and referrals: planned mechanism for client follow-up; provision of medications and/or supplies as needed; performance of any necessary clinical procedures; and provision of referrals as needed • *Title X Guidelines,7.2*	[ ] [ ] [ ] [ ]	[ ] [ ] [ ] [ ]
7. The agency ensures that revisit schedules are individualized based upon the client's need for education, counseling, and clinical care beyond that provided at the initial and annual visit. • *Title X Guidelines, 8.3*	[ ]	[ ]
COMMENTS		

Note: Medical record/chart audit findings should be incorporated into the appropriate sections.

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Program Guidelines For Project Grants For Family Planning Services

United States Department of Health and Human Services
Office of Public Health and Science
Office of Population Affairs
Office of Family Planning
4350 East West Highway, Suite 200
Bethesda, Maryland 20814

January 2001

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B. Regulations: Grants for Family Planning Services under Title X of the Public Health Service Act

C. Sterilization of Persons in Federally Assisted Family Planning Projects

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Resource Documents

PART I

1.0 Introduction to the Program Guidelines

This document, *Program Guidelines for Project Grants for Family Planning Services (*Guidelines), has been developed by the Office of Population Affairs (OPA), U.S. Department of Health and Human Services (DHHS), to assist current and prospective grantees in understanding and utilizing the family planning services grants program authorized by Title X of the Public Health Service Act, 42 U.S.C. 300, et seq. The Office of Population Affairs also provides more detailed guidance, updated clinical information and clarification of specific program issues in the form of periodic Program Instructions to the Regional Offices.

This document is organized into two parts. Part I (sections 1-6) covers project management and administration, including the grant application and award process. Part II (sections 7-11) covers client services and clinic management.

Reference is made throughout the document to specific sections of the Title X law and implementing regulations, which are contained in *Attachments A and B,* respectively. (Reference to specific sections of the regulations will appear in brackets, e.g., [45 CFR Part 74, Subpart C].) Federal sterilization regulations are contained in *Attachment C.* The DHHS regional offices are listed in *Attachment D.* Selected other materials that provide additional guidance in specific areas are classified as *Resource Documents.*

1.1 DEFINITIONS

Throughout this document, the word "must" indicates *mandatory* program policy. "Should" indicates *recommended* program policy relating to components of family planning and project management that the project is urged to utilize in order to fulfill the intent of Title X. The words "can" and "may" indicate suggestions for consideration by individual projects.

The "grantee" is the entity that receives a Federal grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding. The "project" consists of those activities described in the grant application and supported under the approved budget. "Delegate/contract agencies" are those entities that provide family planning services with Title X funds under a negotiated, written agreement with a grantee. "Service sites" are those locations where services actually are provided by the grantee or delegate/contract agency.

2.0 The Law, Regulations, and Guidelines

To enable persons who want to obtain family planning care to have access to such services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-572), which added Title X, "Population Research and Voluntary Family Planning Programs" to the Public Health Service Act. Section 1001 of the Act (as amended) authorizes grants "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)" (*see Attachment A*). The mission of Title X is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children.

The regulations governing Title X [42 CFR Part 59, Subpart A] set out the requirements of the Secretary, Department of Health and Human Services, for the provision of family planning services funded under Title X and implement the statute as authorized under Section 1001 of the Public Health Service Act. Prospective applicants and grantees should refer to the regulations (*see Attachment B*). This document, *Program Guidelines for Project Grants for Family Planning Services*, interprets the law and regulations in operational terms and provides a general orientation to the Federal perspective on family planning.

3.0 The Application Process

3.1 ELIGIBILITY

Any public or nonprofit private entity located in a state (which, by definition, includes the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands [Midway, Wake, et al.], the Marshall Islands, the Federated States of Micronesia and the Republic of Palau) is eligible to apply for a Title X family planning services project grant [59.2, 59.3].

To promote the purposes of Section 1001 of the Act in the most cost effective and efficient manner, grants will be made to public and non-profit private entities to foster projects most responsive to local needs. A non-profit private agency, institution, or organization must furnish evidence of its non-profit status in accordance with instructions accompanying the project grant application form. Under the law, grants cannot be made to entities that propose to offer only a single method or an unduly limited number of family planning methods. A facility or entity offering a single method can receive assistance under Title X by participating as a delegate/contract agency in an approvable project that offers a broad range of acceptable and effective medically approved family planning methods and services [59.5(a)(1)].

3.2 NEEDS ASSESSMENT

An assessment of the need for family planning services must be conducted prior to applying for a competitive grant award. The needs assessment documents the need for family planning services for persons in the service area and should include:

- Description of the geographic area including a discussion of potential geographic, topographic, and other related barriers to service;

- Demographic description of the service area including objective data pertaining to individuals in need of family planning services, maternal and infant morbidity/mortality rates, birth rates and rates of unintended pregnancies by age groups, poverty status of the populations to be served, cultural and linguistic barriers to services, etc.;

- Description of existing services and need for additional family planning services to meet community/cultural needs;

- Need indicators that include rates of STDs and HIV prevalence (including perinatal infection rates) in the grantee area;

- Identification and descriptions of linkages with other resources related to reproductive health; and

- Identification and discussion of high priority populations and target areas.

Grantees should perform periodic reassessment of service needs. Competitive grant applications must include a full and updated needs assessment.

3.3 THE APPLICATION

The Department of Health and Human Services' Office of Population Affairs administers the Title X Family Planning Program through the DHHS Regional Offices. An annual announcement of the availability of Title X service grant funds sets forth specific application requirements and evaluation criteria. Applications must be submitted to the Office of Grants Management for Family Planning Services on the form required by the Department. The application forms are available from the Office of Grants Management for Family Planning Services. Assistance regarding programmatic aspects of proposal preparation is available from the Regional Office. For assistance with administrative and budgeting aspects of proposal preparation, contact the Office of Grants Management for Family Planning Services.

Unless otherwise instructed, applicants are to respond to the standard instructions contained in the application kit and to the PHS supplemental instructions. An application must contain:

- a needs assessment
- a narrative description of the project and the manner in which the applicant intends to conduct it in order to carry out the requirements of the law and regulations;
- a budget that includes an estimate of project income and costs, with justification for the amount of grant funds requested [59.4(c)(2)] and which is consistent with the terms of Section 1006 of the Act, as implemented by regulation [59.7(b)];
- a description of the standards and qualifications that will be required for all personnel and facilities to be used by the project;
- project objectives that are specific, realistic, and measurable; and
- other pertinent information as required [59.4(c)(4)].

The application must address all points contained in section 59.7(a) of the regulations, which are the criteria DHHS Regional Offices will use to decide which family planning projects to fund and in what amount. The application shall not include activities that cannot be funded under Title X, such as abortion, fundraising, or lobbying activities.

3.4 PROJECT REQUIREMENTS

Projects must adhere to:

- Section 59.5 and all other applicable provisions of the regulations, which list the requirements to be met by each project supported by Title X.
- The applicable requirements of these *Program Guidelines for Project Grants for Family Planning Services.*
- Other Federal regulations which apply to grants made under Title X [59.10]. For assistance in identifying other relevant regulations, contact the Regional Office.

3.5 NOTICE OF GRANT AWARD

The notice of grant award will inform the grantee how long DHHS intends to support the project without requiring it to recompete for funds [59.8]. This period of funding is called the "project period." The project will be funded in increments called "budget periods." The budget period is normally twelve months, although shorter or longer budget periods may be established for compelling administrative or programmatic reasons.

4.0 Grant Administration

All grantees must comply with the applicable legislative, regulatory and administrative requirements described in the *Public Health Service Grants Policy Statement*. A copy of the *Public Health Service Grants Policy Statement* may be obtained from the Office of Grants Management for Family Planning Services.

5.0 Legal Issues

5.1 VOLUNTARY PARTICIPATION

Use by any individual of project services must be solely on a voluntary basis. Individuals must not be subjected to coercion to receive services or to use or not to use any particular method of family planning. Acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other service or assistance from or participation in any other programs of the applicant [59.5(a)(2)].

Project personnel must be informed that they may be subject to prosecution under Federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure.

5.2 CONFIDENTIALITY

Every project must assure client confidentiality and provide safeguards for individuals against the invasion of personal privacy, as required by the Privacy Act. No information obtained by the project staff about individuals receiving services may be disclosed without the individual's written consent, except as required by law or as necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual [59.11].

5.3 CONFLICT OF INTEREST

Grantees must establish policies to prevent employees, consultants, or members of governing or advisory bodies from using their positions for purposes of private gain for themselves or for others.

5.4 LIABILITY COVERAGE

Grantees and/or delegates/contractors should ensure the existence of adequate liability coverage for all segments of the project funded under the grant, including all individuals providing services. Governing boards should obtain liability coverage for their members.

5.5 HUMAN SUBJECTS CLEARANCE (RESEARCH)

Grantees considering clinical or sociological research using Title X clients as subjects must adhere to the legal requirements governing human subjects research at 45 CFR Part 46, as applicable. A copy of these regulations may be obtained from the Regional Office. Grantees must advise the Regional Office in writing of research projects involving Title X clients or resources in any segment of the project.

6.0 Project Management

6.1 STRUCTURE OF THE GRANTEE

Family planning services under Title X grant authority may be offered by grantees directly and/or by delegate/contract agencies operating under the umbrella of the grantee. However, the grantee is responsible for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by delegate/contract agencies. Grantees must therefore have a negotiated, written agreement with each delegate/contract agency and establish written standards and guidelines for all delegated project activities consistent with the appropriate section(s) of the *Program Guidelines for Project Grants for Family Planning Services,* as well as other applicable requirements such as Subpart C of 45 CFR Part 74, or Subpart C of 45 CFR Part 92. If a delegate/contract agency wishes to subcontract any of its responsibilities or services, a written negotiated agreement that is consistent with Title X requirements and approved by the grantee must be maintained by the delegate/contractor. Delegate/contract agencies should be invited to participate in the establishment of grantee standards and guidelines.

6.2 PLANNING AND EVALUATION

All projects receiving Title X funds must provide services of high quality and be competently and efficiently administered. To meet these requirements, each competitive application must include a plan which identifies overall goals and specific measurable objectives for the project period. The objectives may be directed to all clients or to specific groups of clients and must be consistent with Title X objectives. The plan must include an evaluation component that addresses and defines indicators by which the project intends to evaluate itself.

6.3 FINANCIAL MANAGEMENT

Grantees must maintain a financial management system that meets the standards specified in Subpart C of 45 CFR Part 74 or Subpart C of 45 CFR Part 92, as applicable, as well as any other requirements imposed by the Notice of Grant Award, and which complies with Federal standards to safeguard the use of funds. Documentation and records of all income and expenditures must be maintained as required.

! Charges, Billing, and Collections

A grantee is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the project. The policies and procedures should be approved by the governing authority or board of the grantee and the Regional Office.

Clients must not be denied project services or be subjected to any variation in quality of services because of the inability to pay. Billing and collection procedures must have the following characteristics:

(1) Charges must be based on a cost analysis of all services provided by the project. At the time of services, clients who are responsible for paying any fee for their services must be given bills directly. In cases where a third party is responsible, bills must be submitted to that party.

(2) A schedule of discounts must be developed and implemented with sufficient proportional increments so that inability to pay is never a barrier to service. A schedule of discounts is required for individuals with family incomes between 101% and 250% of the Federal poverty level. Fees must be waived for individuals with family incomes above this amount who, as determined by the service site project director, are unable, for good cause, to pay for family planning services.

(3) Clients whose documented income is at or below 100% of the Federal poverty

level must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services.

(4) Individual eligibility for a discount must be documented in the client's financial record.

(5) Bills to third parties must show total charges without applying any discount.

(6) Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement with the Title XIX or the Title XX state agency at either the grantee level or delegate/contract agency level is required.

(7) Bills to clients must show total charges less any allowable discounts.

(8) Eligibility for discounts for minors who receive confidential services must be based on the income of the minor.

(9) Reasonable efforts to collect charges without jeopardizing client confidentiality must be made.

(10) A method for the "aging" of outstanding accounts must be established.

(11) Voluntary donations from clients are permissible. However, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies. Donations from clients do not waive the billing/charging requirements set out above.

(12) Client income should be re-evaluated at least annually.

Effective financial management will assure the short and long term viability of the project, including the efficient use of grant funds. Technical assistance in achieving this objective is available from the Regional Office. Title X projects offering services that are not required by the statute, regulations or these Guidelines should whenever possible seek other sources of funding for such services before applying Title X funds to those activities.

! Financial Audit

Audits of grantees and delegate/contract agencies must be conducted in accordance with the provisions of 45 CFR Part 74, Subpart C, and 45 CFR Part 92, Subpart C, as applicable. The audits must be conducted by auditors meeting established criteria for qualifications and independence.

6.4 FACILITIES AND ACCESSIBILITY OF SERVICES

Facilities in which project services are provided should be geographically accessible to the population served and should be available at times convenient to those seeking services, i.e., they should have evening and/or weekend hours in addition to daytime hours. The facilities should be adequate to provide the necessary services and should be designed to ensure comfort and privacy for clients and to expedite the work of the staff. Facilities must meet applicable standards established by the Federal, state and local governments (e.g., local fire, building and licensing codes).

Projects must comply with 45 CFR Part 84, which prohibits discrimination on the basis of handicap in Federally assisted programs and activities, and which requires, among other things, that recipients of Federal funds operate their Federally assisted programs so that, when viewed in their entirety, they are readily accessible to people with disabilities. A copy of Part 84 may be obtained from the Regional office. Projects must also comply with any applicable provisions of the Americans With Disabilities Act (Public Law 101-336).

Emergency situations may occur at any time. All projects must therefore have written plans and procedures for the management of emergencies.

6.5 PERSONNEL

Grantees and delegate/contract agencies are reminded of their obligation to establish and maintain personnel policies that comply with applicable Federal and state requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, and Title I of the Americans With Disabilities Act. These policies should include, but need not be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures. Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to and able to deal effectively with the cultural and other characteristics of the client population [59.5 (b)(10)].

Grantees must also ensure that:

- Projects are administered by a qualified project director;
- The clinical care component of the project operates under the responsibility of a medical director who is a licensed and qualified physician with special training or experience in family planning;
- Protocols exist that provide all project personnel with guidelines for client care;

- Personnel records are kept confidential;

- Licenses of applicants for positions requiring licensure are verified prior to employment and that there is documentation that licenses are kept current.

6.6 TRAINING AND TECHNICAL ASSISTANCE

Projects must provide for the orientation and in-service training of all project personnel, including the staffs of delegate agencies and service sites. All project personnel should participate in continuing education related to their activities. Documentation of continuing education should be maintained and used in evaluating the scope and effectiveness of the staff training program.

