



**NEW YORK STATE DEPARTMENT OF HEALTH
OFFICE OF MEDICAID MANAGEMENT**

REQUEST FOR PROPOSALS

**"MEDICAID DISEASE AND CARE MANAGEMENT
DEMONSTRATION PROGRAMS"**

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Proposals to be submitted to:

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**REQUEST FOR PROPOSALS
MEDICAID DISEASE AND CARE MANAGEMENT
DEMONSTRATION PROGRAMS
March 21, 2005**

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PART I – Introduction and Background

A. Introduction:

The NYS Department of Health is soliciting proposals for Medicaid Disease and Care Management Demonstration (CMD) Programs. The Department is seeking to test several smaller demonstration projects which apply intensive interventions to high risk Medicaid patients to improve the quality and cost-effectiveness of the recipient's care.

1. Description of the Problem:

Some Medicaid recipients with chronic conditions are heavy users of health care and account for a disproportionate share of expenditures. For example, over eighty percent (80%) of total NYS Medicaid expenditures are attributed to twenty-six percent (26%) of enrollees. This special population is characterized as having chronic diseases such as HIV/AIDS; those in receipt of developmental disabilities, mental health or substance abuse services; those requiring long term care; and those with a delivery and birth.

The health care system does not always provide adequate management of services for these high cost recipients because of a variety of complex problems associated with care delivery. Recipients, particularly in the Medicaid fee-for-service program, have multiple co-morbidities, are uncertain how to care for their own disease states, do not tend to use a single "medical home" for care, and are not always able to readily access the specific type of care that is needed. In addition, there are indications that providers are not all fully aware of recent treatment guidelines, may not be able to coordinate with other service providers to assure appropriate care, and are not always able to provide preventative care to avoid unnecessary utilization. As a result, there are subsets of recipients who are inappropriately utilizing expensive or ineffective services, and are in need of additional care management.

Organizations, providers and local government entities have been developing improved approaches to address the needs of specific high cost and high utilization Medicaid recipients. In a variety of health care settings, organizations have knowledge of the needs of such recipients, and awareness of the specific types of problems which lead to excessive costs and utilization. Through their efforts, innovative programs and interventions can be applied which generally seek to limit unnecessary care or to promote greater use of cost-effective alternatives.

The DOH is seeking to test such innovative approaches to addressing the complex care needs of Medicaid recipients who have chronic illnesses, and require enhanced management of their care.

The Department encourages bidders with a wide range of different types of care management approaches to apply, including:

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- a. standard “disease management” programs aimed at treating a specific disease state,
- b. claims data analysis to identify a broad spectrum of aberrant care patterns, followed by interventions with selected providers/patients
- c. other innovative efforts developed to address specific improvements in care delivery and management.

Demonstrations must have measurable outcomes related to changes in recipient care and service utilization, use high quality standards of care, and result in net savings for State Medicaid costs. It is anticipated that the demonstrations will initially be limited to a relatively small population within a specific service area in order to effectively test the impact. The Department reserves the right during the course of the demonstration period to expand the service area and number of recipients under the management of the contractor, if the initial demonstration proves effective and additional funding is available.

B. Overview of the RFP:

Key aspects of the RFP and procurement process include the following:

- a. A wide variety of innovative disease and care management approaches will be considered.
- b. The demonstrations should address the needs of a target group of recipients with chronic illnesses, who have demonstrated unnecessary hospitalizations and emergency room admissions.
- c. Demonstrations must include provision of high quality, preventive health care.
- d. All demonstrations should be designed to result in net cost savings through improved care management.
- e. Participation in the demonstrations by recipients is voluntary; bidders may not prevent recipients from receiving medically necessary care.
- f. The Department will be responsible for selecting the specific recipients who will be subject to intervention, consistent with the requirements of the demonstration, as well as a control group of recipients.
- g. An evaluation will be completed which compares the outcomes of the control group to those who have received additional care management under the demonstration. Through this evaluation, the Department will be able to determine the effectiveness of the intervention provided.

This RFP follows the following format:

PART I provides general information on the procurement process, such as who may bid, service area requirements, target populations to be addressed by the demonstrations, and other related information to assist bidders. A general

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description of the NYS Medicaid Program, including currently ongoing patient management initiatives of the Department, is also included.

PART II provides the **Bid Requirements** and responsibilities for bidders, as well as specifications that bidders must meet when undertaking a demonstration program.

PART III provides specific **Administrative** information about the procurement requirements to be met by the bidders such as due date, mailing address, bidders' conference and other processes to be used by the Department to assure an equitable process. This section also includes a description of the bid selection process to be used by the Department.

PART IV presents the **Contractual Provisions** that will be included, together with this RFP, the bidders' response and other standard materials included as appendices to the RFP, in the final contract. The contract provisions list the contractor responsibilities, as well as the specifics for Contractor's Performance and Basis of Payment.

C. General Information for Bidders:

Legislation was enacted in 2004 which authorizes the Department to establish up to six (6) demonstrations (see **Attachment 1**). Consistent with the legislation, the Department is seeking proposals which may include, but are not limited to the following:

- a. Use proactive provider and/or patient management tools and techniques.
- b. Promote adherence to evidence-based clinical guidelines for care.
- c. Improve provider and/or patient communication.
- d. Utilize the latest information technology for continuous application of evidence-based guidelines to claims data.
- e. Effectively communicate indicated interventions to providers and/or patients.
- f. Monitor patient and/or provider response to evidence-based interventions.

The legislation requires that the CMDs selected be geographically diverse and representative of both urban and rural counties in NYS. The current legislation also limits the total number of demonstration programs selected, and further restricts selection so that no more than one-third (1/3) of the awards may be made to bids which provide services in a single social services district. In the event that current legislation is amended to address these factors, the DOH may select additional proposals submitted in response to this RFP, consistent with the revised legislative guidelines. Currently, funding available for these demonstrations is \$4.5 million. In the event the amount of funding available in legislation to support the CMDs is amended, the DOH may select additional proposals submitted in response to this RFP, consistent with the revised funding level.

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1. Who May Bid?

Bids will be accepted from local government organizations, for-profit organizations or not-for-profit organizations. Bidders must demonstrate expertise in the management or coordination of care, or experience providing cost-effective community based care to persons with chronic diseases. Minimum qualifications for this RFP are defined in PART II.B.2. All bids must be submitted by a prime contractor, as defined in PART II.B.2. Local governments may choose to (a) operate a CMD themselves or (b) sponsor a proposal, and submit a bid using the expertise of for-profit or not-for-profit organizations as subcontractors. However, such for-profit or not-for-profit subcontractors must demonstrate that they meet the minimum qualifications for this RFP.

2. Service Area Requirements:

Bidders are required to identify the specific service area of New York State where they intend to operate their demonstration project. The service area should include a sufficient number of potential enrollees to provide a valid test of the effectiveness of the interventions being used. **Attachment 2** provides data on potential care management enrollees by county, by disease state and region.

For the purpose of this RFP, regions have been defined based on the DOH Hospital Regions and New York City, with a map of the four (4) regions included as **Attachment 3**. In order to test and compare a variety of CMD models, a bidder may submit only one bid in response to the RFP, addressing a specific service area. The service area for each demonstration may be a single region, one or more contiguous counties within a region, limited to a single social service district or a specific catchment area within a county. Note that to address the limitation of funding and legislative requirement of geographic diversity, the Department may elect to contract with the bidder for only a portion of its proposed service area. Contracts will be awarded in such a manner to avoid overlap and duplication of effort within the same service area.

3. Bid Limitations:

Because of limited funding and the interest in testing different models of CMDs, the maximum award for any individual CMD will be limited to one million, five hundred thousand dollars (\$1,500,000) per twenty-four (24) month contract awarded. A bidder may submit only one bid for consideration. The DOH does not intend to approve a single CMD that would include a service area which includes more than one of the regions as defined in **Attachment 3**.

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4. Contract Period:

All contracts will be for a period of twenty-four (24) months duration commencing with the date of the contract approval by the Office of the State Comptroller (OSC). The Department is seeking demonstration proposals that can be rapidly implemented, and effectively operated for this period. Deliverables will be based on specifications outlined in this RFP and the contract. The Department may extend the term of the contract if funding is made available and the evaluation recommended such an extension.

5. Care Management Populations:

The demonstrations are aimed at Medicaid populations who have chronic health problems and high expenditures because of inappropriate or less than effective care or services. Medicaid recipients that are in an environment where their health care needs are already being addressed by a comprehensive case manager or other health management service identified in the Medicaid State Plan will not be included in the demonstration population. Medicaid recipients will be excluded from the intervention group if they are:

- a. Domiciled or residing in a developmental center, mental health institution or hospice.
- b. Enrolled in a Medicaid Managed Care plan, a Managed Long Term Care plan, or Family Health Plus,
- c. Diagnosed with HIV/AIDS and currently enrolled in a Special Needs Plan or other HIV/AIDS, care management plans.

6. Conditions of Recipient Participation:

- a. The contractor shall be subject to the following conditions regarding the enrollment of Medicaid recipients, and in the operation of a CMD:
 - 1) Enrollment in the CMD intervention is voluntary on the part of the prospective CMD enrollees.
 - 2) Once enrolled in the intervention, enrollees may opt-out at will. Enrollees who opt-out, may also choose to re-activate their enrollment at any time.
 - 3) The contractor may not deny access to Medicaid approved services.
 - 4) Enrollees maintain their ability to use any Medicaid participating provider.
 - 5) Recipient disenrollment from the CMD will occur as a result of the following:
 - a) Loss of Medicaid eligibility;
 - b) Death; or
 - c) No longer a fee-for-service Medicaid recipient.

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- b.** Contractors who undertake direct interventions with recipients shall be required to receive agreements from intervention enrollees as to their willingness to participate in the demonstration.

7. Payment:

Payment will be provided to selected contractors for the care management services provided, including approved implementation costs and operation costs. Payment will be made consistent with the contract provisions, the DOH approved definition of an intervention recipient, the bid price and the final service area(s) approved by the Department. DOH will reimburse the contractor for each intervention enrollee who is concurrently enrolled in the Medicaid program and the CMD and is subject to care management by the contractor. A per member per month (PMPM) payment process will be used (see **Attachment 7**). Reimbursement will occur on a monthly basis following implementation and will consist of a PMPM fee paid each month per intervention enrollee.

The specifications for the RFP do not employ contingency fees nor require the contractor to be at financial risk to achieve net program savings on the cost of Medicaid services. The Department shall not approve proposals utilizing such approaches. However, the Department will conduct an evaluation of the demonstration proposals to determine both the cost effectiveness of the interventions and the quality of health care outcomes achieved.

8. Contract Management by DOH:

DOH will monitor the performance of the contractor through established performance standards listed in Part II.B. Bidders are also required to provide project-specific performance standards as part of their bid. If approved by the DOH, these standards will also be utilized by the DOH to monitor contractor's performance.