Training through regional training centers is available to all projects under the Title X program. In addition to training, grantees may receive technical assistance for specific project activities. Technical assistance is provided by contract from the OPA and administered through the Regional Office. Information on training and technical assistance is available from the Regional Office.

6.7 REPORTING REQUIREMENTS

Grantees must:

(1) comply with the financial and other reporting requirements of 45 CFR Part 74 or 45 CFR Part 92, as applicable; and

(2) comply with other reporting requirements as required by DHHS.

6.8 REVIEW AND APPROVAL OF INFORMATIONAL AND EDUCATIONAL MATERIALS

An advisory committee of five to nine members (the size of the committee can differ from these limits with written documentation and approval from the Regional Office) who are broadly representative of the community must review and approve all informational and educational (I&E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X. Oversight responsibility for the I&E committee(s) rests with the grantee. The grantee may delegate the I & E operations for the review and approval of materials to delegate/contract agencies.

The I&E committee(s) must:

- Consider the educational and cultural backgrounds of the individuals to whom the materials are addressed;
- Consider the standards of the population or community to be served with respect to such materials;
- Review the content of the material to assure that the information is factually correct;
- Determine whether the material is suitable for the population or community to which it is to be made available; and
- Establish a written record of its determinations [59.6].

The committee(s) may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff. However, final approval of the I& E material rests with the committee(s).

6.9 COMMUNITY PARTICIPATION, EDUCATION, AND PROJECT PROMOTION

Boards and advisory committees for family planning services should be broadly representative of the population served.

! Community Participation

Title X grantees and delegate/contract agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project (1) by persons broadly representative of all significant elements of the population to be served, and (2) by persons in the community knowledgeable about the community's needs for family planning services [59.5(b)(10)].

The I& E advisory committee may serve the community participation function if it meets the above requirements, or a separate group may be identified. In either case, the grantee project plan must include a plan for community participation. The community participation committee must meet annually or more often as appropriate.

- Community Education

  Each family planning project must provide for community education programs [59.5(b)(3)]. This should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

  Community education should serve to enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial.

- Project Promotion

  To facilitate community awareness of and access to family planning services, projects must establish and implement planned activities whereby their services are made known to the community [59.5(b)(3)]. Projects should review a range of strategies and assess the availability of existing resources and materials. Promotion activities should be reviewed annually and be responsive to the changing needs of the community. For more information, contact the Regional Offices.

6.10 PUBLICATIONS AND COPYRIGHT

Unless otherwise stipulated, publications resulting from activities conducted under the grant need not be submitted to DHHS for prior approval. The word "publication" is defined to include computer software. Grantees should ensure that publications developed under Title X do not contain information which is contrary to program requirements or to accepted clinical practice. Federal grant support must be acknowledged in any publication. Except as otherwise provided in the conditions of the grant award, the author is free to arrange for copyright without DHHS approval of publications, films, or similar materials developed from work supported by DHHS. Restrictions on motion picture film production are outlined in the *Public Health Service Grants Policy Statement*. Any such copyrighted materials shall be subject to a royalty-free, non-exclusive, and irrevocable right of the Government to reproduce, publish, or otherwise use such materials for Federal purposes and to authorize others to do so [45 CFR 74.36][45 CFR 92.34].

6.11 INVENTIONS OR DISCOVERIES

Family planning projects must comply with Government-wide regulations, 37 CFR Part 401, which apply to the rights to inventions made under government grants, contracts and cooperative agreements.

PART II

7.0 Client Services

Projects funded under Title X must provide clinical, informational, educational, social and referral services relating to family planning to clients who want such services. All projects must offer a broad range of acceptable and effective medically approved family planning methods and services either on-site or by referral [59.5(a)(1)]. Projects should make available to clients all methods of contraception approved by the Federal Food and Drug Administration.

Part II of this document has been developed to assist grantees in determining those services which will be provided to fulfill the mission of Title X.

- Projects must provide services stipulated in the law or regulations, or which are required by these Guidelines for the provision of high quality family planning services.

- Projects may also provide those services that are intended to promote the reproductive and general health care of the family planning client population.

7.1 SERVICE PLANS AND PROTOCOLS

The service plan is the component of the grantee's project plan, as set forth in the competitive application, which identifies those services to be provided to clients under Title X by the project. As part of the project plan, all grantees must assure that delegate/contractors have written clinical protocols and plans for client education, approved by the grantee and signed by the service site Medical Director, which outline procedures for the provision of each service offered and which are in accordance with state laws. Clinical protocols must be consistent with the requirements of these Guidelines.

Under exceptional circumstances, a waiver from a particular requirement may be obtained from the Regional Office upon written request from a grantee. In submitting a request for an exception, the grantee must provide epidemiologic, clinical, and other supportive data to justify the request and the duration of the waiver.

7.2 PROCEDURAL OUTLINE

The services provided to family planning clients, and the sequence in which they are provided, will depend upon the type of visit and the nature of the service requested. However, the following components must be offered to and documented on all clients at the initial visit:

Education

- Presentation of relevant information and educational materials, based upon client needs and knowledge;

Counseling

- Interactive process in which a client is assisted in making an informed choice;

Informed Consent

- Explanation of all procedures and obtaining a general consent covering examination and treatment and, where applicable, a method specific informed consent form;

History

- Obtaining of a personal and family medical and social history;

Examination

- Performance of a physical examination and any necessary clinical procedures, as indicated;

Laboratory Testing

- Performance of routine and other indicated laboratory tests;

Follow-up & Referrals

- Planned mechanism for client follow-up;
- Performance of any necessary clinical procedures;
- Provision of medications and/or supplies as needed; and
- Provision of referrals as needed.

Return visits, with the exception of routine supply visits, should include an assessment of the client's health status, current complaints, and evaluation of birth control method, as well as an opportunity to change methods. The following components must be offered to and documented on all clients at the return visit:

History

C Updating a personal and family medical and social history;

Examination

C Performance of a physical examination and any necessary clinical procedures, as indicated;

Laboratory Testing

C Performance of routine and other indicated laboratory tests;

Follow-up & Referrals

C Planned mechanism for client follow-up;

- Performance of any necessary clinical procedures;

C Provision of medications and/or supplies as needed; and

C Provision of referrals as needed.

7.3 EMERGENCIES

Emergency situations involving clients and/or staff may occur at any time. All projects must therefore have written plans for the management of on-site medical emergencies. At a minimum, written protocols must address vaso-vagal reactions, anaphylaxis, syncope, cardiac arrest, shock, hemorrhage, and respiratory difficulties. Protocols must also be in place for emergencies requiring transport, after-hours management of contraceptive emergencies, and clinic emergencies. All project staff must be familiar with these plans. Appropriate training, including training in CPR, should be available to staff.

7.4 REFERRALS AND FOLLOW-UP

Grantees must assure that delegate/contract agencies provide all family planning services listed in Section 8.0 under "Required Services," either on-site or by referral. When required services are to be provided by referral, the grantee must establish formal arrangements with a referral agency for the provision of services and reimbursement of costs, as appropriate.

Agencies must have written policies/procedures for follow-up on referrals that are made as a result of abnormal physical examination or laboratory test findings. These policies must be sensitive to clients' concerns for confidentiality and privacy.

For services determined to be necessary but which are beyond the scope of the project, clients must be referred to other providers for care. When a client is referred for non-family planning or emergency clinical care, agencies must:

- Make arrangements for the provision of pertinent client information to the referral provider. Agencies must obtain client's consent to such arrangements, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality;

- Advise client on their responsibility in complying with the referral; and

- Counsel client on the importance of such referral and the agreed upon method of follow-up.

Efforts may be made to aid the client in identifying potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care. Agencies must maintain a current list of health care providers, local health and human services departments, hospitals, voluntary agencies, and health services projects supported by other Federal programs to be used for referral purposes. Whenever possible, clients should be given a choice of providers from which to select.

8.0 Required Services

The services contained in this section must be provided by all projects funded under Title X.

The client's written informed voluntary consent to receive services must be obtained prior to the client receiving any clinical services. In addition, if a client chooses a prescription method of contraception, a method-specific consent form must be obtained and updated routinely at subsequent visits to reflect current information about that method.

8.1 CLIENT EDUCATION

Grantees and/or delegate/contract agencies must have written plans for client education that include goals and content outlines to ensure consistency and accuracy of information provided. Client education must be documented in the client record. The education provided should be appropriate to the client's age, level of knowledge, language, and socio-cultural background and be presented in an unbiased manner. A mechanism to determine that the information provided has been understood should be established.

Education services must provide clients with the information needed to:

- Make informed decisions about family planning;
- Use specific methods of contraception and identify adverse effects;
- Perform breast/testicular self examination;
- Reduce risk of transmission of sexually transmitted diseases and Human Immunodeficiency Virus (HIV);
- Understand the range of available services and the purpose and sequence of clinic procedures; and
- Understand the importance of recommended screening tests and other procedures involved in the family planning visit.

Clients should be offered information about basic female and male reproductive anatomy and physiology, and the value of fertility regulation in maintaining individual and family health. Additional education should include information on reproductive health and health promotion/disease prevention, including nutrition, exercise, smoking cessation, alcohol and drug abuse, domestic violence and sexual abuse.

! Method-Specific Informed Consent

Written informed consent, specific to the contraceptive method, must be signed before a prescription contraceptive method is provided. Prior to implementation, informed consent forms should be approved by the service site Medical Director.

The consent forms must be written in a language understood by the client or translated and witnessed by an interpreter. To provide informed consent for contraception, the client must receive information on the benefits and risks, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the contraceptive method chosen. Specific education and consent forms for the contraceptive method provided must be part of

the project's service plan.

The signed informed consent form must be a part of the client's record. All consent forms should contain a statement that the client has been counseled, provided with the appropriate informational material, and understands the content of both. The method-specific consent form should be renewed and updated when there is a major change in the client's health status or a change to a different prescriptive contraceptive method.

Federal sterilization regulations [42 CFR Part 50, Subpart B], which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for by the project (see Attachment C).

8.2 COUNSELING

The primary purpose of counseling in the family planning setting is to assist clients in reaching an informed decision regarding their reproductive health and the choice and continued use of family planning methods and services. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety about reproductive issues and to enhance their capacity to arrive at a decision that reflects their considered self-interest.

The counseling process involves mutual sharing of information. Persons who provide counseling should be knowledgeable, objective, nonjudgmental, sensitive to the rights and differences of clients as individuals, culturally aware and able to create an environment in which the client feels comfortable discussing personal information. The counselor must be sufficiently knowledgeable to provide accurate information regarding the benefits and risk, safety, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the various contraceptive methods. Additionally, the counselor should be knowledgeable about the other services offered by the agency. Documentation of counseling must be included in the client's record.

! Method Counseling

Method counseling refers to an individualized dialogue with a client that covers the following:

- Results of physical exam and lab studies;
- Effective use of contraceptive methods, including natural family planning (NFP), and the benefit and efficacy of the methods;
- Possible side effects/complications;
- How to discontinue the method selected and information regarding back-up

method use, including the use of certain oral contraceptives as post-coital emergency contraception;

- Planned return schedule;
- Emergency 24-hour telephone number;
- Location where emergency services can be obtained; and
- Appropriate referral for additional services as needed.

! Sexually Transmitted Disease (STD) and HIV Counseling

All clients must receive thorough and accurate counseling on STDs and HIV. STD/HIV counseling refers to an individualized dialogue with a client in which there is discussion of personal risks for STDs/HIV, and the steps to be taken by the individual to reduce risk, if necessary. Persons found to have behaviors which currently put them at risk for STD/HIV must be given advice regarding risk reduction and must be advised whether clinical evaluation is indicated. All projects must offer, at a minimum, education about HIV infection and AIDS, information on risks and infection prevention, and referral services. On an optional basis, clinics may also provide HIV risk assessment, counseling and testing by specially trained staff. When the project does not offer these optional services, the project must provide the client with a list of health care providers who can provide these services.

8.3 HISTORY, PHYSICAL ASSESSMENT, AND LABORATORY TESTING

! History

At the initial comprehensive clinical visit, a complete medical history must be obtained on all female and male clients. Pertinent history must be updated at subsequent clinical visits. The comprehensive medical history must address at least the following areas:

- Significant illnesses; hospitalizations; surgery; blood transfusion or exposure to blood products; and chronic or acute medical conditions;
- Allergies;
- Current use of prescription and over-the-counter medications;
- Extent of use of tobacco, alcohol, and other drugs;

- Immunization and Rubella status;
- Review of systems;
- Pertinent history of immediate family members; and
- Partner history
  - injectable drug use
  - multiple partners
  - risk history for STDs and HIV
  - bisexuality.

Histories of reproductive function in female clients must include at least the following:

- Contraceptive use past and current (including adverse effects);
- Menstrual history;
- Sexual history;
- Obstetrical history;
- Gynecological conditions;
- Sexually transmitted diseases, including HBV;
- HIV;
- Pap smear history (date of last Pap, any abnormal Pap, treatment); and
- In utero exposure to diethylstilbestrol (DES).

Histories of reproductive function in male clients must include at least the following:

- Sexual history;
- Sexually transmitted diseases (including HBV);

- HIV; and
- Urological conditions.

! Physical Assessment (female)

For many clients, family planning programs are their only continuing source of health information and clinical care. Therefore, an initial complete physical examination, including height and weight, examination of the thyroid, heart, lungs, extremities, breasts, abdomen, pelvis, and rectum, should be performed.

While most client services will necessarily relate to fertility regulation, family planning clinics must provide and encourage clients to use health maintenance screening procedures, initially and as indicated. Clinics must provide and stress the importance of the following to all clients:

- Blood pressure evaluation;
- Breast exam;
- Pelvic examination which includes vulvar evaluation and bimanual exam;
- Pap smear;
- Colo-rectal cancer screening in individuals over 40; and
- STD and HIVscreening, as indicated.

Following counseling about the importance of the above preventive services, if a client chooses to decline or defer a service, this should be documented in their record. Counseling must include information about the possible health risks associated with declining or delaying preventive screening tests or procedures.

All physical examination and laboratory test requirements stipulated in the prescribing information for specific methods of contraception must be followed. Physical examination and related prevention services should not be deferred beyond 3 months after the initial visit, and in no case may be deferred beyond 6 months, unless if in the clinician's judgment there is a compelling reason for extending the deferral. All deferrals, including the reason(s) for deferral, must be documented in the client record. Project protocols should be developed accordingly.