9. Evaluation:

DOH will perform the final evaluation of each CMD addressing the following four areas:

- a.** Cost of intervention enrollees compared to the cost of the control group;
- b.** Changes in health care utilization patterns of intervention enrollees;
- c.** Health-related outcomes of intervention enrollees.
- d.** Quality and effectiveness of intervention services provided by the contractor to intervention enrollees.

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Each approved demonstration will be evaluated to determine if it achieved the legislative intent of having the costs of the demonstration interventions plus the Medicaid services provided to the recipients equal to ninety-five percent (95%) or less of the expected total costs of services without the intervention. The Department shall utilize a control group evaluation methodology to assure an accurate evaluation, and the ability to generalize the results of the demonstration to the full Medicaid population.

The DOH may choose to employ an independent contractor for aspects of the evaluation. The outcomes of the evaluation shall be provided to the Governor and the NYS Legislature. Detailed information on the evaluation process, and the roles and responsibilities of the contractor and the DOH demonstration regarding the evaluation is provided in **PART II and Attachment 5 (Medicaid Disease and Care Management Demonstration Evaluation)**.

D. Background

1. General Information on the NYS Medicaid Program

The NYS Medicaid program is a federal, State and locally funded program that provides a comprehensive package of medical services to eligible low-income persons in the State. In NYS, the DOH administers the Medicaid program. There are four (4) million individuals currently enrolled, receiving services through the fee-for-service (FFS) program, managed care or residing in institutional settings. The program reflects NYS' continued commitment to an effective and affordable delivery system that promotes quality health care, protects patients and assures access to appropriate services. The program is operated in conjunction with DOH's mission to ensure that high quality and appropriate health services are available to all New York residents at a reasonable cost.

a. Fee-for-Service (FFS)

The NYS Medicaid program provides coverage for medically necessary care and services, including prescription drugs and certain categories of nonprescription drugs and supplies. Both FFS and managed care enrollees receive prescription benefits under the FFS program. The FFS system is a traditional payment process under which physicians and other providers receive payment for individual services based on DOH-approved reimbursement rates. There are approximately two (2) million recipients receiving care through the FFS system.

b. Managed Care

Currently, approximately two (2) million of the total Medicaid enrollees are served through managed care plans. The DOH's waiver to provide mandatory managed care, the Partnership Plan, allows for certain

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services and costs, such as pharmacy benefits, to be “carved out” of the managed care rate.

This RFP does **not** cover Medicaid recipients enrolled in managed care plans. The managed care plans are expected to provide CM within the framework of their plan.

c. Family Health Plus

Family Health Plus is an expansion of the regular Medicaid program which builds upon the Child Health Plus model so that parents can have the same coverage as their children through managed care plans. Single adults without children are also eligible for Family Health Plus. Family Health Plus managed care plan enrollees are **not** included in the scope of this RFP. Currently there are approximately four hundred eighty thousand (480,000) enrollees in Family Health Plus.

2. Current DOH Patient Management Initiatives

Demonstrations funded under this RFP are not anticipated to duplicate or overlap the specific functions and service areas of existing Medicaid programs for the management of patient care. These include the following:

a. Asthma and Diabetes Quality Improvement Project (QIP)

For the past four years, the Office of Medicaid Management (OMM) has conducted the asthma and diabetes QIPs in twenty-five (25) community health centers and Article 28 clinics primarily in Metropolitan NYC and a few sites in the Capital Region. The QIP was developed using the nationally recognized “Chronic Care Model,” an approach to change medical practice based on evidence-based guidelines and empowering patients to self-manage their health. The QIPs have included a number of educational interventions for medical providers and their staff, including academic detailing, peer report cards and feedback, distribution of evidence-based guidelines, distribution of practice and patient educational tools (flow charts, care reminder stickers, assessment forms, action plans, etc.) and statewide teleconferencing by clinical experts in asthma and diabetes. QIP outcomes have included reduction in emergency department and inpatient hospital utilization and improvement in key clinical indicators for asthma and diabetes.

b. Pediatric Asthma Initiatives of the Drug Utilization Review (DUR) Program

As part of an asthma educational intervention program, the DUR program implemented a pilot program to notify primary care providers or local district social services (LDSS) of pediatric recipients (ages two to 17) who had either been hospitalized or who had emergency department visits with a primary diagnosis of asthma. The intent of the intervention was to inform the primary care providers and the local districts of the availability

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of a pediatric asthma case management program being conducted in their region by a DOH sponsored asthma coalition.

c. Partnerships and Collaborations

OMM has developed a number of collaborations in an effort to develop and implement strategies to better serve the health needs of the Medicaid populations. These partners include DOH Public Health divisions, Centers for Disease Control (CDC), community coalitions, practitioners and their associations, LDSS and a number of health plans. To date a few of these initiatives have included the development of practitioner and patient tools for the appropriate use of antibiotics and development of the NYS Asthma Guidelines.

d. Other Related Medicaid Care Management Programs

The Medicaid program undertakes a series of care management programs to assure improved health outcomes and appropriate utilization of Medicaid benefits:

1) Utilization Management

a) **Utilization Thresholds:** Medicaid pays for a limited number of certain health services per benefit year unless additional services have been approved. Providers may seek an exception for individuals and gain approval for additional health services during the enrollee's benefit year.

b) **Prior Authorization (PA):** For specific drugs and durable medical equipment (DME), the prescriber must obtain a PA to assure that the product is clinically appropriate for the patient's condition. The program is designed to assure medical necessity and appropriate use of medications and DME.

2) Drug Utilization Review (DUR)

The Department has a fully operational DUR program which includes the following:

a) **Prospective Drug Utilization Review (ProDUR):** The ProDUR program provides an alert to the pharmacist regarding a patient's drug therapy at the point of sale (POS) before a prescription is filled. The review compares the new claim to a patient's ninety (90) day claim history, and alerts the pharmacist to potential therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or clinical abuse/misuse at the POS. Savings from these interventions totaled one hundred forty (140) million dollars in 2003.

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b) Retrospective Drug Utilization Review (RetroDUR): The RetroDUR program educates physicians by targeting prescribing and utilization patterns that may need improvement. Physicians are alerted to potential drug therapy problems among their patients, such as therapeutic duplication, drug-disease contraindications, incorrect drug dosage or duration, drug-induced illness, or clinical abuse/misuse.

3) Recipient Restriction Program (RRP)

Selected Medicaid recipients with a demonstrated pattern of abusive utilization of Medicaid services must receive their medical care from designated primary providers. Currently, approximately four thousand (4,000) recipients are restricted.

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A. Scope of Work and Implementation

1. General Information:

This section of the RFP describes the specifications for operation of the CMDs, and the required information to be submitted by bidders as to how they propose to meet those specifications. Because of the diversity of anticipated approaches to care management, the specifications below address key elements of demonstration operation which can be anticipated for all proposed programs.

2. General Requirements for All Potential Contractors:

The contractor will be required to adhere to all applicable RFP requirements as well as all contract provisions as stated in PART IV of this RFP. In addition, the contractor will be subject to all current laws and regulation and any revisions in federal or State legislation or regulations which may be enacted or implemented during the period of performance of this contract that are directly applicable to the detailed requirements of this contract. The contractor will be subject to monitoring and evaluation by the DOH.

3. Implementation and Work Plan

The State is seeking a contractor who can implement the CMD quickly and efficiently. The bidder will be required to submit a proposed work plan for completion of all contract activities which includes a timeline for implementation as part of their bid. The timeline should reflect the ability to complete all preparation and implementation activities within four (4) months of the contract being signed. In addition, the selected contractor will be responsible to submit a detailed implementation work plan and schedule of deliverables one week after the contract is signed. This final work plan will be subject to approval by the DOH.

4. Requirements for Disclosure of Contacts

New York State Executive Order #127 (EO127) provides for increased disclosure in the public procurement process. The process requires identification of all contacts from businesses and their representatives relative to procurement contracts. See **Attachment 9** for a copy of the order and applicable forms.

In general, the Executive Order requirements include:

- a. Potential bidders and selected contractors must disclose to the State all persons retained, employed or designated by or on behalf of any bidder to

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- attempt to influence the procurement process, and whether that person has a financial interest in the procurement.
- b. A record be made by the State of any individuals, other than those listed by potential bidders and selected contractors, who attempt to influence the process.
 - c. A determination of vendor responsibility must be made as a part of the selection decision, including consideration of a failure to comply with the requirements of Executive Order #127.
 - d. Any finding that a contractor did not disclose complete information or did not cooperate completely with implementation of the order shall be considered in the vendor responsibility determination.
 - e. All procurement contracts include language certifying that the vendor has disclosed all parties retained, employed or designated by or on behalf of the vendor to influence the procurement process.
 - f. All procurement contracts contain language allowing termination of the contract if the certification is found to be intentionally false or intentionally incomplete.
 - g. Any member, officer or employee of a covered state entity who fails to comply with the executive order shall be subject to appropriate disciplinary action.

In light of this executive order, each bidder and subcontractor MUST fill out and submit a "Contractor Disclosure of Prior Non-Responsibility Determinations" form with their bid for this procurement.

In addition, a "Contractor Disclosure of Contacts" form must be filled out for each person who has been designated by the bidder to contact the State for the purpose of participating in the CMD procurement. **This includes ALL references included in the proposal, as well as any lobbyists, attorneys or other representatives who might seek to contact NYS government concerning this RFP.**

B. Format for Volume I, Technical Proposal

Volume I, the Technical Proposal, must include the following information regarding the bidder and their qualifications to implement and operate the CMD, as well as a detailed description of how the CMD will function. All bid responses must be prepared in accordance with the format and content described below. As noted in PART III. G, **the Technical Proposal MUST not include any price figures related to the bid.**

1. Letter of Transmittal

A letter of transmittal on company letterhead (or official government letterhead for local government bidders) must be submitted, addressed to the Issuing Agency. The letter is to be signed by an authorized official of the company or governmental organization, binding the bidder to the

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requirements of this RFP. The letter must affirm that the proposal and all provisions of the offer price are to remain in effect for a minimum of two hundred forty (240) calendar days. The transmittal letter must also include a statement indicating a willingness and capability to execute and perform a contract containing the terms and conditions specified in this RFP. Failure to include a letter of transmittal binding the bidder to the requirements of this RFP will result in disqualification of the bid.

2. Qualifications and Experience

All bidders will be required to submit evidence that they meet the minimum qualifications for the RFP. Bidders that are corporate or business organizations (including for-profit and not-for-profit) should submit their organizational qualifications consistent with the requirements in PART II, Section B.2.a below. Bidders which are governmental organizations should submit their organizational qualifications consistent with the requirements in PART II, Section B.2.b.

a. Corporate Organization Qualifications (To be Completed by all Corporations and Business Bidders Including For-Profit and Not-for-Profit Entities)

This section of the bidder's proposal contains information about overall corporate experience, financial stability and organization capacity. It also contains documentation of the bidder's experience with the specific functions to be undertaken in response to this RFP.