! Physical Assessment (male)

Family planning clinics also may be an important source of reproductive health care for male clients. Physical examination should be made available to male clients, including height and weight, examination of the thyroid, heart, lungs, breasts, abdomen, extremities, genitals and rectum. Examination should also include palpation of the prostate, as appropriate, and instructions in self-examination of the testes. Clinics should stress the importance of the following to male clients:

- Blood pressure evaluation;
- Colo-rectal cancer screening in individuals over 40; and
- STD and HIVscreening, as indicated.

! Laboratory Testing

Specific laboratory tests are required for the provision of specific methods of contraception. Laboratory tests can also be important indicators of client health status and useful for diagnostic purposes. Pregnancy testing must be provided onsite. The following laboratory procedures must be provided to clients if required in the provision of a contraceptive method, and may be provided for the maintenance of health status and/or diagnostic purposes, either on-site or by referral:

- Anemia assessment
- Gonorrhea and chlamydia test
- Vaginal wetmount
- Diabetes testing
- Cholesterol and lipids
- Hepatitis B testing
- Syphilis serology (VDRL, RPR)
- Rubella titer
- Urinalysis

- HIV testing

- Notification of Abnormal Lab Results

A procedure which addresses client confidentiality must be established to allow for client notification and adequate follow-up of abnormal laboratory results.

- Other Laboratory Services or Procedures

Other procedures and lab tests may be indicated for some clients and may be provided on-site or by referral.

! Revisits

Revisit schedules must be individualized based upon the client's need for education, counseling, and clinical care beyond that provided at the initial and annual visit.

Clients selecting hormonal contraceptives, intrauterine devices (IUDs), cervical caps, or diaphragms for the first time should be scheduled for a revisit as appropriate after initiation of the method to reinforce its proper use, to check for possible side effects, and to provide additional information or clarification. A new or established client who chooses to continue a method already in use need not return for this early revisit unless a need for reevaluation is determined on the basis of the findings at the initial visit.

8.4 FERTILITY REGULATION

! Reversible Contraception

Currently, the reversible methods of contraception include barrier methods (female and male), IUDs, fertility awareness methods, natural family planning, and hormonal methods (injectables, implants, orals). Certain oral contraceptive regimens have been found by the Federal Food and Drug Administration to be safe and effective for use as postcoital emergency contraception when initiated within 72 hours after unprotected intercourse. More than one method of contraception can be used simultaneously by a client and may be particularly indicated to minimize the risks of STDs/HIV and pregnancy. Consistent and correct use of condoms should be encouraged for all persons at risk for STDs/HIV.

- Permanent Contraception

  The counseling and consent process must assure that the client's decision to undergo sterilization is completely voluntary and made with full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures. Federal sterilization regulations, which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for by the project (see Attachment C).

8.5 INFERTILITY SERVICES

Grantees must make basic infertility services available to women and men desiring such services. Infertility services are categorized as follows:

- *Level I* Includes initial infertility interview, education, physical examination, counseling, and appropriate referral.
- *Level II* Includes such testing as semen analysis, assessment of ovulatory function and postcoital testing.
- *Level III* More sophisticated and complex than Level I and Level II services.

Grantees must provide Level I infertility services as a minimum. Level II infertility services may be offered in projects with clinicians who have special training in infertility. Level III services are considered to be beyond the scope of Title X program.

8.6 PREGNANCY DIAGNOSIS AND COUNSELING

Projects must provide pregnancy diagnosis and counseling to all clients in need of this service. Pregnancy testing is one of the most common reasons for a first visit to the family planning facility. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning.

Pregnancy cannot be accurately diagnosed and staged through laboratory testing alone. Pregnancy diagnosis consists of a history, pregnancy test, and physical assessment, including pelvic examination. Projects should have available a pregnancy test of high sensitivity. If the medical examination cannot be performed in conjunction with the laboratory testing, the client must be counseled as to the importance of receiving a physical assessment as soon as possible, preferably within 15 days. This can be done on-site, by a provider selected by the client, or by a provider to which the client has been referred by the project. For those clients with positive pregnancy test results who elect to continue the pregnancy, referral for early initiation of prenatal care should be made. Clients planning to carry their pregnancies

to term should be given information about good health practices during early pregnancy, especially those which serve to protect the fetus during the first three months (e.g., good nutrition, avoidance of smoking, drugs, and exposure to x-rays). For clients with a negative pregnancy diagnosis, the cause of delayed menses should be investigated. If ectopic pregnancy is suspected, the client must be referred for immediate diagnosis and therapy.

Projects must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

- Prenatal care and delivery;
- Infant care, foster care, or adoption; and
- Pregnancy termination.

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling [59.5(a)(5)].

Clients who are found not to be pregnant should be given information about the availability of contraceptive and infertility services, as appropriate.

8.7 ADOLESCENT SERVICES

Adolescent clients require skilled counseling and age-appropriate information. Appointments should be available to them for counseling and clinical services as soon as possible.

Adolescents seeking contraceptive services must be informed about all methods of contraception. Abstinence as well as contraceptive and safer sex practice options to reduce risks for STD/HIV and pregnancy must be discussed with all adolescents. It is important not to assume that adolescents are sexually active simply because they have come for family planning services. As the contraceptive needs of adolescents frequently change, counseling should prepare them to use a variety of methods effectively.

Adolescents must be assured that the counseling sessions are confidential and, if follow-up is necessary, every attempt will be made to assure the privacy of the individual. However, counselors should encourage family participation in the decision of minors to seek family planning services and provide counseling to minors on resisting attempts to coerce minors into engaging in sexual activities. Title X projects may not require written consent of parents or guardians for the provision of services to minors. Nor can the project notify parents or guardians before or after a minor has requested and received Title X family planning services.

8.8 IDENTIFICATION OF ESTROGEN-EXPOSED OFFSPRING

The children of women who received DES or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility related risks. As part of the medical history, clients born between 1940 and 1970 should be asked if their mothers took estrogens during pregnancy. Clients prenatally exposed to exogenous estrogens should receive information/education and special screening either on-site or by referral.

9.0 Related Services

The following related health services, which can improve quality of care, may be offered if skilled personnel and equipment are available.

9.1 GYNECOLOGIC SERVICES

Family planning programs should provide for the diagnosis and treatment of minor gynecologic problems so as to avoid fragmentation or lack of health care for clients with these conditions. Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine. More complex procedures, such as colposcopy, may be offered, provided that clinicians performing these services have specialized training.

9.2 SEXUALLY TRANSMITTED DISEASES (STD) AND HIV/AIDS

The increasing incidence and prevalence of STDs, particularly among adolescents, requires that family planning projects increase their efforts to provide education and information about the more common STDs and HIV/AIDS. Projects should make available detection and treatment of the more common STDs. At-risk clients should be urged to undergo examination and treatment as indicated, either directly or by referral. When treatment is provided on-site, appropriate follow-up measures must be undertaken.

Gonorrhea and chlamydia tests must be available for clients requesting IUD insertion. Tests for gonorrhea, syphilis, chlamydia and HIV should be provided as indicated by client request or evidence of increased risk for infection.

Grantees and/or delegate contract agencies must comply with state and local STD reporting requirements.

9.3 SPECIAL COUNSELING

Clients should be offered appropriate counseling and referral as indicated regarding future planned pregnancies, management of a current pregnancy, and other individual concerns (e.g., substance use and abuse, sexual abuse, domestic violence, genetic issues, nutrition, sexual concerns, etc.) as indicated. Preconceptional counseling should be provided if the client's history indicates a desired pregnancy in the future.

9.4 GENETIC INFORMATION AND REFERRAL

Basic information regarding genetic conditions should be offered to family planning clients who request or are in need of such services. Extensive genetic counseling and evaluation is beyond the scope of the Title X program. Referral systems should be in place for those who require further genetic counseling and evaluation

9.5 HEALTH PROMOTION/DISEASE PREVENTION

Family planning programs should, whenever possible, provide or coordinate access to services intended to promote health and prevent disease. Programs are encouraged to assess the health problems prevalent in the populations they serve and to develop strategies to address them.

9.6 POSTPARTUM CARE

Family planning programs may provide postpartum care in collaboration with local agencies or institutions which provide prenatal and/or intrapartum care. If a family planning program undertakes responsibility for postpartum care, such care should be directed toward assessment of the woman's physical health, initiation of contraception if desired, and counseling and education related to parenting, breast feeding, infant care, and family adjustment.

10.0 Clinic Management

10.1 EQUIPMENT AND SUPPLIES

Equipment and supplies must be appropriate to the type of care offered by the project. Projects are expected to follow applicable Federal and state regulations regarding infection control.

10.2 PHARMACEUTICALS

Agencies must be operated in accordance with Federal and state laws relating to security and record keeping for drugs and devices. The inventory, supply, and provision of pharmaceuticals must be conducted in accordance with state pharmacy laws and professional practice regulations.

It is essential that each facility maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients. Projects should also ensure access to other drugs or devices that are necessary for the provision of other medical services included within the scope of the Title X project.

10.3 MEDICAL RECORDS

Projects must establish a medical record for every client who obtains clinical services. These records must be maintained in accordance with accepted medical standards and State laws with regard to record retention. Records must be:

- Complete, legible and accurate, including documentation of telephone encounters of a clinical nature;
- Signed by the clinician and other appropriately trained health professionals making entries, including name, title and date;
- Readily accessible;
- Systematically organized to facilitate prompt retrieval and compilation of information;
- Confidential;
- Safeguarded against loss or use by unauthorized persons;
- Secured by lock when not in use; and
- Available upon request to the client.

! Content of the Client Record

The client's medical record must contain sufficient information to identify the client, indicate where and how the client can be contacted, justify the clinical impression or diagnosis, and warrant the treatment and end results. The required content of the medical record includes:

- Personal data;
- Medical history, physical exam, laboratory test orders, results, and follow-up;
- Treatment and special instructions;
- Scheduled revisits;
- Informed consents;
- Refusal of services; and
- Allergies and untoward reactions to drug(s) recorded in a prominent and specific location.

The record must also contain reports of clinical findings, diagnostic and therapeutic orders, and documentation of continuing care, referral, and follow-up. The record must allow for entries by counseling and social service staff. Projects should maintain a problem list at the front of each chart listing identified problems to facilitate continuing evaluation and follow-up. Client financial information should be kept separate from the client medical record. If included in the medical record, client financial information should not be a barrier to client services.

! Confidentiality and Release of Records

A confidentiality assurance statement must appear in the client's record. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality [59.11]. HIV information should be handled according to law, and kept separate whenever possible. When information is requested, agencies should release only the specific information requested. Information collected for reporting purposes may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Upon request, clients transferring to other providers must be provided with a copy or summary of their record to expedite continuity of care.

10.4 QUALITY ASSURANCE AND AUDIT

A quality assurance system must be in place that provides for ongoing evaluation of project personnel and services. The quality assurance system should include:

- An established set of clinical, administrative and programmatic standards by which conformity would be maintained;
- A tracking system to identify clients in need of follow-up and/or continuing care;
- Ongoing medical audits to determine conformity with agency protocols;
- Peer review procedures to evaluate individual clinician performance, to provide feedback to providers, and to initiate corrective action when deficiencies are noted;
- Periodic review of medical protocols to insure maintenance of current standards of care;
- A process to elicit consumer feedback; and
- Ongoing and systematic documentation of quality assurance activities.

TITLE X - POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES

SEC. 1001 [300]

(a)The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family [1] participation in projects assisted under this subsection.

(b)In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c)The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(d)For the purpose of making grants and contracts under this section, there are authorized to be appropriated $30,000,000 for the fiscal year ending June 30, 1971; $60,000,000 for the fiscal year ending June 30, 1972; $111,500,000 for the fiscal year ending June 30, 1973, $111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $115,000,000 for fiscal year 1976;
$115,000,000 for the fiscal year ending September 30, 1977;
$136,400,000 for the fiscal year ending September 30, 1978;
$200,000,000 for the fiscal year ending September 30, 1979;
$230,000,000 for the fiscal year ending September 30, 1980;
$264,500,000 for the fiscal year ending September 30, 1981;
$126,510,000 for the fiscal year ending September 30, 1982;
$139,200,000 for the fiscal year ending September 30, 1983;
$150,030,000 for the fiscal year ending September 30, 1984; and
$158,400,000 for the fiscal year ending September 30, 1985.

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[1] So in law. See section 931(b)(I) of Public Law 97-35 (95 Stat. 570). Probably should be “family”.

FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES

SEC. 1002 [300a]

(a)The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b)The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c)For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d)For the purpose of making grants under this section, there are authorized to be appropriated $10,000,000 for the fiscal year ending June 30, 1971; $15,000,000 for the fiscal year ending June 30, 1972; and $20,000,000 for the fiscal year ending June 30, 1973.

TRAINING GRANTS AND CONTRACTS; AUTHORIZATION OF APPROPRIATIONS

SEC. 1003 [300a-1]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002 of this title.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $2,000,000 for the fiscal year ending June 30, 1971; $3,000,000 for the fiscal year ending June 30, 1972; $4,000,000 for the fiscal year ending June 30, 1973; $3,000,000 each for the fiscal years ending June 30, 1974 and June 30, 1975; $4,000,000 for fiscal year ending 1976; $5,000,000 for the fiscal year ending September 30, 1977; $3,000,000 for the fiscal year ending September 30, 1978; $3,100,000 for the fiscal year ending September 30, 1979; $3,600,000 for the fiscal year ending September 30, 1980; $4,100,000 for the fiscal year ending September 30, 1981; $2,920,000 for the fiscal year ending September 30, 1982; $3,200,000 for the fiscal year ending September 30, 1983; $3,500,000 for the fiscal year ending September 30, 1984; and $3,500,000 for the fiscal year ending September 30, 1985.

RESEARCH

SEC. 1004 [300a-2]

The Secretary may -

(1) conduct, and

(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

INFORMATIONAL AND EDUCATIONAL MATERIALS

SEC. 1005 [300a-3]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $750,000 for the fiscal year ending June 30, 1971; $1,000,000 for the fiscal year ending June 30, 1972; $1,250,000 for the fiscal year ending June 30, 1973; $909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $2,000,000 for fiscal year 1976; $2,500,000 for the fiscal year ending September 30, 1977; $600,000 for the fiscal year ending September 30, 1978; $700,000 for the fiscal year ending September 30, 1979; $805,000 for the fiscal year ending September 30, 1980; $926,000 for the fiscal year ending September 30, 1981; $570,000 for the fiscal year ending September 30, 1982; $600,000 for the fiscal year ending September 30, 1983; $670,000 for the fiscal year ending September 30, 1984; and $700,000 for the fiscal year ending September 30, 1985.

REGULATIONS AND PAYMENTS

SEC. 1006 [300a-4]

(a)Grants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this title shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less than the percentage of its costs for which the fiscal year 1975 grant was made.

(b)Grants under this title shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c)A grant may be made or contract entered into under section 1001 or 1002 for a family planning service project or program only upon assurances satisfactory to the Secretary that--

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term "low-income family" shall be defined by the Secretary in

accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d)(1) A grant may be made or a contract entered into under section 1001 or 1005 only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this title and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

VOLUNTARY PARTICIPATION

SEC. 1007 [300a-5]

The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

PROHIBITION OF ABORTION

SEC. 1008 [1] [300a-6]

None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

[1] Section 1009 was repealed by section 601(a)(1)(G) of Public Law 105-362 (112 Stat. 3285).

(2) The trainee is not eligible or able to continue in attendance in accordance with its standards and practices.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

§ 58.232 What additional Department regulations apply to grantees?

Several other Department regulations apply to grantees. They include, but are not limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure
45 CFR part 16—Procedures of the Departmental Grant Appeals Board
45 CFR part 46—Protection of human subjects
45 CFR part 74—Administration of grants
45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964
45 CFR part 81—Practice and procedure for hearings under part 80 of this title
45 CFR part 83—Regulation for the administration and enforcement of sections 794 and 855 of the Public Health Service Act
45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying

[49 FR 38116, Sept. 27, 1984. Redesignated and amended at 61 FR 6131, Feb. 16, 1996]

§ 58.233 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6131, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 58.234 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

Subparts E–F [Reserved]

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

Subpart A—Project Grants for Family Planning Services

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Subpart A—Project Grants for Family Planning Services

AUTHORITY: 42 U.S.C. 300a–4.

SOURCE: 65 FR 41278, July 3, 2000, unless otherwise noted.

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Low income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). ''Low-income family'' also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Midway, Wake, *et al.*), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and

may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.[1]

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning. A project must:

(i) Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any persons from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX or XXI agency is required.

(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by §59.6.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral

[1] Section 205 of Pub. L. 94–63 states: ''Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both.''

to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to—

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate, that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended.

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

(v) Establish a written record of its determinations.

§59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients, and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of nonfederal resources within the community to be served and the degree to which those resources are committed to the project; and

(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for three to five years.

(b) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 74 or Part 92, as applicable.

§59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

37 CFR Part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure

45 CFR Part 16—Procedures of the Departmental Grant Appeals Board

45 CFR Part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and

Human Services effectuation of Title VI of the Civil Rights Act of 1964
45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title
45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance
45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

AUTHORITY: Sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a–4; sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a–1.

SOURCE: 37 FR 7093, Apr. 8, 1972, unless otherwise noted.

§ 59.201 Applicability.

The regulations in this subpart are applicable to the award of grants pursuant to section 1003 of the Public Health Service Act (42 U.S.C. 300a–1) to provide the training for personnel to carry out family planning service programs described in sections 1001 and 1002 of the Public Health Service Act (42 U.S.C. 300, 300a).

§ 59.202 Definitions.

As used in this subpart:

(a) *Act* means the Public Health Service Act.

(b) *State* means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, or the Trust Territory of the Pacific Islands.

(c) *Nonprofit* private entity means a private entity no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(d) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(e) *Training* means job-specific skill development, the purpose of which is to promote and improve the delivery of family planning services.

§ 59.203 Eligibility.

(a) *Eligible applicants.* Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart.

(b) *Eligible projects.* Grants pursuant to section 1003 of the Act and this subpart may be made to eligible applicants for the purpose of providing programs, not to exceed three months in duration, for training family planning or other health services delivery personnel in the skills, knowledge, and attitudes necessary for the effective delivery of family planning services: *Provided,* That the Secretary may in particular cases approve support of a program whose duration is longer than three months where he determines (1) that such program is consistent with the purposes of this subpart and (2) that the program's objectives cannot be accomplished within three months because of the unusually complex or specialized nature of the training to be undertaken.

[37 FR 7093, Apr. 8, 1972, as amended at 40 FR 17991, Apr. 24, 1975]

§ 59.204 Application for a grant.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.[1] The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

(Sec. 6(c), Public Health Service Act, 84 Stat. 1506 and 1507 (42 U.S.C. 300, 300a–1, and 300a–4))

[37 FR 7093, Apr. 8, 1972, as amended at 49 FR 38116, Sept. 27, 1984]

§ 59.205 Project requirements.

An approvable application must contain each of the following unless the Secretary determines that the applicant has established good cause for its omission:

(a) Assurances that:

(1) No portion of the Federal funds will be used to train personnel for programs where abortion is a method of family planning.

(2) No portion of the Federal funds will be used to provide professional training to any student as part of his education in pursuit of an academic degree.

(3) No project personnel or trainees shall on the grounds of sex, religion, or creed be excluded from participation in, be denied the benefits of, or be subjected to discrimination under the project.

(b) Provision of a methodology to assess the particular training (e.g., skills, attitudes, or knowledge) that prospective trainees in the area to be served need to improve their delivery of family planning services.

(c) Provision of a methodology to define the objectives of the training program in light of the particular needs of trainees defined pursuant to paragraph (b) of this section.

(d) Provision of a method for development of the training curriculum and any attendant training materials and resources.

(e) Provision of a method for implementation of the needed training.

(f) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program.

(g) Provision of a method and criteria by which trainees will be selected.

§ 59.206 Evaluation and grant award.

(a) Within the limits of funds available for such purpose, the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 1003 of the Act, taking into account:

(1) The extent to which a training program will increase the delivery of services to people, particularly low-income groups, with a high percentage of unmet need for family planning services;

(2) The extent to which the training program promises to fulfill the family planning services delivery needs of the area to be served, which may include, among other things:

(i) Development of a capability within family planning service projects to provide pre- and in-service training to their own staffs;

(ii) Improvement of the family planning services delivery skills of family planning and health services personnel;

(iii) Improvement in the utilization and career development of paraprofessional and paramedical manpower in family planning services;

(iv) Expansion of family planning services, particularly in rural areas, through new or improved approaches to

[1] Applications and instructions may be obtained from the Program Director, Family Planning Services, at the Regional Office of the Department of Health and Human Services for the region in which the project is to be conducted, or the Office of Family Planning, Office of the Assistant Secretary for Health, Washington, DC 20201.

program planning and deployment of resources;

(3) The capacity of the applicant to make rapid and effective use of such assistance;

(4) The administrative and management capability and competence of the applicant;

(5) The competence of the project staff in relation to the services to be provided; and

(6) The degree to which the project plan adequately provides for the requirements set forth in § 59.205.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either: (1) On the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) Allowability of costs shall be in conformance with the applicable cost principles prescribed by Subpart Q of 35 CFR part 74.

(d) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.

(e) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.207 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 59.208 Use of project funds.

(a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with the statute, the regulations of this subpart, the terms and conditions of the award, and, except as may otherwise be provided in this subpart, the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

(b) Prior approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

(c) The Secretary may approve the payment of grant funds to trainees for:

(1) Return travel to the trainee's point of origin.

(2) Per diem during the training program, and during travel to and from the program, at the prevailing institutional or governmental rate, whichever is lower.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.209 Civil rights.

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d *et seq.*) and in particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation impelmenting such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the

approval of the President (45 CFR part 80).

§ 59.210 Inventions or discoveries.

Any grant award pursuant to § 59.206 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

§ 59.211 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 59.212 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) [Reserved]

(c) *Accounting for grant-related income*—(1) *Interest.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(d) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (c)(1) of this section;

(iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or

assignees by setoff or other action as provided by law.

[36 FR 18465, Sept. 15, 1971, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.213 [Reserved]

§ 59.214 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

§ 59.215 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to all other grantee organizations under this subpart.

45 CFR PART 74

Subpart:
A General.
B Cash Depositories.
C Bonding and Insurance.
D Retention and Custodial Requirements for Records.
F Grant-Related Income.
G Matching and Cost Sharing.
K Grant Payment Requirements.
L Budget Revision Procedures.
M Grant Closeout, Suspension, and Termination.
O Property.
Q Cost Principles.

[38 FR 26199, Sept. 19, 1973]

PART 59a—NATIONAL LIBRARY OF MEDICINE GRANTS

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

Sec.
59a.1 Programs to which these regulations apply.
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Subpart B—Establishment of Regional Medical Libraries

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SOURCE: 56 FR 29189, June 26, 1991, unless otherwise noted.

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

AUTHORITY: 42 U.S.C. 286b–2, 286b–5.

§ 59a.1 Programs to which these regulations apply.

(a) The regulations of this subpart apply to grants of funds, materials, or both, for establishing, expanding, and improving basic medical library resources as authorized by section 474 of the Act (42 U.S.C. 286b–5).

(b) This subpart also applies to cooperative agreements awarded for this purpose. In these circumstances, references to ''grant(s)'' shall include ''cooperative agreements(s).''

§ 59a.2 Definitions.

Undefined terms have the same meaning as provided in the Act. As used in this subpart:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Project period—See § 59a.5(c).

Related instrumentality means a public or private institution, organization, or agency, other than a medical library, whose primary function is the acquisition, preservation, dissemination, and/or processing of information relating to the health sciences.

Secretary means the Secretary of Health and Human Services and any other official of the Department of Health and Human Services to whom the authority involved is delegated.

examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the request is granted, the institution must file periodic progress reports as requested by the OSI. If satisfactory progress is not made in the institution's investigation, the OSI may undertake an investigation of its own.

(6) Upon receipt of the final report of investigation and supporting materials, the OSI will review the information in order to determine whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness and competence. The OSI may then request clarification or additional information and, if necessary, perform its own investigation. While primary responsibility for the conduct of investigations and inquiries lies with the institution, the Department reserves the right to perform its own investigation at any time prior to, during, or following an institution's investigation.

(7) In addition to sanctions that the institution may decide to impose, the Department also may impose sanctions of its own upon investigators or institutions based upon authorities it possesses or may possess, if such action seems appropriate.

(b) The institution is responsible for notifying the OSI if it ascertains at any stage of the inquiry or investigation, that any of the following conditions exist:

(1) There is an immediate health hazard involved;

(2) There is an immediate need to protect Federal funds or equipment;

(3) There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;

(4) It is probable that the alleged incident is going to be reported publicly.

(5) There is a reasonable indication of possible criminal violation. In that instance, the institution must inform OSI within 24 hours of obtaining that information. OSI will immediately notify the Office of the Inspector General.

§ 50.105 Institutional compliance.

Institutions shall foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested. An institution's failure to comply with its assurance and the requirements of this subpart may result in enforcement action against the institution, including loss of funding, and may lead to the OSI's conducting its own investigation.

Subpart B—Sterilization of Persons in Federally Assisted Family Planning Projects

§ 50.201 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

§ 50.202 Definitions.

As used in this subpart:

Arrange for means to make arrangements (other than mere referral of an individual to, or the mere making of an appointment for him or her with, another health care provider) for the performance of a medical procedure on an individual by a health care provider other than the program or project.

Hysterectomy means a medical procedure or operation for the purpose of removing the uterus.

Institutionalized individual means an individual who is (1) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness, or (2) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

Mentally incompetent individual means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose unless he or she has been declared competent for

purposes which include the ability to consent to sterilization.

Public Health Service means the Office of the Assistant Secretary for Health, Health Resources and Services Administration, National Institutes of Health, Centers for Disease Control, Alcohol, Drug Abuse and Mental Health Administration and all of their constituent agencies.

The *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Sterilization means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

[43 FR 52165, Nov. 8, 1978, as amended at 49 FR 38109, Sept. 27, 1984]

§ 50.203 Sterilization of a mentally competent individual aged 21 or older.

Programs or projects to which this subpart applies shall perform or arrange for the performance of sterilization of an individual only if the following requirements have been met:

(a) The individual is at least 21 years old at the time consent is obtained.

(b) The individual is not a mentally incompetent individual.

(c) The individual has voluntarily given his or her informed consent in accordance with the procedures of § 50.204 of this subpart.

(d) At least 30 days but not more than 180 days have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of premature delivery or emergency abdominal surgery, if at least 72 hours have passed after he or she gave informed consent to sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 50.204 Informed consent requirement.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this section and § 50.205 of this subpart.

(a) A person who obtains informed consent for a sterilization procedure must offer to answer any questions the individual to be sterilized may have concerning the procedure, provide a copy of the consent form, and provide orally all of the following information or advice to the individual who is to be sterilized:

(1) Advice that the individual is free to withhold or withdraw consent to the procedure any time before the sterilization without affecting his or her right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled:

(2) A description of available alternative methods of family planning and birth control;

(3) Advice that the sterilization procedure is considered to be irreversible;

(4) A thorough explanation of the specific sterilization procedure to be performed;

(5) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(6) A full description of the benefits or advantages that may be expected as a result of the sterilization; and

(7) Advice that the sterilization will not be performed for at least 30 days except under the circumstances specified in § 50.203(d) of this subpart.

(b) An interpreter must be provided to assist the individual to be sterilized if he or she does not understand the language used on the consent form or the language used by the person obtaining the consent.

(c) Suitable arrangements must be made to insure that the information specified in paragraph (a) of this section is effectively communicated to any individual to be sterilized who is blind, deaf or otherwise handicapped.

(d) A witness chosen by the individual to be sterilized may be present when consent is obtained.

(e) Informed consent may not be obtained while the individual to be sterilized is:

(1) In labor or childbirth;

(2) Seeking to obtain or obtaining an abortion; or

(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

(f) Any requirement of State and local law for obtaining consent, except one of spousal consent, must be followed.

§ 50.205 Consent form requirements.

(a) *Required consent form.* The consent form appended to this subpart or another consent form approved by the Secretary must be used.

(b) *Required signatures.* The consent form must be signed and dated by:

(1) The individual to be sterilized; and

(2) The interpreter, if one is provided; and

(3) The person who obtains the consent; and

(4) The physician who will perform the sterilization procedure.

(c) *Required certifications.* (1) The person obtaining the consent must certify by signing the consent form that:

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify by signing the consent form, that:

(i) Shortly before the performance of the sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized. Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed. If premature delivery occurs or emergency abdominal surgery is required within the 30–day period, the physician must certify that the sterilization was performed less than 30 days but not less than 72 hours after the date of the individual's signature on the consent form because of premature delivery or emergency abdominal surgery, as applicable. In the case of premature delivery, the physician must also state the expected date of delivery. In the case of emergency abdominal surgery, the physician must describe the emergency.

(3) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally, read the consent form and explained its contents and to the best of the interpreter's knowledge and belief, the individual to be sterilized understood what the interpreter told him or her.

§ 50.206 Sterilization of a mentally incompetent individual or of an institutionalized individual.

Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any mentally incompetent individual or institutionalized individual.