1) Minimum Requirements:

Each corporate bidder must clearly demonstrate in this section that it has adequate experience and capacity to meet the minimum qualifications to bid:

- a)** At least two (2) years of demonstrated expertise in the management and coordination of care to persons with chronic disease, or providing cost effective community based care to patients with chronic disease, or
- b)** Previous experience operating a care management or utilization review program specifically addressing persons with chronic diseases.

Only proposals from those firms deemed qualified based on meeting the minimum qualifications, as determined by the State in its sole judgment, shall be evaluated further. A qualified bidder must be a single, totally responsible prime contractor with all proposed subcontractors committed in writing to the intent of fulfilling specified roles identified in the bid. The prime contractor

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must be able to meet the minimum qualifications (not with a subcontractor) in order to be considered for this bid.

2) Corporate Structure and Organization

Provide a summary description [one (1) page maximum] of the bidder's organizational structure, corporation type (individual, partnership or corporation), ownership and reporting relationships between the parent organization, if any, and related companies. Include current percentage of gross revenue attributable to Medicaid care management programs if applicable.

3) Affiliations and Conflict of Interest

Bidders must disclose all business and financial relationship with other entities which may, or may be perceived to present a potential conflict of interest. Examples of affiliations may be, but are not limited to: provider networks or health plans, hospital systems, durable medical equipment suppliers, and pharmaceutical companies. Describe the organizational linkage, the degree of integrations/collaboration and firewalls between the organization.

Information provided by the contractor to the State which is considered trade secret by the DOH, consistent with the provisions on page III-8 of this RFP, will be kept confidential as permitted by the New York State Public Officer's Law.

4) Financial Capacity

Provide audited financial statements for the latest two years, including the auditor's report and footnotes sections for each year, for the bidder and any subcontractors proposed for this contract. If audited financial statements are proprietary in nature, this must be indicated in the proposal.

If not required to have audits performed (i.e. an LLC), a statement to that effect must be included. If not required to have independent audits performed, other evidence of financial capacity to perform must be included. At a minimum, this must include a current Dunn and Bradstreet report. Additionally, a statement must be included from a bank confirming a sufficient level of assets to ensure financial capacity as of the end of your last fiscal year. Confirmation from someone within your organization (CFO, Comptroller, etc.) is not acceptable.

5) Legal Proceedings

Provide disclosure of all significant litigation affecting the bidder whether as a defendant or as plaintiff at any time during the past five (5) years relating to the provision of care management or disease management services.

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6) Responsibility Questionnaire

Complete and submit the "Responsibility Questionnaire", included in **Attachment 8**. This document must be completed and returned with the bid.

7) Summary of Corporate Experience and References

This section is designed to provide detailed information and references to support the bidder's experience in undertaking the CMD operations included in this RFP.

The bidder is required to complete and submit one copy of **Form TP-1, Summary of Experience and References**, for each of the three (3) reference clients.

Note: A "Contractor Disclosure of Contacts" form (**Attachment 9**) must be completed for each contact name provided as a reference.

The DOH is particularly interested in current or prior experience providing care management services for other Medicaid programs. **Form TP-1, Summary of Experience and References, must** be filled out for each State Medicaid program serviced by the bidder.

On **Form TP-1, Summary of Experience and References**, bidders are required to provide information regarding documented cost savings associated with programs that they have developed and implemented for other clients in the past. This is for the purpose of evaluating the technical experience of the bidder. **Do not include any projected savings or price information for the NYS Medicaid proposal in this section.** Financial information for the proposed strategy for NYS should only be included in the Financial Proposal, Volume II.

8) Experience with State and Federal Legal and Program Requirements

The DOH will give preference to bidders who have demonstrated experience operating a CMD which operates within the complex requirements of public-funded healthcare, including Medicaid.

Describe the organization's experience in designing and operating a care management program that is required to be in compliance with the following:

- a) State law, administrative rules and guidelines.
- b) HIPAA Regulations on Electronic Data Interchange and Reporting.
- c) CMS and State requirements related to the Medicaid program.

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9) Subcontractors

List all subcontractors proposed for this contract, providing the following information for each:

- a) A letter of commitment to undertake the specific functions proposed for NYS Medicaid, signed by an authorized representative of the proposed subcontractor, must be included with the proposal.
- b) Firm name, address and contact person. (Include a "Contractor Disclosure of Prior Non-Responsibility Determinations" form with this bid for each subcontractor.) Also include a "Contractor Disclosure of Contacts" form (**Attachment 9**) for all contacts.
- c) Subcontractors will be required to complete and submit with the bid, a "Responsibility Questionnaire" if the subcontract equals or exceeds \$100,000 over the life of the contract.
- d) Complete description of specific responsibilities to be undertaken by each subcontractor under this contract. Include the percentage of work and effort to be completed by the subcontractor under this contract.
- e) Top-level organizational chart that indicates the reporting relationships with the prime contractor proposed as part of this RFP.
- f) Descriptive information concerning experience with completing the specific functions for which they will be responsible under this contract.
- g) At least three (3) business references that can demonstrate the subcontractors' prior and/or current experience with the specific functions included in this RFP which they will be completing. (The DOH is particularly interested in current/prior experience with other Medicaid programs. If the subcontractor is presently, or has previously, provided services for any other state Medicaid programs, those references must be included). For each subcontractor reference, complete and submit a **Form TP-1, Summary of Corporate Experience and References**.

b. Local Government Qualifications

(To Be Completed by all Bidders Which Are Governmental Entities, Including State, County or Municipal Governments.)

Local government organizations are eligible to sponsor and undertake a CMD program if they have a strong willingness to do so, and demonstrate experience sufficient to undertake the demonstration proposal.

1) Minimum Requirements for Government Organizations:

Each governmental bidder must clearly demonstrate in this section that it has a strong willingness to undertake a CMD program.

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Each bidder must submit a narrative demonstrating the governmental organization's intent and interest in sponsoring a CMD for Medicaid recipients with chronic disease, and willingness to undertake the demonstration project. Include a discussion of the goals and objective of the CMD, government supports and resources that will be in place to conduct or sponsor a CMD, and the commitment of the governmental entity to support the demonstration.

Only proposals from governmental organizations deemed qualified based on meeting these minimum qualifications, as determined by the State in its sole judgment, shall be evaluated further.

A qualified bidder must be a single, totally responsible prime contractor with any proposed subcontractors committed in writing to the intent of fulfilling specified roles identified in the bid.

2) Summary of Local Government Experiences and References

This section is designed to provide information and references to support the bidder's experience in undertaking the CMD operations included in PART II of this RFP. The bidder must complete copies of **Form TP-1, Summary of Experience and References**, summarizing previous experience with the management and coordination of care to persons with chronic disease, or providing cost effective community based care to patients with chronic disease. The experience should provide detailed information on the governmental organization's specific experiences and qualifications that are applicable to the requirements of the RFP. A "Contractor Disclosure of Contacts" form (**Attachment 9**) must be completed and submitted for each contact name. In addition, a reference or appropriate contact person must be provided so that experience and qualifications can be confirmed.

Note: In this section, bidders are asked to provide information regarding cost savings associated with programs that they have developed and implemented in the past. This is for the purpose of evaluating the technical experience of the bidder. **Do not include any projected savings or price information for the NYS Medicaid proposal in this section.** Financial information for the proposed strategy for NYS should only be included in the Financial Proposal, Volume II.

3) Experience with State and Federal Legal and Program Requirements

Describe the organization's experience with management and coordination of care to persons with chronic disease, and/or providing

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cost effective community based care to patients with chronic disease that is required to be in compliance with the following:

- a) State law, administrative rules and guidelines.
- b) HIPAA Regulations on Electronic Data Interchange and Reporting.
- c) CMS requirements related to the Medicaid program.

4) Subcontractors

Refer to PART II, B.2.a.9 for subcontractor information and requirements which must be submitted.

5) Affiliations and Conflict of Interest

Potential conflicts of interest, both actual and perceived, must be disclosed by the bidder, consistent with the requirements in PART II, B.2.a.3.

3. Technical Approach Proposed:

The DOH is seeking to test several types of CMDs that may utilize a wide range of different approaches to care management. Because of the diversity of activities among proposals, the outline of required responses for Key Functions may include some activities which would not apply to some bid proposals. Therefore, **bidders are required to address all applicable requirements, and to notate in their proposals when a particular requirement listed below is not applicable to their proposed approach.** If the approach proposed by the bidder includes additional activities to those outlined below, the bidder should list these additional activities, providing specificity as to how they will be addressed in the demonstration.

a. Management Summary

The proposal must include a Management Summary that condenses and highlights the proposed CMD, providing evaluators a broad understanding of the entire proposal. The summary should demonstrate the bidder's understanding of the State's priorities. The bidder must clearly describe:

- 1) The nature of the specific problem to be addressed by the CMD.
- 2) The specific goals and objectives of the CMD.
- 3) The care management model being proposed, including the demonstration's specific intervention focus, (i.e. recipient, medical providers, other). In addition, this summary must provide the identity and specific role of any proposed subcontractors.
- 4) A description of the number and severity levels of intervention populations proposed.
- 5) Specific type and number of anticipated outcomes including areas of cost savings to be achieved.
- 6) Any key dependencies on which the proposal is based.

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b. Proposed Service Area

As detailed in PART I Section C.2, a bidder may submit only one bid addressing a specific service area. Regions have been defined by the DOH, with a map of the regions included in **Attachment 3**. The proposed service area must be limited to a single region, however the service area proposed may be an entire region, one or more contiguous counties within a region, or limited to a single social service district or a specific catchments area (such as a municipality) within a county. Any bidder that submits more than one proposal will have all their proposals rejected.

All bids must include a completed **Form TP-2, Service Area Proposal**, indicating the entire proposed service area for the operation of the CMD, with a description of the target population which is to be addressed by the bidder in each county or area of a county. In developing your proposal, please refer to **Attachment 2** for recent Medicaid statistics by county, for current data on the frequency of specific chronic disease states in the target population. (Note: bidders are not limited to proposing a CMD for one of the disease(s) provided in Attachment 2, nor does their proposal have to be disease specific.) The proposal should include a justification for the selection of this service area for the proposed CMD.

c. Target Population:

Describe the specific target population to be addressed by the CMD, including:

- 1) The specific characteristics of the population who will be subject to the demonstration, including health status, level of service utilization, and other presenting characteristics.
- 2) The number of recipients proposed for direct intervention, and the specific type of intervention planned;
- 3) The specific formula you propose to identify potential intervention enrollees.

d. Scalability:

The Department reserves the right during the course of the demonstration to expand the service area and number of recipients under the management of the contractor, if the initial demonstration proves effective and sufficient funding becomes available. The bidder is encouraged to explicitly detail the scalability of their proposal, describing how the proposed model could be increased in scale for an expanded service area and larger population.

- 1) Provide a plan on how to increase the service area and population base of the current CMD.

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- 2) Provide a detailed explanation of the additional required resources, number of additional required intervention enrollees and the estimated timeframe for implementation and operation for the enlarged CMD.
- 3) Describe any limitations or complications which would apply if the program were to be expanded appreciably.

e. **Demonstration Key Functions:**

The following **Key Functions** are common to care management models.

Bidders are required to provide a detailed description on how they will complete the applicable Key Functions and associated specifications for the proposed CMD. The bidder must demonstrate their capacity to administer and monitor all applicable Key Functions. The bidder is also expected to include a description of expected health outcomes and how outcomes will be measured and evaluated.

The bidder is instructed to respond to all applicable Key Functions and associated questions and specifications as appropriate for the proposed CMD. If Key Functions listed below are not applicable to the model of intervention being proposed by the bidder, the proposal should specifically notate in the bid which functions or activities are not included in the bidder's proposed approach.

1) **Intervention Population Selection:**

The DOH will be responsible for selecting the specific recipients who will be subject to intervention, as well as the control group. The process for selection of the intervention and control groups will include the following steps:

- a) DOH will identify a set of prospective enrollees in the selected service area which meet the bidder's general requirements for intervention
- b) Contractors will be required to assign a disease severity indicator to each recipient identified by the DOH as prospective CMD enrollees.
- c) The DOH will then assign prospective CMD enrollees, through a stratified random selection process, to the potential intervention and control groups.
- d) Contractors will then undertake enrollment and intervention with recipients identified by the DOH as potential intervention enrollees.
- e) Replacement or backfill of intervention enrollees will follow the same process on a quarterly basis.

This multi-step process is detailed in **Attachment 4**, Process and Data Flow for Selection of the Intervention Enrollees. The bidder is instructed to refer to **Attachment 4** for a complete narrative description

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and flow chart regarding this Key Function. **Appendix O** provides key definitions for all demonstration populations.

Bid Response Requirements:

The technical proposal must include the following information regarding the proposed approach to meet these requirements regarding selection of the intervention population:

- a) Describe how you will complete the data exchange processes required for the selection of the intervention and control groups and specific roles of the DOH and the bidder.
- b) Describe your proposed criteria for a severity index and specifically how you will identify those enrollees at highest risk for non-adherence to medical care and treatment.
- c) Provide the specific definition you are proposing for the intervention enrollee group which will be used as the basis of payment for CMD.

(**Note:** The final definition of intervention enrollees will be subject to DOH approval.)

2) Enrollment of Eligible Recipients and/or Providers:

Contractors will be required to actively enroll individuals and/or providers into their demonstration program.

Bid Response Requirements:

The technical proposal must include the following information regarding the proposed approach to enrollment of eligible recipients or providers:

- a) Describe how the enrollment process will be conducted, what strategies and communications will be used to solicit enrollee and/or providers buy-in to participate and a description of the personnel that will conduct enrollment.
- b) Describe what procedures and strategies you will employ to locate potential enrollees when addresses or telephone numbers prove not to be accurate.
- c) Describe how you will obtain the participation of recipients with cognitive or physical disabilities.
- d) Describe the specific process to be used to track the number of attempts to reach a potential enrollee, active acceptance, refusal to participate and disenrollment of enrollees.
- e) Describe the process by which enrollees and/or providers notify the bidder that they wish to no longer participate in the CMD.
- f) Describe how the status of enrollment by recipients and/or providers will be monitored, tracked and reported.

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3) Enrollee Assessment:

Recipients subject to care management either directly or indirectly by the demonstration must be assessed individually as to their medical/health condition, service needs and other relevant information. The assessment will then form the basis for determining the type of intervention which is appropriate.

Bid Response Requirements:

The technical proposal must include the following information regarding the bidder's proposed approach to meet requirements related to enrollee assessment:

- a) Describe how initial and ongoing assessments will be conducted.
- b) Identify the best practices and evidence-based clinical guidelines on which the assessments will be based. Describe how the clinical assessment protocols maintain consistency with current best practices and evidence-based clinical care.
- c) List the specific factors which will be used to assess the recipient's status, current utilization and needs.
- d) Describe how the enrollee's co-morbid conditions and disease severity level will be incorporated into the assessment process.
- e) Describe how the assessment will be coordinated with other Medicaid management services (i.e. Retrospective and Prospective Drug Utilization Review, prior authorization for medications and services, etc.) to avoid duplications and potential negative impact.
- f) Provide a description of the specific personnel who will perform the assessment services. Include minimum qualifications, profession types, licensure, certification or specialized training, etc. Indicate the ratio of care managers to enrollees/medical providers.

4) Care Plan Development and Intervention Implementation:

Following assessment of the enrollee's needs for improved management, the bidder is required to develop a care plan which will address the needs identified in the assessment. The bidder will then undertake specific interventions to improve the effectiveness and efficiency of the services and care being provided.

Bid Response Requirements:

The technical proposal must include the following information regarding the bidder's proposed approach to meet requirements related to care plan development and intervention implementation:

- a) Describe the care plan development including how data analysis, health assessment findings, co-morbid conditions, disease severity level; enrollee and caregiver/family member concerns and medical provider collaboration, etc. will be addressed in the care plan.

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- b) Provide a complete description of the care management services and interventions that will be utilized. How will the effectiveness of these activities be measured and evaluated to determine if enrollees are meeting established goals?
- c) Describe the strategies that will be utilized to manage the care of enrollees who may have mental illness and/or substance abuse issues, are children, have special health care needs, are functionally or cognitively impaired, are non compliant to medical care and treatment or do not have a “medical home”.
- d) Describe policies and procedures to manage urgent or emergent enrollee care issues.
- e) Describe how clinical care issues and recommendations will be conveyed to the treating medical provider(s). Describe opportunities the medical provider will have for clinical discussion and feedback on the recommendations.
- f) Describe any provider-based interventions that will be utilized to improve adherence to best practices and evidence-based care. Describe how the effectiveness of these interventions will be monitored and evaluated.
- g) Describe how the medical provider will be monitored for compliance to care recommendations and best practices to achieve high quality cost effective care. Describe how interventions will be documented, monitored and tracked.
- h) Provide a description of the specific personnel who will perform the care plan development and interventions. Include minimum qualifications, profession types, licensure, certification or specialized training, etc. Provide the ratio of care managers to enrollees/medical providers.
- i) Describe how intervention outcomes will be monitored and tracked by the bidder and what data sources will be used.
- j) Describe strategies to link enrollees with ancillary services that may be required to improve the efficiency of care, such as pharmacy, medical equipment and supplies.

5) Outreach and Awareness:

It is anticipated that bidders will undertake general outreach and awareness activities to gain acceptance and support among providers and/or recipients who will be involved in the demonstration.

Bid Response Requirements:

The technical proposal must include a description of how the bidder intends to undertake such outreach and awareness, including the following:

- a) Describe the specific nature and extent of outreach that will be employed to identify community resources and to assure

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participation in the demonstration, including; local government agencies, community-based partners, medical providers, hospitals and potential enrollees, etc.

- b) Describe the strategies that will be utilized to solicit and ensure recipient and provider buy-in, and continued participation in the demonstration.
- c) Describe strategies that will be utilized to recruit medical providers to serve as a “medical home” for enrollee as needed.
- d) Provide the anticipated outcomes from community and medical provider outreach that are expected to occur. Identify the length of the outreach and awareness period. Describe how outreach activities and outcomes will be monitored, tracked and evaluated.

6) Communications:

The contractor must assure that all communications with recipients and/or their medical providers are appropriate, clinically accurate and culturally sensitive. The contractor will be responsible to overcome barriers to ensure equal access for all enrollees when written or oral communication is utilized. The DOH will be responsible to approve all written communications to recipients and providers, prior to distribution, during the course of the contract.

Bid Response Requirements:

The technical proposal must include a description of how the bidder intends to assure appropriate communications, including the following:

- a) Describe the methods of communication that will be utilized in the demonstration, i.e., telephone, written, face-to-face, etc.
- b) Describe how enrollees and medical providers will be assured timely access to the bidder's care management organization and care managers.
- c) Describe languages that will be made available for all methods of communication other than English. At what grade level will written communications for enrollees be prepared?
- d) Provide samples of publications/materials for enrollees and/or medical providers that will be utilized in the demonstration, i.e. outreach and information, assessment tools, care plans, notification and alert letters, provider and enrollee educational materials, enrollee and medical provider profiles, etc.

7) Quality Assurance:

Every contractor is required to self-monitor all demonstration activities to assure continued quality assurance and quality improvement, and to maintain a system to report to the DOH on such activities, and the outcomes of quality assurance activities.

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Bid Response Requirements:

The technical proposal must include a description of how the bidder intends to monitor quality of operations, implement improvements on an ongoing basis and report on the outcomes, including the following:

- a) Describe the quality assurance plan and processes that will be utilized to assure enrollee and/or medical provider customer satisfaction (i.e., employee surveillance and training, surveys, complaint/resolution process, etc.).
- b) Describe the plan and processes that will be in place for ongoing program quality improvement.
- c) Identify the specific personnel responsible for monitoring and reporting quality assurance functions.

8) Outcomes Measurement and Clinical Effectiveness:

As part of the final program evaluation, the DOH intends to undertake a review the clinical outcomes, as well as utilization and financial outcomes, associated with the demonstration.

Bid Response Requirements:

The technical proposal submitted by bidders must include a description of the specific types of programmatic and clinical measures which are being proposed to serve as the basis for measuring clinical outcomes and clinical effectiveness of the demonstration. For each outcome measurement proposed, the bidder must list the specific types of data which will be collected and the source for each. (See **Attachment 6** for standard clinical performance measures for several chronic disease states). The DOH reserves the right to approve all outcomes measurements and clinical effectiveness reviews which are included in the final evaluation.

- a) Provide a list of the evaluation questions, which you propose to be applied in order to measure the clinical and cost effectiveness of the demonstration.
- b) Describe the specific types of changes in service utilization that are proposed to be measured and evaluated. Specifically describe how you would recommend related cost savings be determined.
- c) Describe the types of clinical performance measures to be applied in the evaluation. How will the changes be reported, measured and evaluated? How will the changes in clinical performance measures be confirmed (i.e., claims data review, medical record review, etc.)?
- d) Describe the types of health-related outcomes relating to enrollee behavior modification, capacity for self-management, and improved relationships with providers that will be addressed.

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- e) Describe specific measurements of changes in provider actions, including improved patient management, and provider use of health care resources, that will be measured.

9) Reporting Requirements:

Contractors will be required to submit reports and data which will be used by the Department to assess whether the contractor is meeting program objectives, timeframes and performance standards. The format for all reports must be approved by the DOH and are subject to revision during the contract period. The contractor will be responsible for all costs associated with the production and dissemination of the reports. The contractor is required to provide data to the DOH on a timely basis consistent with the requirements of this RFP.