§ 50.207 Sterilization by hysterectomy.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of any hysterectomy solely for the purpose of rendering an individual permanently incapable of reproducing or where, if there is more than one purpose to the procedure, the hysterectomy would not be performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) Except as provided in paragraph (c) of this section, programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy not covered by paragraph (a) of this section only if:

(1) The person who secures the authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make her permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(c)(1) A program or project is not required to follow the procedures of paragraph (b) of this section if either of the following circumstances exists:

(i) The individual is already sterile at the time of the hysterectomy.

(ii) The individual requires a hysterectomy because of a life-threatening emergency in which the physician determines that prior acknowledgment is not possible.

(2) If the procedures of paragraph (b) of this section are not followed because one or more of the circumstances of paragraph (c)(1) exist, the physician who performs the hysterectomy must certify in writing:

(i) That the woman was already sterile, stating the cause of that sterility; or

(ii) That the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.208 Program or project requirements.

(a) A program or project must, with respect to any sterilization procedure or hysterectomy it performs or arranges, meet all requirements of this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

§ 50.209 Use of Federal financial assistance.

(a) Federal financial assistance adminstered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this section or another form approved by the Secretary is used.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, and as applicable, either acknowledgments of receipt of hysterectomy information or certification of an exception for hysterectomies.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.210 Review of regulation.

The Secretary will request public comment on the operation of the provisions of this subpart not later than 3 years after their effective date.

APPENDIX TO SUBPART B OF PART 50—REQUIRED CONSENT FORM

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from _____ (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a _____. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on ____ (day), ____ (month), ____ (year).

I, _____, hereby consent of my own free will to be sterilized by _____ by a method called _____. My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or

Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form.

Signature _____

Date: _____

(Month, day, year)

You are requested to supply the following information, but it is not required:

Race and ethnicity designation (please check)

Black (not of Hispanic origin) _____

Hispanic _____

Asian or Pacific Islander _____

American Indian or Alaskan native _____

White (not of Hispanic origin) _____

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

Interpreter _____

Date _____

STATE OF PERSON OBTAINING CONSENT

Before _____ (name of individual), signed the consent form, I explained to him/her the nature of the sterilization operation _____, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure.

Signature of person obtaining consent _____

Date _____

Facility _____

Address _____

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon _____ (name of individual to be sterilized), on _____ (date of sterilization), _____ (operation), I explained to him/her the nature of the sterilization operation _____ (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(*Instructions for use of alternative final paragraphs:* Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested):

Premature delivery
Individual's expected date of delivery: _____
Emergency abdominal surgery:
(Describe circumstances): _____

Physician _____
Date _____

[43 FR 52165, Nov. 8, 1978, as amended at 58 FR 33343, June 17, 1993]

Subpart C—Abortions and Related Medical Services in Federally Assisted Programs of the Public Health Service

AUTHORITY: Sec. 118, Pub. L. 96–86, Oct. 12, 1979, unless otherwise noted.

SOURCE: 43 FR 4570, Feb. 2, 1978, unless otherwise noted.

§ 50.301 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, appropriated to the Department of Health and Human Services and administered by the Public Health Service.

§ 50.302 Definitions.

As used in this subpart: (a) *Law enforcement agency* means an agency, or any part thereof, charged under applicable law with enforcement of the general penal statutes of the United States, or of any State or local jurisdiction.

(b) *Medical procedures performed upon a victim of rape or incest* means any medical service, including an abortion, performed for the purpose of preventing or terminating a pregnancy arising out of an incident of rape or incest.

(c) *Physician* means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she practices.

(d) *Public health service* means: (1) An agency of the United States or of a State or local government, that provides health or medical services; and

(2) A *rural health clinic*, as defined under section 1(d)(aa)(2) of Pub. L. 95–210, 91 Stat. 1485; except that any agency or facility whose principal function is the performance of abortions is specifically excluded from this definition.

§ 50.303 General rule.

Federal financial participation is not available for the performance of an abortion in programs or projects to which this subpart applies except under circumstances described in § 50.304 or § 50.306.

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 50.304 Life of the mother would be endangered.

Federal financial participation is available in expenditures for an abortion when a physician has found, and so certified in writing to the program or project, that on the basis of his/her professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.

(Sec. 101, Pub. L. 95–205, 91 Stat. 1461, Dec. 9, 1977)

[43 FR 13868, July 21, 1978]

§ 50.305 [Reserved]

§ 50.306 Rape and incest.

Federal financial participation is available in expenditures for medical procedures performed upon a victim of rape or incest if the program or project has received signed documentation from a law enforcement agency or public health service stating:

(a) That the person upon whom the medical procedure was performed was reported to have been the victim of an incident of rape or incest;

(b) The date on which the incident occurred;

(c) The date on which the report was made, which must have been within 60 days of the date on which the incident occurred;

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Office of Family Planning
Regional Program Consultants

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AZ, CA, HI, NV, and the six U.S. Associated Pacific jurisdictions

Region X

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Office of Family Planning
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Revised: 12/2002

Resource List for Title X Family Planning Programs

The following is a list of selected resources that provide additional guidance in specific areas. It is intended to assist programs in administering their Title X grant and in providing services to clients. The list is not intended to be exhaustive, nor does it imply endorsement of any of the non-governmental resources.

The Law, Regulations, and Guidelines

The Title X Family Planning statute (42 USC 300 et. seq.) and regulations can be obtained from :

- Office of Family Planning
  Office of Population Affairs
  Office of Public Health and Science
  U.S. Department of Health and Human Services
  4350 East West Highway, Suite 200
  Bethesda, MD 20817
  (301) 594-4008
  http://www.hhs.gov/opa/

- Office of Population Affairs Clearinghouse
  P.O. Box 30686
  Bethesda, MD 20824-0686
  301-654-6190
  E-mail: OPA@Tascon.com

Application, Grants Administration, and Legal Issues

- Grants Management
  Http://www.hhs.gov/grantsnet

- *Grants Process Policy Notices for Title X Family Planning Services*, rev. 1999
  (Available from Title X Grants Management Office. 1301 Young Street, Ste.766, Dallas, TX 75202; 214-767-3490)

Project Management and Reporting Requirements

- Annual Report for OPA Title X Family Planning Program Grantees Forms and Instructions (Available from the Regional Office).

- Office of Pharmacy Affairs, Health Resources and Services Administration, U.S. Department of Health and Human Services. http://www.bphc.hrsa.gov/odpp/

Client Services

- Cultural Competence
  http://www.omhrc.gov/clas/index.htm

- Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency. Federal Register, Vol. 65, No. 169. 52762 – 52774. http://www.hhs.gov/ocr/lep/

- U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services*, 2nd Edition. Chapter 63 Counseling to Prevent Unintended Pregnancy. Washington, DC: U.S. Department of Health and Human Services, 1996. http://odphp.osophs.dhhs.gov/pubs/guidecps/

- Hatcher, Robert A., et. al. *Contraceptive Technology, Seventeenth Revised Edition*, Ardent Media, Inc. 1998.

- American College of Obstetricians and Gynecologists. *Emergency Oral Contraception. ACOG Practice Patterns.* Number 3. Washington, DC: The American College of Obstetrics and Gynecologists, December, 1996.

- *Your Contraceptive Choices for Now, for Later.* Bethesda, MD: U.S. Department of Health and Human Services, Public Health Service, Office of Population Affairs. Updated Spring 1998.

- Green M, Palfrey JS, eds. 2000 *Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents.* Arlington, VA: National Center for Education in Maternal and Child Health. http://www.brightfutures.org./

- American Medical Association. ***Guidelines for Adolescent Preventive Services (GAPS)***: *recommendations and rationale.* Chicago: American Medical Association. 1994

‘ *Primary and Preventive Health Care for Female Adolescents*, American College of Obstetricians and Gynecologists, November 1999.

‘ American College or Obstetricians and Gynecologists, *Guidelines for Women's Health Care*, 1996.

‘ Centers for Disease Control and Prevention. *1998 Guidelines for Treatment of Sexually Transmitted Diseases*. MMWR 1998: 47 (RR-1); 1-118. http://www.cdc.gov/nchstp/dstd/1998_STD_Guidlines/98m1633.pdf

‘ Centers for Disease Control and Prevention. *Revised Guidelines for HIV Counseling, Testing and Referral.* October 17, 2000. http://www.cdc.gov/hiv/frn.htm

Health Promotion/Disease Prevention

‘ U.S. Department of Health and Human Services. *Healthy People 2010*. 2nd ed. With Understanding and Improving Health and Objectives for Improving Health. 2 vols. . Washington, DC: U.S. Government Printing Office, November, 2000. http://www.health.gov/healthypeople/

‘ *Guidelines for Health Education and Risk Reduction Activities* CDC, National Center for Prevention Services, Division of Sexually Transmitted Diseases/HIV Prevention Publication date: 04/01/1995 http://aepo-xdv-www.epo.cdc.gov/wonder/PrevGuid

‘ U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services*, 2nd Edition. Chapter 63 Counseling to Prevent Unintended Pregnancy. Washington, DC: U.S. Department of Health and Human Services (HHS), 1996. http://odphp.osophs.dhhs.gov/pubs/guidecps/

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ATTACHMENT W

NEW YORK STATE DEPARTMENT OF HEALTH
SCHOOL HEALTH PROGRAM

DRAFT

SCHOOL BASED HEALTH CENTERS

PERFORMANCE EFFECTIVENESS REVIEW TOOL
(PERT)

SELF ASSESSMENT:

PROVIDER: _____

PROGRAM DIRECTOR: _____

DATE COMPLETED: _____

VALIDATION:

NYSDOH REVIEWER(S): _____

_____

SBHC SITE(S):	SITE COORDINATOR/PHONE NO:	DATE VISITED:

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PURPOSE:

The Performance Effectiveness Review Tool (**PERT**) is a document that includes the compilation of New York State Department of Health (**NYSDOH**) regulations, program guidelines and administrative policies. The PERT is completed to determine the quality and effectiveness of a school based health center (**SBHC**) and its compliance with contractual requirements. The self-assessment and validation sections of the PERT provide assurance that the required Principles and Guidelines for School Based Health Centers in New York (**Guidelines**) are being adequately met.

Early, Periodic Screening, Diagnosis and Treatment (**EPSDT**), also known as Child/Teen Health Plan (**C/THP**) in New York State is a federally mandated program that establishes standards for pediatric care, including a periodicity schedule that helps ensure that all children (0-21 years) receive quality, comprehensive health care services that are age specific to their growth and development. The current schedule is generally consistent with American Academy of Pediatrics (**AAP**) guidelines and recommendations, and compliance is **required** for all Medicaid (**MA**), MA Managed Care (**MA/MC**), and Child Health Plus (**CHP**) providers in New York State.

PERT PROCESS:

SELF ASSESSMENT-completed by the SBHC staff

- The PERT utilizes a process of provider self assessment and subsequent validation by a NYSDOH review team.
- This process provides the SBHC with an opportunity to assess its program's quality and effectiveness by determining if the SBHC has **met** the various components of the Guidelines, as identified by specific items throughout the PERT. The SBHC staff **describes** how each item listed is used to carry out SBHC activities. For those items that are "**not met**", staff must describe reasons and what efforts and progress have been made to address that item.
- If an item is met, the box should be checked. If an item is not met, the box should be left blank.
- The SBHC staff should also identify the areas where they need additional technical assistance (**TA**).
- This portion is completed by the SBHC and returned to NYSDOH one week prior to the on-site review.
- 4next to the section means this section must be completed for the pre-opening certification.

VALIDATION completed by NYSDOH staff

- The validation process includes (1) review of the self assessment portion of the PERT; (2) a Comprehensive Site Review visit at selected SBHC site(s) by NYSDOH staff; and 93) completion of the Review Summary which outlines the SBHC's strengths, needs and priority actions and recommendations needed for program improvement.
- This portion is completed during the NYSDOH site review.

EXIT CONFERENCE

- The Comprehensive Site Review visit concludes with an exit conference during which findings are summarized and recommendations for improvement are made.

FOLLOW-UP

- After completion of the Comprehensive Site Review, NYSDOH regional staff will send a letter to the SBHC Program Director. It will include a copy of the completed and validated PERT, including the Clinical Record Review and the Site Review Summary which addresses strengths, areas needing improvement and priority items that require immediate attention and an action plan. An **ACTION PLAN** must be submitted to NYSDOH within 6 weeks of receipt of the summary. It should include strategies for approval and activities to correct the item, policies and procedures to support the activities, a timeline for implementation, staff responsible, and evaluation measures. TA from NYSDOH is available as needed throughout the process. Additional on-site visits to evaluate changes, operational improvements and the degree of progress will be scheduled as necessary.

DIRECTIONS

SECTION I: ADMINISTRATIVE REVIEW:

To be completed by the SBHC staff.

SECTION II: SITE SPECIFIC REVIEW:

To be completed by the SBHC staff.

SELF ASSESSMENT:

For the items/requirements in Sections I and II, the SBHC staff should check the **( )** next to each item, if met. As applicable, describe where it can be found in the **LOCATION** column (i.e. policy and procedure manual #). Where indicated, describe how the SBHC uses the checked items to carry out the required SBHC activities, including those noted in the workplan. Staff must also identify areas where TA is needed.

To complete the self-assessment, the SBHC must check all appropriate items specific to its program. As an example, see Section I B. Outreach/Education #4. At the bottom of the page the SBHC **DESCRIBES** how any checked items are used to carry out SBHC activities (i.e.) "SBHC staff is present for all pre-K enrollments. School Office provides packet of information for other new school enrollees and refers to SBHC for further information. SBHC is staffed during all school "open house" nights for enrollment, health information or tours by parents visiting the school. Direct mailings are used to remind parents to re-enroll/update demographic information. Telephone calls are also used for this purpose. The SBHC has its own "homework Hotline" telephone number listed in the newspaper for pre-recorded information as well as information on health topics. The SBHC now publishes its own newsletter quarterly. Articles are still submitted to school and local newspapers."

NYSDOH VALIDATION:

In Sections I and II, NYSDOH staff will provide comments and/or an explanation noting whether or not the item/requirement is fully met.

SECTION III: CLINICAL RECORD REVIEW:

To be completed by NYSDOH review team. Generally, the NYSDOH review team will randomly select and review a minimum of 10 charts per site that are reflective of the SBHC enrollment. Depending on the number of students enrolled, the review team will have the discretion of either reviewing more or fewer records. The chart review tool to be used is enclosed.

SECTION IV: COMPREHENSIVE SITE REVIEW SUMMARY:

To be completed by the NYSDOH review team. Based on the information obtained from the Self Assessment, Validation, and Clinical Record Review Sections, the NYSDOH review team will summarize the SBHC's strengths, needs, and priority actions and recommendations needed for program improvement.