The contractor will be required to provide at a minimum the following reports on a monthly, quarterly, annual and final basis.

a) Monthly Reports

- i. Enrollment Status by Medicaid client identification number (CIN) and name of each prospective enrollee as follows:
 - Enrolled
 - Not enrolled
- ii. Progress Report- a brief narrative providing the status of all CMD key functions and activities.

Monthly reports are due to the Department by the tenth (10) day of the month following the close of the reporting period.

b) Quarterly Reports (Report on all applicable)

By Medicaid CIN, using MS Excel or Access (or other table or series of tables), for each intervention enrollee record provide the following data:

- i. Indicator of current enrollment status of intervention enrollee, who:
 - Has been contacted and enrolled,
 - Declined enrollment
 - Disenrolled, or
 - Not yet contacted.
- ii. Total number of interventions completed with, or on behalf of the enrollee.
- iii. Total number of initial health assessments completed.
- iv. Indicator of established medical home, with date established.
- v. Indicator of established care plan, with date established.

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- vi. Total number of enrollee/medical provider complaints/resolution status.

Quarterly reports are due the Department by the tenth (10) day of the month following the close of the reporting period.

c) Annual/Final Reports

- i. Report on DOH approved clinical performance measures outcomes.
- ii. Results from enrollee and medical provider satisfaction survey. (if applicable)
- iii. Narrative report documenting enrollee and/or medical provider obstacles and issues and contractor recommendations and resolutions.
- iv. Summary report of all findings, health outcomes, areas of anticipated savings due to change in utilization management and recommendations for the CMD.

Annual reports are due to the Department no later than thirty (30) calendar days following the close of the reporting period.

Bid Response Requirements:

The technical proposal must include the following regarding the bidder's ability to complete the reporting requirements:

- a) Describe the data systems that will be used to collect and transfer data, consistent with DOH requirements.
- b) Describe how the data system will be used to meet reporting, monitoring and evaluation requirements.
- c) Provide examples of proposed monthly report formats to be used. Include any standard metrics currently used to define progress or success of intervention activities. Include a detailed definition of the metric and how it is measured.

10) Contract Performance Standards:

The contractor will be required to meet the following performance standards established by the DOH:

- a) Provisions of a CMD detailed work plan and schedule of deliverable within thirty (30) days of contract approval. The detailed work plan and schedule is subject to DOH approval.
- b) Provision of all contract services and deliverables consistent with the approved work plan and schedule of deliverables.
- c) Provision of urgent and emergent enrollee care management services based on DOH approved policies and procedures.

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- d) Completion all enrollee and/or provider interventions consistent with nationally recognized prevention and treatment standards utilizing evidence-based clinical guidelines as approved by the DOH.
- e) All enrollee and/or provider communications are clinically accurate, culturally sensitive and of an appropriate level of language for the target audience. DOH review and approval will be required for all written communications.
- f) Completion and submission of all required reporting to the DOH by the specified due date.

Bid Response Requirements:

The technical proposal should include a description of how the contractor intends to meet these specific performance standards. In addition, the contractor must submit additional performance standards, consistent with the specific types of CMD operation being proposed. While the DOH intends to apply additional performance standards, customized to the specific demonstration being proposed, such additional standards will be subject to final approval by the DOH. The technical proposal must include the following:

- a) Describe the bidder's ability and willingness to meet the performance standards included in this section. Describe how the bidder will submit data to the DOH to assure timely and accurate tracking of performance.
- b) Provide at least four (4) additional performance standards which are proposed by the bidder for measuring the progress and outcomes of the specific demonstration being proposed. All performance standards must include specific outcomes, and be defined in quantitative terms to assure that they are measurable. For each performance standard proposed, describe the specific data, data source and frequency of reporting proposed to measure compliance with the standard.

f. General Operations:

In addition to the Key Functions in Section B.3.e, all contractors will be required to meet specifications and performance standards associated with the following general operations. The technical proposal must include a response as specified below to each of the following general operations requirements:

1) Work Plan and Schedule of Deliverables:

Bid Response Requirement:

The proposal must include a project work plan that identifies the tasks and DOH deliverables, project milestones, and start and finish dates

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for key activities associated with program implementation and operation.

- a) Provide an overall work plan summarizing the proposed schedule, and the key activities required to design, implement and operate the CMD detailed in this proposal.
- b) Identify the milestones/deliverables to be met during the implementation phase of the program, and your schedule for meeting them. Sufficient detail should be provided to enable effective monitoring of all tasks.
- c) List the assumptions which support the plan timeframes and the constraints identified that may affect the successful execution of the plan. All assumptions should be realistic, consistent with the requirements of this RFP and consistent with the State's objectives. Attach all assumptions to the work plan.

Note: Assumptions used by the bidder will not alter the bidder's responsibilities or limit the scope of this project.

Note: Because of Medicare Part D implementation, the enrollment of dual eligible recipients (i.e. Medicaid and Medicare enrolled) into the intervention group by the contractors will not occur until July 1, 2006 or thereafter.

2) Organizational Chart

Bid Response Requirement:

The proposal must include an organizational chart, which defines the proposed organizational structure to undertake the design, implementation and operation of this contract. Include the key positions, relationship to the organization's management, lines of reporting, and number and levels of staff. Identify the relationship of managers and care management staff that will be completing each of the key functions described below.

3) Proposed Key Personnel and Staffing

The DOH desires a management team and staffing that possesses a high level of creative and technical skills as well as extensive experience relevant to conducting the key demonstration operational functions included in this RFP.

Bid Response Requirement:

For each key personnel position proposed, complete a copy of the **Form TP-3 Key Personnel**. Provide a brief job description, including duties and responsibilities of the position, the name of the individual selected, the individual's relevant professional experience, education

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and qualifications, and three (3) references from previous supervisors and employers. Indicate the percentage of time that each manager/director identified will be dedicated to the NYS Medicaid account. All references should be current and verifiable, including contact name, address, e-mail, and phone number. Include a “Contractor Disclosure of Contacts” form (**Attachment 9**) for each reference.

Key personnel positions must include at least the following:

a) Contract Manager

The contract manager is the primary point of contact for the contractor’s performance under the contract with the authority to make decisions that are binding on the contractor. This position will manage the contract on a day-to-day basis and be the primary liaison between DOH and the contractor.

b) Medical Director

The medical director will be responsible for clinical management and appropriateness of services provided by the CMD. The medical director must have significant, appropriate clinical experience in the clinical area addressed by the demonstration. In addition, the medical director must be in good standing with the licensure board without history of restricted license or other disciplinary action, or sanctions by Medicare or Medicaid. It is expected that the Medical Director will maintain membership in state medical associations and appropriate specialty professional organizations. The medical director is not required to be a full time position, but the bidder must demonstrate that adequate access to the medical director is available to assure that management services are clinically appropriate.

c) Care Manager Staffing

The care managers will coordinate and provide CM services to enrollees and/or providers, as required via the telephone, written correspondence and/or face-to-face enrollee contact.

Bid Response Requirement:

- i. Describe the qualifications and experience of the contractor's personnel who will be responsible for care management for recipients and/or providers.
- ii. Describe the initial and ongoing training that is provided to care managers to assure that they provide accurate and clinically correct information based on evidence-based guidelines to enrollees.

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- iii. Describe the clinical oversight that will be provided by clinical professionals to assure for provision of accurate and appropriate CM services.

d) Staff Training and Quality Management:

Bid Response Requirement:

The technical proposal must include a description of how key personnel, clinical oversight and care management staff will undergo training, and how quality management will be maintained during the demonstration period.

- i. Describe the process for how staff will be initially trained during implementation.
- ii. Describe the process for measuring the ongoing quality of staff performance, particularly as it relates to interaction with providers and recipients.
- iii. Describe the ongoing monitoring and training process proposed for the demonstration.

4) Communication with DOH

The contractor is required to maintain regular telephone and e-mail contact with the DOH contract manager and designated staff at least once every two (2) weeks, or as approved by the DOH, throughout the contract period. The contractor is also expected to participate in periodic status meetings in person or by teleconference and provide regular status reports on a schedule to be determined by the DOH.

Bid Response Requirement

The technical proposal must include a description of how the contractor plans to communicate with DOH over the life of the contract.

5) Prime Contractor

The prime contractor will be totally responsible for meeting all provisions of the contract. If subcontractors are utilized, the prime contractor will have ultimate responsibility for achieving all deliverables and meeting performance standards contained in the contract.

Bid Response Requirement:

The Technical Proposal must identify the specific entity which will sign the contract agreement with the State and serve as the prime contractor. If subcontractor(s) are being proposed, the bidder must also describe how the subcontractor(s) will be supervised and managed, including the following:

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- a) Describe the organizational relationship between the prime contractor and the subcontractor(s).
- b) Describe how day-to-day operations of the subcontractor will be supervised, and by whom.
- c) Describe what audit, accounting and oversight procedures will be used to assure appropriate performance by the subcontractor(s).
- d) Describe how subcontractor deliverables will be monitored, the timeliness tracked and the quality validated.

6) HIPAA Compliance/Confidentiality

The contractor must ensure ongoing compliance regarding its operations with all relevant requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). See **Appendix H**.

In addition, the selected contractor will be required to complete, and have approved, a New York State Data Exchange Application and Agreement prior to being allowed access to Medicaid confidential data. A copy of the application is provided as **Appendix N**.

Bid Response Requirement:

The Technical Proposal must include a description of the processes the contractor will have in place to assure HIPAA compliance and Medicaid Confidentiality requirements are met.

7) Disaster Recovery

The contractor will be responsible to maintain and test a disaster recovery plan designed to minimize any disruption of the contractor's services. It is the sole responsibility of the contractor to maintain an adequate backup system to conduct the care management services required of this contract.

Bid Response Requirement:

The Technical Proposal must describe in detail the features of the proposed disaster recovery arrangements to be provided.

8) NYS Department of Health Institutional Review Board (IRB)

The contractor shall obtain IRB approval for the CMD as required. The contractor will be responsible to obtain and document initial and ongoing informed consent for intervention enrollees. The contractor shall complete and submit the IRB application forms and provide all supporting documentation as required to the IRB board. These activities must be completed prior to implementation. A copy of the application is provided in **Appendix G**.

Bid Response Requirement:

PART II – Bid Requirements

Describe your understanding of the above requirements, and how the bidder intends to meet these requirements.

9) Phase Down Plan

At completion or termination of the CMD, the contractor will be responsible to provide a phase down operation plan. The contractor will be required to transition enrollees and their providers out of the CMD assuring adequate notice to all parties. The contractor shall return all data files and relevant materials to DOH. The contractor must also provide all final reports as described in the scope of work and cooperate with DOH in the final evaluation of the CMD.