GLOSSARY

COMPREHENSIVE SITE REVIEW
An official program review to be conducted by a NYSDOH team to evaluate all aspects of the operation of school based health center projects. This evaluation will be conducted at a minimum every three years.

FOCUSED SITE REVIEW
An official program review to be conducted by a NYSDOH team to review selected aspects of the operation of a school-based health center(s). This review may be conducted between comprehensive site reviews based on performance as measured by previous comprehensive site reviews and the ability to achieve workplan goals and objectives.

INTERIM VISITS/CONTACT
Site visits or telephone calls made by regional office staff or central office staff for follow-up on comprehensive site reviews and/or to provide needed technical assistance and consultation between review visits.

"NEW SITE"
A school-based health center that has not previously been in operation. This may apply to a provider who already operates other school based health center sites or one who has never operated any sites.

PERT
The Performance Effectiveness Review Tool is used to evaluate the operation of the school based health center(s). The tool includes an administrative and site-specific self-assessment to be completed by the school based health center provider and an on-site validation to be completed by NYSDOH school health regional and/or central office staff. The tool is used for pre-opening certification, focused reviews and comprehensive site reviews.

PRE-OPENING CERTIFICATION VISIT
A site visit to a newly established school based health center site by NYSDOH regional staff to conduct an evaluation of the provider's readiness to provide services. Selected portions of the PERT, including the self-assessment and NYSDOH validation, will be used to determine program readiness.

PRE-OPENING TECHNICAL ASSISTANCE
Technical assistance and consultation provided by regional staff and/or central office staff to the provider in preparation for the opening of a new school based health center.

SELF-ASSESSMENT
A narrative description of strategies employed by a school based health center provider to meet programmatic guidelines and/or achieve goal and objectives of a workplan. This narrative is completed by the school based health center provider using the PERT prior to a pre-opening, focused or comprehensive site review.

SITE-REVIEW TEAM
NYSDOH staff comprised of regional and central office staff and other resource persons as needed to conduct the Comprehensive Site Review. Regional office staff will act as team leader in the coordination of the site review. Central and regional office staff will jointly determine the other team members, when indicated.

SECTION I
ADMINISTRATIVE REVIEW

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4 A. ORGANIZATION/ADMINISTRATION	**LOCATION**	**NYSDOH VALIDATION**
( ) 1. Current Mission Statement		
( ) 2. Organizational Chart (Attach copy which shows Article 28/SBHC relationship and annual renewal/revision.)		
( ) 3. Agreements/Contracts/MOUs ( ) NYSDOH approval ( ) Article 28 (**A28**) provider. *( ) Clinical training and internships ( ) School district(s), including in-school resources ( ) 24 hour back-up facility ( ) Medicaid Managed Care Organizations ( ) Child Health Plus Organizations ( ) Third party payors ( ) Transfer/referral agreements As applicable: ( ) County Public Health ( ) County Social Services Departments ( ) County Mental Health Services ( ) NYC Board of Education ( ) Adolescent Pregnancy Prevention Program(s) ( ) PCAPs/MOMS ( ) Others (list) *Should include description of duties, orientation, and supervision in the SBHC per A28 guidelines		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is "not met", describe the reason(s) and what effort(s)/progress has been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4**B. OUTREACH/EDUCATION AND ENROLLMENT**	**LOCATION**	**NYSDOH VALIDATION**
( ) 1. SBHC staff and school personnel cooperate/coordinate publicity and outreach.		
( ) 2. A person(s) is designated for outreach.		
( ) 3. Information of SBHC enrollment eligibility and services is shared with whole student body and faculty/staff at least twice a year.		
4. Students are recruited. Procedures include: ( ) school enrollment ( ) mailings ( ) bulletin board/posters ( ) student newspapers ( ) campaign/PSAs ( ) newspaper articles ( ) other (specify) _____ _____		
5. Enrollment process includes: ( ) securing the consent for care ( ) securing a signed release for medical records (to and from other providers) ( ) assisting with MA or CHP enrollment and ( ) transmitting all billing/fiscal information to A28.		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is "not met", describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4**C. PERSONNEL**	**LOCATION**	**NYSDOH VALIDATION**
( ) 1. The program assures recruitment and employment without regard to age, sex, race, religion or sexual orientation.		
( ) 2. Standards exist for provider credentials, assuring employees are qualified by license and registration (where applicable).		
( ) 3. Job descriptions/orientation plan, curricula vitae and resumes are on file.		
( ) 4. Copies of staff licenses, registrations and certifications are up-to-date.		
( ) 5. Employee records are maintained in accordance with Title 10/NYCRR. ( ) Medical requirements Staff Development: ( ) Child Abuse/Neglect ( ) Infectious Disease Control ( ) Right to Know ( ) CPR/First Aid Training ( ) Confidentiality (HIV and general) ( ) Other professional training ( ) Annual Performance Evaluation		
( ) 6. Procedures exist for staff reporting illnesses which may impact personnel and/or student health.		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is “not met”, describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4**D. WRITTEN POLICIES, PROCEDURES & PROTOCOLS**	**LOCATION**	**NYSDOH VALIDATION**
( ) 1. ADMINISTRATION Policies, procedures & protocols are: ( ) developed, reviewed and/or revised annually ( ) available at each site Policies, procedures and protocols include: ( ) maintenance of records at SBHC and at 24 hour back-up facility for after-hours, weekends and vacations ( ) transfer of records for referrals upon request and consent ( ) communication with primary care provider (**PCP**) ( ) documentation of reportable incidents/findings (in collaboration with school as appropriate) and follow-up ( ) communication with parents re: non-confidential and emergency services ( ) communication with appropriate school personnel re: emergency services necessary for enrolled students ( ) School-Based Health Center Guidelines		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is "not met", describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4**D. WRITTEN POLICIES, PROCEDURES & PROTOCOLS**	**LOCATION**	**NYSDOH VALIDATION**
2. a. CLINICAL SERVICES – Administration ( ) Nurse Practitioner/Physician's Assistant has current, signed collaborative agreement with physician. ( ) Current protocols for triage, treatment and comprehensive physical exam exist. ( ) Staff have access to medical reference materials *( ) Medications: prescriptions, stock, administration, security and disposal *( ) Laboratory *( ) Specimen collection/transport *( ) Reporting of results/posting/follow-up ( ) Medical record format reflects EPSDT. ( ) Referrals for off-site services, coordination and follow-up exist. Systems exist for: ( ) appointment scheduling and follow-up ( ) logging and tracking walk-ins, including the documentation of chief complaint, clinical assessments and interventions ( ) tracking need, timing and documentation for comprehensive physical assessments ( ) tracking immunizations, lead, TB and other EPSDT required screenings ( ) maintenance of adequate supplies/equipment *Describe procedures and attach A28 policies and procedures for these items.		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is "not met", describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4**D. WRITTEN POLICIES, PROCEDURES & PROTOCOLS**	**LOCATION**	**NYSDOH VALIDATION**
2.b. CLINICAL SERVICES – Delivery **This is a review of your written policies and procedures. The actual practice of these protocols will be evaluated in the Site Specific section of the PERT.**		
COMPREHENSIVE HISTORY AND PHYSICAL ASSESSMENT ( ) growth ( ) nutrition ( ) anthropometry ( ) age-appropriate developmental ( ) immunizations ( ) reproductive ( ) psychosocial/behavioral	Please attach a blank medical record and assessment tools that are used	
SCREENINGS (per EPSDT) ( ) vision, including color perception ( ) hearing ( ) speech/articulation ( ) dental ( ) scoliosis ( ) lead (as indicated) ( ) sickle cell testing (as indicated) ( ) TB sensitivity/Mantoux		
INTERIM EXAMS/CARE ( ) follow-up acute and/or abnormal findings ( ) chronic disease management/medications ( ) new acute ( ) urgent ( ) emergent ( ) sports/work physicals	.	

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is “not met”, describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4**D. WRITTEN POLICIES, PROCEDURES & PROTOCOLS**	**LOCATION**	**NYSDOH VALIDATION**
2. b. CLINICAL SERVICES - Delivery		
HEALTH EDUCATION AND HEALTH COUNSELING ( ) general health and specific diagnosis ( ) nutrition ( ) psychosocial/behavioral (smoking, substance abuse, violence) ( ) HIV/AIDS (pre and post test) ( ) other Sessions available to: ( ) individual ( ) parents only ( ) group ( ) student with parent Materials and resources used: ( ) Additional health counseling based on high risk indicators		
DENTAL (if applicable) Preventive Services Treatment Services ( ) examination ( ) restoration ( ) x-rays ( ) extractions ( ) oral prophalyxis ( ) other (specify) ( ) fluoride supplements (drops/tabs) ( ) sealants ( ) referral for diagnosis/treatment ( ) follow-up ( ) other (specify)		
MENTAL HEALTH ( ) assessment (specify tools used) Sessions available to: ( ) follow-up specific diagnosis ( ) individual ( ) crisis management ( ) group *( ) referral process ( ) parents only ( ) treatment ( ) student with parent(s) Materials and resources used: *Describe relationship with any in-school mental health resources		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is “not met”, describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4**D. WRITTEN POLICIES, PROCEDURES & PROTOCOLS**	**LOCATION**	**NYSDOH VALIDATION**
3. ENVIRONMENTAL (OSHA standards are applied.) ( ) infection control ( ) medical waste, including sharps ( ) security ( ) disposal ( ) routine cleaning and maintenance ( ) equipment calibration and maintenance ( ) fire drills ( ) disaster plan ( ) medical emergency plan/crisis plan ( ) coordination of medical emergencies for enrolled and non-enrolled students ( ) defined roles and responsibilities of individual SBHC staff and school personnel		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is "not met", describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4E. FISCAL MANAGEMENT	**LOCATION**	**NYSDOH VALIDATION**
1. ADMINISTRATION ( ) A28 has staff responsible for SBHC fiscal management. name(s), title(s), and location: _____ ( ) A system of routine periodic communication between SBHC and A28 exists. ( ) Periodic review and discussion of encounter and financial data to assess program stability, growth, and financial viability occurs. ( ) An annual SBHC budget is calculated (reflects total cost of operations and projected revenue). In-kind and other funding streams are identified (attach current budget). ( ) Written policies and procedures exist for fiscal management of the SBHC.		
2. ACCOUNTING/RECORD KEEPING: ( ) The A28 maintains an accounting manual which is consistent with general accounting principles for program/fiscal management. ( ) Date of last fiscal audit _____ ( ) Receipts and expenditures are identified for each contract/source of funds. ( ) FTE levels are consistent with operating budget. ( ) DOH purchased equipment is tagged. ( ) Inventories for purchased equipment are maintained, current, and annually updated. Person responsible: _____ ( ) For funded programs, vouchers are prepared at least quarterly. and submitted to NYSDOH with a copy to the regional office. A copy is maintained on site with original supporting documentation. ( ) Budget modification requests are submitted to regional staff for review and recommendations.		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is “not met”, describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4**E. FISCAL MANAGEMENT**	**LOCATION**	**NYSDOH VALIDATION**
3. BILLING: ( ) Staff responsible for billing SBHC services Name(s), title(s), location(s): _____ _____ _____ ( ) On site SBHC services are provided with no out-of-pocket expense to the family. ( ) A sliding fee scale that is consistent with expanded MA and Child Health Plus guidelines is in place and operationalized. (Attach copy.) ( ) Procedures are in place for determining and verifying third party insurance status including: ( ) Medicaid ( ) Child Health Plus ( ) Managed Care ( ) Private Insurance ( ) There is third party notification and billing for all eligible visits using the appropriate locator codes. ( ) There is follow-up of all claim denials. ( ) Third party revenues are readily identifiable and returned to the program to enhance and sustain the SBHC.		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is “not met”, describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4F. DATA MANAGEMENT POLICIES/PROCEDURES	**LOCATION**	**NYSDOH VALIDATION**
1. CONFIDENTIALITY restricts access and use of: ( ) computer files/logs ( ) schedules and appointment books ( ) client records ( ) SBHC data		
2. COLLECTION/USE OF AGGREGATE DATA is: ( ) shared with A28 Board of Directors ( ) shared with SBHC Advisory Council ( ) incorporated into CQI/QA Process		
3. REPORTING REQUIREMENTS: ( ) Quarterly Report preparation ( ) Annual Profile preparation		( ) submitted to NYSDOH, with copy to the Regional Staff, within 60 days of the end of the reporting period

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is "not met", describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

G. CONTINUOUS QUALITY IMPROVEMENT	**LOCATION**	**NYSDOH VALIDATION**
4( ) 1. A SBHC person is designated as the CQI Coordinator. Designated individual: _____ This individual should be a member of the Health Advisory Council.		
4( ) 2. The CQI committee membership reflects expertise from all health-related disciplines and is responsible for approving the overall CQI plan as well as reviewing and responding to the results. (Attach member's names, titles & affiliations.)		
( ) 3. Critical school and community input is achieved through the reporting of CQI results to the Advisory Council by the CQI Coordinator.		
( ) 4. Together the committee and council review the delivery of SBHC services and provide guidance for ongoing program development.		
( ) 5. The CQI committee meets at least quarterly. (Attach minutes for the previous year.)		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is "not met", describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

G. CONTINUOUS QUALITY IMPROVEMENT	**LOCATION**	**NYSDOH VALIDATION**
6. The CQI Plan developed and implemented is based on needs assessment and previous CQI activities and includes at least the following on a quarterly basis: ( ) a distinct focus on each of the following areas: administration, clinical, consumer satisfaction (patient/student, family and school personnel), community outreach and education and complaint investigation ( ) structure, process and outcome measures appropriate to the area of study ( ) the collection and analysis of data for each area studied/ assessed ( ) the development and implementation of strategies to address areas of concern that need improvement ( ) periodic re-evaluation of new strategies to assess effectiveness		
7. A written CQI Outcome Report (based on the activities in #6) includes the following elements and is reviewed by the CQI Committee: ( ) SBHC policies and procedures that reflect workgroup outcomes and programmatic requirements ( ) strong evidence of continuous communication with staff		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is "not met", describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check **( )** next to item if met. Leave **( )** blank if not met. As applicable, describe where the item can be found in the **LOCATION** column. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4H. ADVISORY COUNCIL	**LOCATION**	**NYSDOH VALIDATION**
( ) 1. The SBHC has an Advisory Council with active member participation, representative of its constituency		
( ) 2.Advisory council membership reflects areas of needed expertise. List members names and titles: (may attach listing). Chair: _____ Administration A28 Provider: _____ SBHC CQI Coordinator:_____ School: _____ School School Nurse: _____ Faculty: _____ Students: _____ Community/Parents: _____ Mental Health: _____ Other: _____		
( ) 3. The SBHC Advisory Council is oriented to its role and the SBHC services.		
( ) 4. Advisory Council meetings are scheduled on a regular basis (at least quarterly). (Attach schedule and minutes.)		

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is "not met", describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check box next to item if test is ordered. Leave box blank if test is not ordered. Check appropriate box if lab specimen is collected and/or performed on site. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4CLIA # _____ **Permanent Facility Identifier** _____

I. LABORATORY TESTS	ORDERED	COLLECTED	PERFORMED	NYSDOH VALIDATION
Hemoglobin/Hematocrit				
Sickle Cell Test				
Lead Screening				
Urinalysis – Microscopic (ppmp only)				
Stool Examination/Culture				
Throat Culture				
Wound Culture				
G.C. Culture				
Syphilis Serology				
Chlamydia Testing				
Pregnancy Test (serum)				
HIV Testing				
Other				

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is "not met", describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

DIRECTIONS: Check box next to item if test is ordered. Leave box blank if test is not ordered. Check appropriate box if lab specimen is collected and/or performed on site. NYSDOH staff completes the **NYSDOH VALIDATION** column.

4I. LABORATORY WAIVED TESTS	**ORDERED**	**COLLECTED**	**PERFORMED**	**NYSDOH VALIDATION**
Dipstick or tablet reagent urinalysis				
Fecal occult blood				
Ovulation test				
Urine pregnancy test (by waived kit)				
Erythrocyte sediment rate				
Blood glucose (approved for home use)				
Hemoglobin-copper sulfate				
Spun micro hematocrit				
Hemoglobin by single analyte instrument				
Blood cholesterol test (by waived instrument)				
Cholesterol L*D*X system				
Strep test (by waived test)				
Serum Pyloritek Test Kit				
Smith Kline Gastrocult				

SUMMARIZE how the SBHC uses the above items/requirements to carry out SBHC activities. If the item/requirement is “not met”, describe the reasons and what efforts and progress have been made to address that item/requirement. Please identify area(s) where TA is needed. (Use additional sheets if necessary.)

4J. WORKPLAN: (dates) _____ to _____

Directions:

- **Attach a copy of the current workplan for all SBHC sites.**
- **For each objective, put an 'S' if the activities are the same of a 'C' if the activities have changed from current work plans.**
- **In the 'Outcomes Achieved' column, specify the progress that has been made for each objective.**
- **If additional objectives were added, please add them to the end of the workplan. Use additional sheets if needed.**

WORKPLAN
D-1

GOAL: _____
_____
_____

Formal needs assessment
Completed by: _____

OBJECTIVES	SPECIFIC ACTIVITIES	TIME FRAME	PERSON(S) RESPONSIBLE	EVALUATION MEASURES
1. By the end of the school year, enrollment in the SBHC will be % of the total high school population (minimum of 70%) or ___ % of the total elementary or middle school population (minimum of 80%).				
2. By the end of the school year, 100% of all of the students enrolled in the SBHC will have a **current** comprehensive physical exam (CPE) on record (either from the SBHC or the student's primary care provider).				
3a. By the end of the school year, 100% of the students enrolled in the SBHC will have a current mental health screening. ---------- 3b. It is expected that ____% of those screened will need further mental health services and will be referred appropriately.				
4. By the end of the school year, 100% of the students identified with asthma will have a treatment plan in place.				
5. 100% of the enrolled students will be up-to-date on required immunizations.				
6. 100% of enrolled students will have a developmentally appropriate risk assessment to include injury, safety, violence, diet/exercise, substance use and passive exposure, abuse and sexuality and a treatment plan in place.				

4**J. WORKPLAN: (dates) _____ to _____**

Directions:

- **Attach a copy of the current workplan for all SBHC sites.**
- **For each objective, put an 'S' if the activities are the same of a 'C' if the activities have changed from current work plans.**
- **In the 'Outcomes Achieved' column, specify the progress that has been made for each objective.**
- **If additional objectives were added, please add them to the end of the workplan. Use additional sheets if needed.**

WORKPLAN
D-1

GOAL: _____
_____
_____

Formal needs assessment
Completed: _____
date

OBJECTIVE	STATUS	OUTCOMES ACHIEVED/DATE	NYSDOH VALIDATION
	S _____ C _____		
	S _____ C. _____		
	S _____ C _____		
	S _____ C _____		
	S _____ C _____		
	S _____ C _____		

DIRECTIONS: Attach copy of the current D-2 form for each SBHC site (from contract or application). Check the "**New**" column if the SBHC is a new site. List the SBHC site in the first column and note any operational or staffing changes in the second column. NYSDOH staff completes **NYSDOH VALIDATION**.

K. SITE-SPECIFIC INFORMATION
(Table D-2: *Please complete one form per school.*)

School Site: _____ **District:** _____ **Provider:**_____
Address: _____
_____

City: _____ **State:** _____ **Zip:** _____
Phone: _____ **Fax:** _____

SBHC Category
_____ **Intermediate**
_____ **Comprehensive**

Total School Population: _____
Grade levels: _____
Total Students Enrolled in SBHC: _____

Socio-economic Status:
% free/reduced lunch _____

Insurance Status Estimates:
% fee-for-service Medicaid: _____
% Medicaid Managed Care: _____
% Other 3rd party fee-for service: _____
% Other 3rd party Managed Care: _____
% Child Health Plus: _____
% Uninsured: _____

Ethnic/Racial Breakdown (% of school population):
Asian: _____ White, non-Hispanic,
Black: _____ non-Asian: _____
Hispanic: _____ Bi-racial: _____
Native American: _____
Unknown: _____

Services: Check the appropriate box to indicate where the following services will be provided:

	On-Site	By Referral
Enrollment, Parental Consent & Outreach		
Comprehensive Health Assessments (Physical/Mental)		
Diagnosis & Treatment for Medical Conditions		
Mental Health and Crisis Intervention		
Prescriptions		
Laboratory Testing		
Reproductive Health Care		
Health Education/Promotion		
Social Services		
Dental Care: Preventive Services		
Dental Care: Treatment Services		
Nutrition Services		
Specialty Care (specify)		
Other:		

STAFFING PATTERN BY NUMBER OF HOURS WORKED PER DAY

DIRECT SERVICE STAFF	# FTEs	Monday		Tuesday		Wednesday		Thursday		Friday	
		Hours per Day		Hours per Day		Hours per Day		Hours per Day		Hours per Day	
		on-	off-	on-	off-	on-	off-	on-	off-	on-	off-
Physician											
NP/PA											
Health Aide											
Soc. Work Sup.											
Social Worker											
Other (list):											
Nutritionist											
Health Educator											
School Nurse											

Total FTEs = _____ 1 FTE = _____ hours per week

DIRECTIONS: Attach copy of the current D-2 form for each SBHC site (from contract or application). Check the '**New'** column if the SBHC is a new site. List the SBHC site in the first column and note any operational or staffing changes in the second column. NYSDOH staff completes **NYSDOH VALIDATION**.

K. SITE-SPECIFIC INFORMATION			
SBHC Site	**NEW**	**CHANGES**	**NYSDOH VALIDATION**
1.			
2.			
3.			
4.			

DIRECTIONS: Signatures must be included with the self-assessment. Signature pages must be submitted in hard copy.

I certify that this information in Section I A-K is true and correct to the best of my knowledge.

_____	_____
Name (Please print)	Title (administrative)
_____	_____ _____
Signature	Date Phone
_____	
E-Mail	

_____	_____
Name (Please print)	Title (fiscal)
_____	_____ _____
Signature	Date Phone
_____	
E-Mail	

SECTION II.
SITE SPECIFIC REVIEW

(Duplicate sections for each site as needed)

DIRECTIONS: Check **( )** if requirement is met. Leave **( )** blank if not met. Under **DESCRIPTION**, describe how the SBHC is consistent with the SBHC guidelines for that issue. NYSDOH staff completes **NYSDOH VALIDATION**.

4A. ACCESSIBILITY	**DESCRIPTION**	**NYSDOH VALIDATION**
( ) 1. SBHC space is clearly marked.		
( ) 2. Security measures do not unduly restrict access.		
( ) 3. Clinic hours are clearly posted.		
( ) 4. Clients and their families are informed that services are available year round, 24 hours a day, 7 days a week.		
( ) 5. The site provides a summer program. (Optional)		
( ) 6. Enrollees are informed that walk-in services are available.		
( ) 7. Clients are seen as close to their appointment time as possible.		

DIRECTIONS: Check **( )** if requirement is met. Leave **( )** blank if not met. Under **DESCRIPTION**, describe how the SBHC is consistent with the SBHC guidelines for that issue. NYSDOH staff completes **NYSDOH VALIDATION**.

4A. ACCESSIBILITY	**DESCRIPTION**	**NYSDOH VALIDATION**
( ) 8. Appointment compliance is within acceptable limits (≥80% at each site).		
9. Daily appointment schedule accommodates the following types of visits: ( ) comprehensive physical examinations (EPSDT) ( ) well child/health guideline ( ) acute care based on triage ( ) chronic disease management/medications ( ) urgent ( ) emergent ( ) walk-ins ( ) referrals ( ) follow-up care		
( ) 10. Mental health services are provided on site and/or by referral.		
4B. RECORD KEEPING	**DESCRIPTION**	**NYSDOH VALIDATION**
( ) 1. All clinical records (including mental health), and any logs are maintained on site in a confidential manner.		
( ) 2. A tickler/tracking system is in place for: ( ) periodicity of comprehensive PE's ( ) subsequent follow-up to treatment or care ( ) follow-up of laboratory testing ( ) follow-up of referrals ( ) follow-up of missed appointments ( ) other		

DIRECTIONS: Check **( )** if requirement is met. Leave **( )** blank if not met. Under **DESCRIPTION**, describe how the SBHC is consistent with the SBHC guidelines for that issue. NYSDOH staff completes **NYSDOH VALIDATION**.

At a minimum, comprehensive and interim visits include the following components: - chief complaint(s), review of systems (ROS), evaluation/re-evaluation of treatment, plan of care per clinical protocols and referral and follow-up.

C. SERVICES AVAILABLE	DESCRIPTION	NYSDOH VALIDATION
1. COMPREHENSIVE HISTORY AND PHYSICAL ASSESSMENT (per EPSDT) ( ) review of systems ( ) growth ( ) nutrition ( ) anthropometry ( ) age-appropriate developmental ( ) reproductive ( ) psychosocial/behavioral ( ) immunizations	Please attach a blank medical record and assessment tools that are used.	
2. SCREENINGS (per EPSDT) ( ) vision, including color perception ( ) hearing ( ) speech/articulation ( ) dental ( ) scoliosis ( ) lead (as indicated) ( ) sickle cell testing (as indicated) ( ) TB sensitivity/Mantoux		
3. INTERIM EXAMS/CARE ( ) follow-up acute and/or abnormal findings ( ) chronic disease management/medications ( ) new acute ( ) urgent ( ) emergent ( ) sports/work physicals		

DIRECTIONS: Check **( )** if requirement is met. Leave **( )** blank if not met. Under **DESCRIPTION**, describe how the SBHC is consistent with the SBHC guidelines for that issue. NYSDOH staff completes **NYSDOH VALIDATION**.

C. SERVICES AVAILABLE	**DESCRIPTION**	**NYSDOH VALIDATION**
4. HEALTH EDUCATION & HEALTH COUNSELING ( ) general health and specific diagnosis ( ) nutrition ( ) psychosocial/behavioral (i.e. smoking, substance abuse, violence) ( ) HIV/AIDS ( ) other Sessions available to: ( ) individual ( ) parents only ( ) group ( ) student with parents Materials & resources used: ( ) Additional health counseling is based on high-risk indicators.	Describe programs/activities	
5. DENTAL (if applicable) Preventive Services Treatment Services ( ) examination ( ) restoration ( ) x-rays ( ) extractions ( ) oral prophalyxis ( ) other (specify) ( ) fluoride supplements (drops/tabs) ( ) sealants ( ) referral for diagnosis/treatment ( ) follow-up ( ) other (specify)		
6. MENTAL HEALTH ( ) systematic assessment (specify tools used) ( ) treatment plan ( ) crisis intervention ( ) referral for psychiatric evaluation and treatment ( ) other referrals Sessions available to: ( ) individual ( ) parents only ( ) group ( ) student with parents List most-used referral professional/agencies: Materials & resources used:		

DIRECTIONS: Check **( )** if requirement is met. Leave **( )** blank if not met. Under **DESCRIPTION**, describe how the SBHC is consistent with the SBHC guidelines for that issue. NYSDOH staff completes **NYSDOH VALIDATION**.

4D. CLINICAL ENVIRONMENT	**DESCRIPTION**	**NYSDOH VALIDATION**
1. GENERAL SAFETY/EMERGENCY ( ) All water used is provided from an approved public water source or alternate source acceptable to NYS. ( ) Medical, fire, & emergency instructions and other procedures, including telephone numbers, are posted. ( ) Smoke detectors and general purpose and chemical fire extinguishers are in working order and within easy access of SBHC. ( ) Exits are clearly marked with escape routes posted. ( ) Passages, corridors, doorways and other means of exit are kept clear and unobstructed. ( ) The SBHC staff have keys for all bathrooms with inside locks; all bolt locks have been removed. ( ) There are no safety hazards from chemical, electrical, temperature-controlled, and/or from mechanical devices. ( ) Cleaning materials are appropriately labeled and stored in a locked, separate area. ( ) Toys in the waiting area are clean, safe, and age appropriate.		
2. PHYSICAL SPACE ( ) Type, size and location of rooms are consistent with SBHC guidelines. ( ) Exam rooms are well lit and ventilated. ( ) The patient's bill of rights is posted and available in other languages as necessary. ( ) The SBHC is equipped with a private phone/fax, affording confidentiality. ( ) Toilet facilities are accessible, clean, and in working order. ( ) There are designated clean and dirty areas. ( ) Hand-washing is located in a sanitary area with hot/cold water, antibacterial liquid soap, and hands-free operation. ( ) There is a designated laboratory area. ( ) There is a supervised infirmary area where students may recline and rest.		

DIRECTIONS: Check **( )** if requirement is met. Leave **( )** blank if not met. Under **DESCRIPTION**, describe how the SBHC is consistent with the SBHC guidelines for that issue. NYSDOH staff completes **NYSDOH VALIDATION**.