Bid Response Requirement:

Provide a plan which describes in detail how the contractor will phase down the demonstration at its completion or termination. Explain how enrollees and their medical providers will be transitioned out of the CMD.

10) Evaluation of Medicaid Disease and Care Management Demonstrations

The DOH is responsible for the evaluation of each demonstration's effectiveness. Detailed information on the evaluation process is provided in **Attachment 5 (Medicaid Disease and Care Management Demonstration Evaluation)**. The contractor shall cooperate with the DOH, and any agent employed by the DOH, in the completion of an evaluation of the programmatic and financial impacts of the demonstration.

Bid Response Requirement:

Describe your understanding of the above requirement and the responsibilities that are required of the contractor.

4. State's Responsibilities

a. Management of Contract(s)

The State will negotiate a contract and any contract amendments with the successful bidder. The State will review and reserve the right to approve or disapprove all contract products and deliverables. The State shall provide support for the interface and integration of systems operations with additional DOH vendors.

b. Program Policies and Regulations

The State develops and promulgates program policies and regulations. The contractor will be apprised in advance of contemplated changes and provided with changes as they are approved. The contractor shall implement management and systems changes required to support these initiatives within defined time frames.

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c. Fraud and Abuse Activities

The State will conduct audits and investigations of CMD related issues and undertake civil and criminal actions, as it deems necessary to prevent or curtail fraud, abuse and unacceptable practices within the Medicaid program. The contractor will timely notify the State of potential fraud and abuse cases and provide program reports and other data as required to support State fraud and abuse activities.

d. Recipient Fair Hearings

The State will be responsible for administering the fair hearing process for CMD enrollees (Medicaid recipients) if required. These fair hearings are provided to allow enrollees (recipients) to appeal determinations or actions of the Department or the contractor regarding services conducted by the CMD.

C. Format for Volume II – Financial Proposal

1. Best Value

The basis for awarding this contract will be Best Value, which optimizes quality, price and efficiency, among the responsive and responsible bidders. Completeness and clarity of price information are essential for the DOH in determining the best value for New York State.

2. General Instructions for Financial Proposal Requirements for Price Submission

For the purposes of the evaluation and selection process, all bidders are required to submit the true and actual price of providing the CMD services as defined in this RFP.

a. Submission of Financial Proposal

The bid price submitted may not include reductions or offsets to the price based on direct or indirect financial support from another entity, including any funds that the State may pursue through federal matching funds or financial participation. The DOH may choose to pursue matching federal funds or federal financial participation (FFP), or other sources of additional funding, however, such funds will not be included in the financial evaluation process. As part of the Technical Proposal evaluation, all business and financial relations with other entities which may, or may be perceived to, present a potential conflict of interest will be analyzed.

b. Forms

The Financial Proposal Form found in **Attachment 8** must be used to submit the financial proposal. The bidder may reproduce this form using their own software. However, the content and format must remain intact. For reproduced forms, all required information must be formatted and

PART II – Bid Requirements

submitted as one (1) page. The Financial Proposal Form is available in a PDF Format on the DOH website.

3. Instructions for Completion of the Financial Proposal Form

a. Bidder Name

Provide the name of the prime bidder organization.

b. Service Area/Region Identification

Identify the region in which the CMD is being proposed (See **Attachment 3** for the definition of regions for the purpose of this bid). If proposing a CMD for a single county or contiguous group of counties, bidders must identify the corresponding region which encompasses the county or group of counties. If proposing a CMD for a group of counties, all counties must be within the same region.

c. Implementation Price

Provide the total price associated with the initial development and implementation of the CMD prior to the full acceptance by the DOH, and initiation of CMD operations. This is considered a one time expense, limited to the first four (4) months in Year 1. The implementation price may not be greater than twenty-five percent (25%) of the total proposed price for Year 1.

d. Operations Price

For all operations, a price should be provided which is consistent to the time periods listed. Price must be reported for two (2) distinct periods, Year 1 and Year 2. Since Year 1 includes a four (4) month implementation phase, operations price should be provided for the remaining eight (8) months of the first year. Operational price in Year 2 should be provided for the complete twelve (12) months including the phase down period as described in PART II. The total proposed operations price will be equivalent to the sum of the sub-price proposed for Year 1 and Year 2.

e. Calculations

Perform the following calculations to complete the form:

- 1) Calculate the total price over the total length of the contract.
- 2) Calculate the total price for each period.
- 3) Calculate the total financial proposal price (the one time Implementation Price in Year 1 must be included in the total price).

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A. Issuing Agency

This RFP is issued by the NYS DOH. The DOH is responsible for the requirements specified herein and for the evaluation of all proposals.

B. Submission of Proposals

1. Contact Office

The following office is the sole point of contact for this RFP.

New York State Department of Health
Office of Medicaid Management
ATTN: Carol A. Lindley
99 Washington Avenue, Suite 720
Albany, New York 12210
Telephone: (518) 473-7735
Fax: (518) 473-4400
E-Mail: ppno@health.state.ny.us (Reference line to read: "CMD RFP")

No publicity or news releases pertaining to this RFP or any contract resulting from this RFP, may be made without prior State approval, and then only in coordination with the Issuing Agency.

2. Type of Contract

The contract entered into as a result of this procurement will include the bidder's proposal, this RFP, contract provisions included in PART IV, as well as the standard clauses for all NYS contracts provided in Appendix A and the General Specifications defined in Appendix D. The Workers' Compensation/Disability Benefits, defined in Appendix E, and Federal Health Insurance Portability and Accountability Act ("HIPAA"), defined in Appendix H will also be incorporated. The contract will provide for good faith negotiations of terms if and when any material changes in scope should occur. See PART IV of this RFP for the specific contract provisions.

3. Procurement Timetable

| ACTION | DATE |
|--|----------------|
| Release of RFP | March 21, 2005 |
| Pre-Bid Conference | April 12, 2005 |
| Official Answers to Pre-Bid Questions | April 19, 2005 |
| Letter of Intent to Bid | April 26, 2005 |
| Final Date for Receipt of Additional Questions | May 17, 2005 |
| Final Official Answers to Written Questions | May 24, 2005 |
| Closing Date for Receipt of Proposals and Public Bid Opening | May 31, 2005 |

Following bidder selection by the Department, the contract and procurement record will be subject to a State review and approval process. The State reserves the right, upon notice to the bidders, to modify any of these dates.

4. Restrictions on Communications with State Personnel

From the issue date of the RFP until a contractor is selected and announced, bidders are not allowed to communicate orally with any State staff except during the bidders' conference. All communications related to this RFP are restricted to written communications except as set forth below and in section B.1. "Contact Office". Letters of intent and written questions may be mailed, e-mailed or faxed by the deadlines included herein to the contact office.

5. Letter of Intent to Bid

The Letter of Intent must be received by the Issuing Agency no later than April 26, 2005. The Letter of Intent to Bid does not commit the bidder to submit a proposal. However, only those firms which have submitted a Letter of Intent to Bid will automatically receive written questions and answers relating to the RFP. Questions and answers and official modifications to the RFP will be available on the DOH website at www.health.state.ny.us.

C. Evaluation Requirements

All proposals received will be reviewed by the DOH to ensure that the bidder has met all administrative requirements of the RFP. See PART III.G of this RFP for required organization and format of bidder proposals and a description of the method of award. Failure to meet these requirements may be cause for rejection of a proposal. Only those firms deemed qualified, as determined by the State in its sole judgment, shall proceed through the evaluation process.

D. RFP Supplements

1. Questions and Answers

All questions relating to the content of this RFP must be forwarded, in writing, to the Issuing Agency. Questions may be submitted via fax, mail or email, but if sent by fax or mail an electronic media version must also be sent.

Questions may be sent via email to ppno@health.state.ny.us, (reference **CMD RFP** in the subject line). Receipt of email submissions will be acknowledged electronically. If an acknowledgement is not received, it is recommended that the bidder confirm that the submission was received using a fax or phone call.

Each question raised must cite the particular RFP section, page number and paragraph to which it refers.

The State's written responses to the Questions and Answers shall be considered a modification to this RFP, and the resultant contract.

2. Pre-Bid Conference

A pre-bid conference will be held on April 12, 2005 at the Empire State Plaza, Concourse Level, Meeting Room 4, Albany, New York 12242. The purpose of this conference is to solicit inquiries and comments from potential bidders in order to enhance the effectiveness of the procurement process. It is requested that no more than three (3) representatives from each organization attend. Reservations are required, and may be made by calling Ms. Janice Rayball at (518) 473-7735 at least three (3) business days prior to the conference. Attendance at the pre-bid conference by bidders is optional.

It is recommended that any questions be forwarded to the Issuing Agency prior to the conference to insure that sufficient analysis can be made before an answer is supplied. Answers furnished during the conference will not be official until confirmed in writing by the Issuing Agency. Official questions raised at, or prior to, the bidder's conference will be released by April 19, 2005. Official answers to additional questions received by May 17, 2005 will be released by May 24, 2005.

3. RFP Amendments

If it becomes necessary to revise any part of this RFP, a supplement will be issued to all potential bidders known to the State who have submitted a letter of intent to bid.

4. Summary Medicaid Data

Potential bidders who have submitted a letter of intent may submit a request for aggregated Medicaid data related to the disease types, and/or counties included in Attachment 2. Every effort will be made to provide these summary requests in a timely manner.

Requests may be sent via email to ppno@health.state.ny.us, (reference **CMD RFP** in the subject line), and must specify either **Excel** or **text** format.

Receipt of email submissions will be acknowledged electronically. If an acknowledgement is not received, it is recommended that the bidder confirm that the submission was received using a fax or phone call.

E. Minimum Qualifications

Bidders will be required to submit a description of their ability to meet the appropriate minimum qualifications using the format provided in PART III of this RFP. The State strongly encourages proposals from firms and government entities with substantial experience in the care management techniques included in this RFP.

Bidders must also submit letters of commitment from all proposed subcontractors, indicating that the subcontractor agrees to complete the specific functions included in the proposal.

F. Incurring Costs

The State is not liable for any cost incurred by bidders prior to issuance of a contract.

G. Bidder's Proposal

Bidders who meet the minimum qualifications and who wish to be considered must submit a complete response to this RFP, using the format defined below.

Proposals must be submitted on paper and CD ROM, in two (2) distinct volumes and separately sealed:

Volume I - Technical Proposal

Volume II - Financial Proposal

In order to be considered, proposals must include all required responses. A Bidder's Checklist is included in **Attachment 8** to assist with the preparation of proposals, which must be completed and submitted with the bid.

No price information is to be included in Volume I. Price information must be included only in Volume II. Any bid submitted with price information in Volume I will be disqualified.