4D. CLINICAL ENVIRONMENT	**DESCRIPTION**	**NYSDOH VALIDATION**
3. SUPPLIES AND EQUIPMENT ( ) Laboratory and other clinical equipment are calibrated at regular intervals with quality control measures in place. ( ) Logs are maintained daily. Person responsible _____ ( ) Expiration dates on laboratory supplies are regularly checked and supplies are replaced. Person responsible _____ ( ) Refrigerator/freezer for "biologicals only" is operational. ( ) Functional thermometers are located in refrigerator, freezer, and incubators if used. ( ) Temperature logs are maintained daily for equipment. Person responsible _____ ( ) Covered waste receptacles, appropriately labeled with biohazard stickers, are in the exam, lab, bathroom, and other needed areas. ( ) Medical waste is clearly marked with biohazard stickers, is in red bags and disposed of in an approved manner. ( ) Sharp containers are locked, appropriately labeled with biohazard stickers and disposed of properly. ( ) A functional eye wash set up is available.		
4. MEDICINE ( ) A formulary or current PDR is available for use on site. ( ) Medication and sharps are appropriately stored in a locked area. This includes biologicals which are stored in refrigerators. ( ) Expiration dates on medications, including emergency meds, are routinely checked and expired medications replaced. Person responsible _____ ( ) Medication inventory process is in place. ( ) Expired drugs are disposed of appropriately. ( ) A labeled emergency box is available, appropriately equipped, and routinely checked for completeness and for expiration dates. Person responsible _____		

DIRECTIONS: Signatures must be included with the self-assessment. Signature pages must be submitted in hard copy. A signature page is required for each site.

I certify that this information in Section II A-D is true and correct to the best of my knowledge.

_____	_____
Name (Please print)	Title

_____	_____	_____
Signature	Date	Phone

_____

E-Mail

SECTION III.
CLINICAL RECORD REVIEW

(Duplicate as needed)

MEDICAL RECORDS
(For Reviewer use only)

PROVIDER _____
SBHC Site _____
Date _____

VISIT CODES: C – Complete physical; I – Interim acute or follow-up visit; M – Mental Health; C/PCP – Complete physical by student's own provider

CHART NUMBER															
TYPE OF VISIT (SEE CODE)															
DATE															
Grade															
Age															
Sex															
Enrollment															
Consent															
Complete History															
Complete Psycho-Social Assessment															
Review of Systems															
Nutrition Assessment															
Age Appropriate Developmental Assessment															
Immunization															
Tuberculin Screen/Testing															
Lead Screening/Testing															
Sickle Cell Status: Assess./Screen															
Anthropometry															
Reproductive Assessment															
Tanner Staging															
Hearing Screening															
Vision Screening															
Dental Screening															
Scoliosis Screening															
B/P															
Labs/Diagnostics															
Impression															
Plan															
Care Coordination															
Health Ed./Counseling															
Referral															
Follow-up															
Resolution															
Chart Legible Dated Signed															
Mental Health Assessment															
Impression															
Plan															
Care Coordination															
Referral															
Follow-up															
Resolution															
Chart Legible Dated Signed															

DOCUMENTATION CODES: T – Thorough documentation in record; P – Inconsistent/partial documentation in record; N/A – Not applicable in this record; M – Minimal documentation in record; U – Not documented in record

CHART AUDIT: ADDITIONAL DISCUSSIONS OF SELECTED FINDINGS

PROVIDER _____ **DATE** _____

SITE _____ **PAGE** _____

Identified Issue(s)	**Identified Issue(s)**
Chart #/Name: _____ Identified Health Issue(s):	**Chart #/Name:** _____ Identified Health Issue(s):
Chart #/Name: _____ Identified Health Issue(s):	**Chart #/Name:** _____ Identified Health Issue(s):
Chart #/Name: _____ Identified Health Issue(s):	**Chart #/Name:** _____ Identified Health Issue(s):

General Comments/Recommendations for Improvement:

SECTION IV.
COMPREHENSIVE SITE REVIEW SUMMARY

NEW YORK STATE DEPARTMENT OF HEALTH
SCHOOL BASED HEALTH CENTER PROGRAM

PERFORMANCE EFFECTIVENESS REVIEW TOOL (PERT)

SECTION IV: COMPREHENSIVE SITE REVIEW SUMMARY

Provider: _____

_____

Date of Review: _____
Reviewers: _____

Facility Provider Administration:	**SBHC Program Director:**
Name _____	**Name** _____
Mailing Address _____	**Mailing Address** _____
Phone _____ **Fax** _____	**Phone** _____ **Fax** _____
E-Mail _____	**E-Mail** _____

COMPREHENSIVE SITE REVIEW SUMMARY (Cont'd.)

1. PROGRAM STRENGTHS: For each PERT section, summarize program strengths. (Administration, Site Specific and Record Review)

COMPREHENSIVE SITE REVIEW SUMMARY (Cont'd.)

2. AREAS IN NEED OF IMPROVEMENT

Administration:

Site Specific:

Clinical Record Review
(See Clinical Review for each site.)

COMPREHENSIVE SITE REVIEW SUMMARY (Cont'd.)

3. PRIORITIES REQUIRING ACTION PLAN

Administration:

Site Specific:

Action Plan due within six weeks of receipt of summary

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OSC Use Only:
Reporting Code:
Category Code:
Date Contract Approved:

FORM A

State Consultant Services - Contractor's Planned Employment From Contract Start Date Through The End Of The Contract Term

State Agency Name: Agency Code:
Contractor Name: Contract Number:
Contract Start Date: / / Contract End Date: / /

Employment Category	Number of Employees	Number of hours to be worked	Amount Payable Under the Contract
Total this page	0	0	$ 0.00
Grand Total			

Name of person who prepared this report:
Title: Phone #:
Preparer's Signature:
Date Prepared: / /
(Use additional pages, if necessary) Page of

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0FORM B

OSC Use Only:
Reporting Code:
Category Code:

State Consultant Services
Contractor's Annual Employment Report
Report Period: April 1, to March 31,

Contracting State Agency Name: Agency Code:
Contract Number:
Contract Term: / / to / /
Contractor Name:
Contractor Address:
Description of Services Being Provided:

Scope of Contract (Choose one that best fits):
Analysis ☐ Evaluation ☐ Research ☐ Training ☐
Data Processing ☐ Computer Programming ☐ Other IT consulting ☐
Engineering ☐ Architect Services ☐ Surveying ☐ Environmental Services ☐
Health Services ☐ Mental Health Services ☐
Accounting ☐ Auditing ☐ Paralegal ☐ Legal ☐ Other Consulting ☐

Employment Category	Number of Employees	Number of Hours Worked	Amount Payable Under the Contract
Total this page	0	0	$ 0.00
Grand Total			

Name of person who prepared this report:
Preparer's Signature:_____
Title: Phone #:
Date Prepared: / /

Use additional pages if necessary) Page of

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New York State Department of Taxation and Finance

Contractor Certification to Covered Agency

(Pursuant to Section 5-a of the Tax Law, as amended, effective April 26, 2006)

ST-220-CA

(6/06)

For information, consult Publication 223, *Questions and Answers Concerning Tax Law Section 5-a* (see *Need Help? on back*).

Contractor name				*For covered agency use only* *Contract number or description*
Contractor's principal place of business	City	State	ZIP code	
Contractor's mailing address *(if different than above)*				*Estimated contract value over the full term of contract (but not including renewals)* $
Contractor's federal employer identification number (EIN)	Contractor's sales tax ID number (if different from contractor's EIN)			
Contractor's telephone number	Covered agency name			
Covered agency address				*Covered agency telephone number*

I, _____ , hereby affirm, under penalty of perjury, that I am _____
(name) *(title)*

of the above-named contractor, that I am authorized to make this certification on behalf of such contractor, and I further certify that:

(Mark an **X** *in only one box)*

☐ The contractor has filed Form ST-220-TD with the Department of Taxation and Finance in connection with this contract and, to the best of contractor's knowledge, the information provided on the Form ST-220-TD, is correct and complete.

☐ The contractor has previously filed Form ST-220-TD with the Tax Department in connection with _____
(insert contract number or description)

and, to the best of the contractor's knowledge, the information provided on that previously filed Form ST-220-TD, is correct and complete as of the current date, and thus the contractor is not required to file a new Form ST-220-TD at this time.

Sworn to this ____ day of _____, 20 _____

_____ _____
(sign before a notary public) *(title)*

Instructions

General information

Tax Law section 5-a was amended, effective April 26, 2006. On or after that date, in all cases where a contract is subject to Tax Law section 5-a, a contractor must file (1) Form ST-220-CA, *Contractor Certification to Covered Agency,* with a covered agency, and (2) Form ST-220-TD with the Tax Department before a contract may take effect. The circumstances when a contract is subject to section 5-a are listed in Publication 223, Q&A 3. This publication is available on our Web site, by fax, or by mail. (See *Need help?* for more information on how to obtain this publication.) In addition, a contractor must file a new Form ST-220-CA with a covered agency before an existing contract with such agency may be renewed.

If you have questions, please call our information center at 1 800 698-2931.

Note: Form ST-220-CA must be signed by a person authorized to make the certification on behalf of the contractor, and the acknowledgement on page 2 of this form must be completed before a notary public.

When to complete this form

As set forth in Publication 223, a contract is subject to section 5-a, and you must make the required certification(s), if:

i. The procuring entity is a *covered agency* within the meaning of the statute (see Publication 223, Q&A 5);

ii. The contractor is a *contractor* within the meaning of the statute (see Publication 223, Q&A 6); and

iii. The contract is a *contract* within the meaning of the statute. This is the case when it (a) has a value in excess of $100,000 and (b) is a contract for *commodities* or *services*, as such terms are defined for purposes of the statute (see Publication 223, Q&A 8 and 9).

Furthermore, the procuring entity must have begun the solicitation to purchase on or after January 1, 2005, and the resulting contract must have been awarded, amended, extended, renewed, or assigned *on or after April 26, 2006* (the effective date of the section 5-a amendments).

Individual, Corporation, Partnership, or LLC Acknowledgment

STATE OF }
: SS.:
COUNTY OF }

On the ____ day of _____ in the year 20___ , before me personally appeared_____ ,

known to me to be the person who executed the foregoing instrument, who, being duly sworn by me did depose and say that

_he resides at _____ ,

Town of _____ ,

County of _____ ,

State of _____; and further that:

[Mark an ***X*** in the appropriate box and complete the accompanying statement.]

☐ (If an individual): _he executed the foregoing instrument in his/her name and on his/her own behalf.

☐ (If a corporation): _he is the_____

of_____ , the corporation described in said instrument; that, by authority of the Board of Directors of said corporation, _he is authorized to execute the foregoing instrument on behalf of the corporation for purposes set forth therein; and that, pursuant to that authority, _he executed the foregoing instrument in the name of and on behalf of said corporation as the act and deed of said corporation.

☐ (If a partnership): _he is a _____

of_____ , the partnership described in said instrument; that, by the terms of said partnership, _he is authorized to execute the foregoing instrument on behalf of the partnership for purposes set forth therein; and that, pursuant to that authority, _he executed the foregoing instrument in the name of and on behalf of said partnership as the act and deed of said partnership.

☐ (If a limited liability company): _he is a duly authorized member of _____ , LLC, the limited liability company described in said instrument; that _he is authorized to execute the foregoing instrument on behalf of the limited liability company for purposes set forth therein; and that, pursuant to that authority, _he executed the foregoing instrument in the name of and on behalf of said limited liability company as the act and deed of said limited liability company.

_____
Notary Public

Registration No.
_____

Privacy notification

The Commissioner of Taxation and Finance may collect and maintain personal information pursuant to the New York State Tax Law, including but not limited to, sections 5-a, 171, 171-a, 287, 308, 429, 475, 505, 697, 1096, 1142, and 1415 of that Law; and may require disclosure of social security numbers pursuant to 42 USC 405(c)(2)(C)(i).

This information will be used to determine and administer tax liabilities and, when authorized by law, for certain tax offset and exchange of tax information programs as well as for any other lawful purpose.

Information concerning quarterly wages paid to employees is provided to certain state agencies for purposes of fraud prevention, support enforcement, evaluation of the effectiveness of certain employment and training programs and other purposes authorized by law.

Failure to provide the required information may subject you to civil or criminal penalties, or both, under the Tax Law.

This information is maintained by the Director of Records Management and Data Entry, NYS Tax Department, W A Harriman Campus, Albany NY 12227; telephone 1 800 225-5829. From areas outside the United States and outside Canada, call (518) 485-6800.

Need help?

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Fax-on-demand forms: 1 800 748-3676

Telephone assistance is available from 8:00 A.M. to 5:00 P.M. (eastern time), Monday through Friday. 1 800 698-2931

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Contractor name				*For covered agency use only* *Contract number or description*
Contractor's principal place of business	City	State	ZIP code	
Contractor's mailing address *(if different than above)*				*Estimated contract value over the full term of contract (but not including renewals)* $
Contractor's federal employer identification number (EIN)	Contractor's sales tax ID number (if different from contractor's EIN)			
Contractor's telephone number	Covered agency name			
Covered agency address				*Covered agency telephone number*

I, _____ , hereby affirm, under penalty of perjury, that I am _____
(name) *(title)*

of the above-named contractor, that I am authorized to make this certification on behalf of such contractor, and I further certify that:

(Mark an **X** *in only one box)*

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: SS.:
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On the ____ day of _____ in the year 20___ , before me personally appeared_____ ,

known to me to be the person who executed the foregoing instrument, who, being duly sworn by me did depose and say that

_he resides at _____ ,

Town of _____ ,

County of _____ ,

State of _____; and further that:

[Mark an ***X*** in the appropriate box and complete the accompanying statement.]

☐ (If an individual): _he executed the foregoing instrument in his/her name and on his/her own behalf.

☐ (If a corporation): _he is the_____

of_____ , the corporation described in said instrument; that, by authority of the Board of Directors of said corporation, _he is authorized to execute the foregoing instrument on behalf of the corporation for purposes set forth therein; and that, pursuant to that authority, _he executed the foregoing instrument in the name of and on behalf of said corporation as the act and deed of said corporation.

☐ (If a partnership): _he is a _____

of_____ , the partnership described in said instrument; that, by the terms of said partnership, _he is authorized to execute the foregoing instrument on behalf of the partnership for purposes set forth therein; and that, pursuant to that authority, _he executed the foregoing instrument in the name of and on behalf of said partnership as the act and deed of said partnership.

☐ (If a limited liability company): _he is a duly authorized member of _____ , LLC, the limited liability company described in said instrument; that _he is authorized to execute the foregoing instrument on behalf of the limited liability company for purposes set forth therein; and that, pursuant to that authority, _he executed the foregoing instrument in the name of and on behalf of said limited liability company as the act and deed of said limited liability company.

_____
Notary Public

Registration No.
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