1. Proposal Specifications

All bidders are required to follow the instructions and required format contained in this RFP in preparing and submitting their response. All response requirements detailed in PART II must be addressed in order for a proposal to be considered complete. Any other information thought to be relevant, but not applicable to the areas identified in the required format detailed below, should be provided as an appendix to the proposal. These requirements are for the purpose of enabling the evaluators to adequately review the proposal. Failure to conform may be sufficient reason for the rejection of the proposal. Upon receipt, bids will be reviewed for completeness. Failure to provide required information may cause rejection of the proposal. A Bidder's Checklist is included in **Attachment 8**, to help assure all required forms and materials are included in the bidder's proposal.

Proposals should be typed, using no less than one and one half spacing, double-sided or on one side, using 8 ½ by 11 inch paper and submitted in three-ring binders. Separate binders should be used for each of the two

volumes specified below. Required forms are included in **Attachment 8**. These forms may be copied, or can be reproduced as long as the reproductions accurately reflect the data content and requirement, and sequence.

Submission of a proposal indicates acceptance by the bidder of the conditions contained in the RFP.

By submitting a proposal, the bidder agrees that it will not make any claims for or have any rights to damages because of any misinterpretation or misunderstanding of the specification or due to lack of information.

Appendix O provides a list of acronyms and definitions used in this RFP.

2. Proposal Format

A bidder's proposal in response to this RFP must be mailed or delivered to the contact office in two (2) distinct, appropriately labeled (Volume I, Technical Proposal and Volume II, Financial Proposal) and sealed packages:

Volume I - Technical Proposal

The Technical Proposal must include the following:

- a. Letter of Transmittal
- b. Qualifications and Experience

Bidders should submit the following consistent with their type of organization.

a. Corporate Organization Qualifications

- 1) Minimum Requirements
- 2) Corporate Structure and Organization
- 3) Affiliations and Conflict of Interest
- 4) Financial Capacity
- 5) Legal Proceedings
- 6) Responsibility Questionnaire
- 7) Summary of Corporate Experience and References
(Includes **Form TP-1**)
- 8) Experience with State and Federal Legal and Program Requirements
- 9) Subcontractors

OR

b. Local Government Organization Qualifications

- 1) Minimum Requirements for Governmental Entities
- 2) Summary of Governmental Experience and References
(Includes **Form TP-1**)
- 3) Experience with State and Federal Legal and Program Requirements

- 4) Subcontractors
- 5) Affiliations and Conflict of Interest

Technical Approach Proposed

- a. Management Summary
- b. Proposed Service Area (includes **Form TP-2**)
- c. Target Population
- d. Scalability
- e. Demonstration Key Functions
 - 1) Intervention Population Selection
 - 2) Enrollment of Eligible Recipients and/or Providers
 - 3) Enrollee Assessment
 - 4) Care Plan Development and Intervention Implementation
 - 5) Outreach and Awareness
 - 6) Communications
 - 7) Quality Assurance
 - 8) Outcomes Measurement and Clinical Effectiveness
 - 9) Reporting Requirements
 - 10) Contract Performance Standards
- f. General Operations
 - 1) Work Plan and Schedule of Deliverables
 - 2) Organizational Chart
 - 3) Proposed Key Personnel and Staffing (Includes **Form TP-3**)
 - 4) Communication with DOH
 - 5) Prime Contractor
 - 6) HIPAA Compliance/Confidentiality
 - 7) Disaster Recovery
 - 8) IRB Requirement
 - 9) Phase Down Plan
 - 10) Evaluation of the Medicaid Disease and Care Management Demonstration

NOTE: VOLUME I MUST NOT INCLUDE ANY PROPOSED PRICE INFORMATION FOR THIS BID.

Volume II - Financial Proposal

Financial Response will include the following:

- a. Financial Proposal Requirements
- b. Form
- c. Assumptions

3. Due Date

To be considered, proposals must arrive at the DOH address listed below on or before 3:00 pm, May 31, 2005. A Public Bid Opening disclosing only the name

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and address of bidders will be held on this date at 3:30 p.m. at 99 Washington Avenue, Suite 816, Albany, New York. Bidders mailing proposals should allow sufficient mail delivery time to insure receipt of their proposals.

The bidder shall submit two (2) originals and ten (10) copies of the proposal on paper and one copy on CD ROM in a Microsoft Office or Adobe Acrobat (PDF) format. The proposal transmittal letter must be signed by a legally responsible corporate officer. The Technical Proposal and Financial Proposal must be packaged separately.

Proposals must be clearly marked as "Medicaid Disease and Care Management Demonstration Bid Proposal: Volume I, Technical Proposal and Volume II, Financial Proposal". The proposal volumes shall be sent to:

New York State Department of Health,
Office of Medicaid Management
ATTN: Carol A. Lindley
99 Washington Avenue, Suite 720
Albany, NY 12210

Proposals must not be submitted by fax or e-mail.

It is the bidders' responsibility to see that bids are mailed or delivered to Suite 720 prior to the due date and time. Late bids due to delay by the carrier or not received in the DOH's mail room in time for transmission to Suite 720 will not be considered.

- a. All evidence and documentation requested under Proposal Requirements must be provided at the time the proposal is submitted.
- b. Proposal transmittal letter must be signed by an official authorized to bind the bidder to its provisions.
- c. For this RFP, the proposal must remain valid for at least two hundred forty (240) calendar days.
- d. Proposals must adhere to the applicable requirements of Appendix D, General Specifications.

4. Economy of Presentation

Each proposal shall be prepared simply and economically, providing straightforward, concise delineation of bidder's capabilities to satisfy the requirements of this RFP. Fancy bindings, colored displays, and promotional material are not required. Emphasis in each proposal must be on completeness and clarity of content. To expedite the evaluation of proposals, it is essential that bidders follow the format and instructions contained herein.

5. Disclosure of Proposal Contents

To the extent permitted by law, bidder's proposals will not be disclosed, except for purposes of evaluation, prior to approval by the Office of the State Comptroller of the resulting contract. All material submitted becomes the property of the State and may be returned at the State's sole discretion. Submitted proposals may be reviewed and evaluated by any person designated by the State, other than one associated with a competing bidder. Selection or rejection of a proposal does not affect this right.

If a bidder believes that any information in its proposal constitutes a trade secret and wishes such information not to be disclosed if requested pursuant to the NYS Freedom of Information Law, Article 6 of the Public Officers Law, the bidder must submit with its transmittal letter a request for non-disclosure of trade secrets. This request must specifically identify page number, line or other appropriate designation that information considered to be a trade secret as well as a detailed explanation of such information. In no case shall entire bids or entire volumes of the bid (Technical or Financial) be considered trade secret.

Failure by a bidder to submit such a letter with its offer identifying trade secrets shall constitute 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.

The State reserves the right to approve or disapprove any such requests for information to be considered proprietary and will notify the bidder as to its determination. After the contract is approved, the contents of the proposals shall be considered public information, with the exception of proprietary information identified by the bidder and approved by the State.

6. State Use of Proposal Ideas

The State has the right to use any or all ideas presented in any proposal received in response to this RFP which are not approved as proprietary information of the bidder and so designated in the proposal, and which:

- a. Were known to the State before submission of such proposal, or
- b. Properly became known to the State thereafter, through other sources or through acceptance of the bidder's proposal.
- c. In no case shall entire proposals or entire parts of proposals (i.e., Technical or Financial) be considered trade secret.

7. Rejection of Proposals

The State reserves the right to reject any and all proposals received as a result of this RFP.

H. Prime Contractor's Responsibilities

The selected contractor will be required to assume primary responsibility for all services offered in the proposal, whether or not that contractor directly provides them. Further, the State will consider the selected contractor to be the sole point of contact with regard to contractual matters. The State reserves the right to approve all subcontractors to be used on the project.

I. Modifications

The State reserves the right to define requirements to meet the DOH's needs and to modify, correct, and clarify requirements at any time during the process provided the changes are justified and that modifications would not materially benefit or disadvantage a bidder.

J. Oral Presentations

The Department reserves the right to request that bidders who are being considered for selection provide oral presentations in order to clarify their bids.

K. Method of Award - Vendor Selection

1. Evaluation Objective

The objective of this evaluation approach is to select bidders proposing the best value CMD which optimizes quality, cost, effectiveness and efficiency. The significant factors upon which bidders will be evaluated are delineated in this Section.

2. Bid Evaluation Process

As part of the bid evaluation process, the State reserves the right to:

- ◆ Seek additional clarifying information from bidders before scoring proposals.
- ◆ Waive or modify minor irregularities in proposals received after prior notification to the bidder.
- ◆ Adjust or correct price figures, with the concurrence of the bidder, if errors exist and can be documented to the satisfaction of DOH and the Office of the State Comptroller.

a. Minimum Organizational Qualifications

Corporate organizations must have sufficient experience, financial stability and organizational capacity to administer CMDs. Corporate qualifications for these entities will be examined to ensure operational experience requirements are fulfilled. Only proposals from those firms deemed qualified based on meeting the minimum qualifications, as determined by the State, shall be evaluated further.

Local government organizations must have a strong willingness to sponsor a CMD and demonstrate experience in this area. Each governmental organization must clearly demonstrate that it meets the minimum qualifications by detailing its intent in sponsoring a CMD. Only proposals from governmental organizations deemed qualified based on meeting the minimum qualifications, as determined by the State, shall be evaluated further.

All subcontractor information will be assessed to ensure there is sufficient, relevant experience. The written commitment of all proposed subcontractors to complete the assignment of specific functions as detailed in the proposal shall be confirmed. The submission of required forms and information relative to Executive Order #127 shall be evaluated for completeness. Proposals from bidders not meeting the minimum qualifications in PART II, B will not be considered further.

b. Prescreening

Proposals (**Volumes I and II**) submitted by qualified bidders will first be prescreened for completeness. Any proposal failing to provide all response requirements as specified in this RFP, and in the prescribed format, may be removed from further consideration and the bidder notified accordingly.

c. Technical Evaluation

The Technical Evaluation Team (TET) will evaluate and score, based on a weighted point system, each bidder's ability to deliver the services described in this RFP. The evaluation of the bidder's technical approach will be based on **Volume I**, of their proposal, responses to any clarifying questions, corporate and personnel reference checks, and commitments by subcontractors. Oral presentations may also be included if required by the Department for clarifying information.

The TET shall evaluate all business and financial relations with other entities which may, or may be perceived to, present a potential conflict of interest. Upon review, the TET may refer proposals to qualified State legal representatives for further review and approval. If the nature of any affiliations, relations or potential conflicts of interest is deemed unacceptable based on the review, the TET shall have the ability to disqualify a proposal.

Each response requirement will be evaluated based on the bidder's understanding of the State's objectives, efficiency and soundness of approach. The State will evaluate proposals as to their overall effectiveness and ability to meet the objectives of this RFP. The detailed evaluation criteria and weight of the components will not be disclosed to

bidders. Information from the financial proposal (**Volume II**), or evaluation thereof, will not be available to the TET during their evaluation.

The total technical proposal score will be normalized based on a maximum score of seventy (70) points for each bid received. The bidder receiving the highest technical score shall receive seventy (70) points, and the remaining bids shall then be normalized against the highest scored proposal received based on the relative ranking of the technical score. Proposals with normalized technical scores of thirty-five (35) or below will be considered non-responsive and ineligible for selection.

d. Financial Evaluation

The Financial Evaluation Team (FET) will evaluate and score each bidder's financial proposal (**Volume II**). Proposed price will be reviewed for completeness and consistency with instructions and **Financial Proposal Form** provided in this RFP. Definitions of price categories have been included in PART II, Section C.

The following financial evaluation process will be applied:

The total bid price of the CMD will be used to calculate the bidder's final financial proposal score. The total price is equal to the sum of the implementation price and total operations price for the total length of the two (2) year CMD.

The total financial proposal score will be normalized based on a maximum score of thirty (30) points. The total financial proposal score will be normalized against the lowest price CMD proposal.

3. Contractor Selection

A Selection Committee will make a recommendation regarding the selection of contractor(s) using the following formula:

The normalized technical plus the normalized financial scores for each bid will be added to provide a total combined score for each bidder.

The Committee will base their selection of responsible bidders on the highest total combined score using the guidelines set forth below. The Committee will select multiple proposals consistent with requirements to address geographic diversity, limitation on the number of proposals addressing services within a single social service district, funding limitations and the need to avoid duplication of services.

- a. After a total combined score is calculated, all bids will be sorted into their respective regions. Proposals will be ranked from highest to lowest; according to their total combined score within a region.

- b.** The initial selection will consist of up to four (4) proposals (one from each region) based on the highest total combined score within the region. If funds have not been exhausted after the initial selection, the Committee may continue to select proposals based on the next highest total combined score regardless of the region in which the CMD has been proposed. In the event that the remaining funds are insufficient to support an additional selection by the Committee, the DOH reserves the right to renegotiate the selected service area of the bidder who would have been selected had sufficient funds been available.

During the selection process the Committee has the right to:

- a.** Bypass a proposal with a lower total combined score that duplicates the services of a prior selection.
- b.** Bypass a proposal based on insufficient funds to support the full proposal and the unwillingness of the bidder to renegotiate the price of the CMD.
- c.** Limit the number of CMDs selected to meet the requirement that proposals which are limited to one (1) social services district to no more than one third (1/3) of the total number of CMDs selected. If less than six (6) CMDs are selected, no more than one (1) such program will be selected.

In the event that current legislation and/or the amount of funding available is amended prior to the selection process being completed, the Committee will make its recommendations consistent with the revised legislative guidelines and funding.

The Committee will recommend the selected bidders to the DOH, who will then approve the final selection. If the State is unsuccessful in negotiating a contract with the selected bidders within an acceptable time frame, the State may begin contract negotiations with the next qualified bidders in order to serve and realize the best interests of the State.

Prior to final selections, this RFP and all responses thereto are subject to various State reviews. In addition, the DOH, Attorney General, and the Office of the State Comptroller must approve the final contract.

L. Debriefing Conferences

Bidders whose proposals are not selected will be notified of their proposal score. The Issuing Agency will schedule the time and location of the debriefing regarding the evaluation of their proposal for those wishing to take advantage of this opportunity. The debriefing will be limited to the evaluation results of the bidder's own proposal.

M. Rights of the Department of Health

The DOH reserves the right to:

1. Reject any or all proposals received in response to this RFP.
2. Waive or modify minor irregularities in proposals received after prior notification to the bidder.
3. Adjust or correct price or price figures with the concurrence of bidder if errors exist and can be documented to the satisfaction of DOH and the State Comptroller.
4. Elect to contract with the bidder for only a portion of the proposed service areas.
5. Negotiate with vendors responding to this RFP within the requirements to serve the best interests of the State.
6. Modify the detail specifications should no bids be received that meet all these requirements.
7. Disqualify a proposal for failure to satisfy one or more mandatory requirements.
8. Delete mandatory requirements unmet by ALL bidders.
9. If the DOH is unsuccessful in negotiating a contract with the selected vendor within an acceptable time frame, the DOH may begin contract negotiations with the next qualified vendor(s) in order to serve and realize the best interests of the State.

N. Term of Contract

The agreement shall be effective upon approval of the OSC. The term of the contract shall be twenty-four (24) months following approval of the contract by the OSC.

The Department may extend the term of the contract if funding is made available and the evaluation recommends such an approval.

PART IV - Contractual Provisions

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PART IV - Contractual Provisions

A. CONTRACTOR RESPONSIBILITIES

1. General Contractor Duties

The contractor shall:

- 1.1.** Assume complete responsibility for the cost and timely completion of all activities and duties required of the contractor by this Agreement in carrying out those activities and duties in a competent and timely manner.
- 1.2.** Notify the State in writing of any changes in the persons designated to bind the contractor.
- 1.3.** Maintain a dedicated administrative organization sufficient, in the judgment of the State, for the contractor to discharge its contractual responsibilities.
- 1.4.** Maintain the level of liaison and cooperation with the State necessary for proper performance of all contractual responsibilities. The parties will remain in contact as needed, and status meetings will be held on a bi-weekly basis or as needed, to be determined by the State.
- 1.5.** Maintain senior management as identified in the proposal unless granted specific written permission to change senior management by the State, which permission shall not be unreasonably withheld. "Senior" shall mean those managers identified as key personnel in accordance with the Request for Proposal (RFP).
- 1.6.** Maintain staffing levels and key personnel, except as changes are approved by the State or caused by resignations or other situations beyond the control of the contractor. The State shall be notified in writing at least one week prior to key staff vacancies when possible. This notification shall contain the date of the vacancy and an indication as to the nature of the change (i.e., resignation or transfer). Staff additions will be made only after State review and approval of the personnel to be added; such approval will not be unreasonably withheld.
- 1.7.** Agree that no aspect of contractor performance under this Agreement will be contingent upon State personnel or the availability of State resources, with the exception of such proposed actions of the contractor which are specifically identified in this Agreement as requiring State approval, policy decisions, policy approvals, or exceptions stated in this Agreement or which require the normal cooperation which can be expected in such a contractual relationship.
- 1.8.** Submit in writing to the State, within three (3) business days of learning of any situation which can reasonably be expected to adversely affect the operation

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of the Medicaid program, a description of the situation and include a recommendation for resolution whenever possible.

- 1.9. Be responsible for full, current and detailed knowledge of, and compliance with, the requirements of applicable Federal and New York State Laws and the pertinent regulations and guidelines promulgated thereunder. The State shall advise the contractor in a timely manner of changes in any such laws or regulations and provide copies as reasonably requested by the contractor.
- 1.10. Implement changes within the scope of work of this Agreement, in accordance with a State approved schedule, including changes required in policy, regulation, statute, or judicial interpretation.
- 1.11. Cooperate fully with any other contractors that may be engaged by the State to work on Medicaid-related activities.
- 1.12. Recognize and agree that any and all work performed outside the scope of this Agreement or without consent of the State shall be deemed by the State to be gratuitous and not subject to charge by the contractor.
- 1.13. Cooperate with the State, any other authorized State agency, and any law enforcement authorities in the investigation, documentation, and litigation of possible fraud and abuse cases or any other possible misconduct which may affect the Medicaid program.
- 1.14. Perform in accordance with the performance standards set forth in the RFP.

2. Accounting Requirements

The contractor shall establish accounting policies and procedures acceptable to the State, maintain records and supply reports to the State periodically and as requested by the State.

2.1. Internal Controls

The contractor must develop and maintain policies and procedures for an internal control system to appropriately safeguard the State's assets. The policies and procedures must explicitly describe the audit trail and detail the checks and balances in the system to prevent diversion and/or misappropriation of payments.

2.2. Accounting Procedure Inclusions

The contractor shall use generally accepted accounting procedures and policies necessary to ensure control of Agreement expenses. The accounting procedures, policies and records related to this contract shall be open to State audit and include, but not be limited to, the following:

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- (a) A definition of accounting relationships with related business organizations and subcontractors.
- (b) A procedure for allocating expenses for items which are not totally dedicated to this Agreement.

2.3. Accounting Records Supplied to the State

The contractor shall provide to the State specified fiscal records and an accounting of expenses for the purposes of the State seeking FFP and/or matching federal funds. Such reports shall be provided in a format as required by the State for such funding.

2.4. Billings to the State

The contractor shall submit monthly billings to the State in the form and calculated in the manner provided for in Section B, 1.5. of this Agreement.

2.5. Accounting Ledgers

The contractor shall maintain separate sets of accounting ledgers, exclusively for this Agreement, that include a record of all revenues and receipts, expenses and disbursements related to the Medicaid Care Management Agreement.

3. **Rights of the State to Facilities and Equipment**

- 3.1. In the event of termination or expiration of this Agreement, any equipment purchased by the contractor solely for the use of the State Medicaid program under this contract shall be transferred to the State or at the State's option, to a successor contractor by the contractor without additional remuneration from the State, except that the State shall pay the contractor (if not the successor contractor) the net depreciated value for equipment which has not been fully depreciated, unless agreed to otherwise in writing.
- 3.2. In the event of termination or expiration of this Agreement, any equipment transferred to the contractor by the State under this Agreement shall be transferred back to the State or at the State's option to a successor contractor without additional remuneration from the State.
- 3.3. Prior written approval by the State shall be required for the contractor's purchase, lease or other acquisition, of equipment and of the contractor's office and storage facilities dedicated to the State Medicaid program. The provisions of this Section shall not apply to consumable supplies, such as paper, clerical and stationery products, which are routinely utilized by the contractor and consumed in the course of performance under this Agreement.
- 3.4. All such equipment and dedicated facilities shall not be disposed of and any lease for such equipment or facility shall preserve, to the extent applicable, the State's equity and purchase option rights.

4. Fair Hearings

4.1. If required by the State, the contractor shall participate in all fair hearings involving recipients or providers where issues include determinations or decisions by the contractor. The State has the authority to decide whether the contractor needs to participate in any given fair hearing and the contractor will so participate if so directed by the State. The contractor shall provide personnel familiar with the facts of the particular case with the ability and authority to review the initial determination. Said hearings shall be conducted in accordance with guidelines and the applicable rules and regulations promulgated by the State. Specific contractor responsibilities in this area are described in the RFP and contained in **Appendix F** and in State Regulations.

5. Review of Deliverables

5.1. The State will review deliverables submitted by the contractor to the State, accept or reject those deliverables, and provide written comments and notice of deficiencies, if any, to the contractor, within twenty-five (25) business days of receipt and will use all reasonable efforts to complete the review in less than the allotted time. The contractor shall correct the deficiencies cited by the State and resubmit the deliverable for approval within ten (10) 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. The contractor shall respond to all State comments and incorporate such response into its resubmission of the deliverable; full response by the contractor, in the reasonable judgment of the State, to the State's comments within ten (10) business days will constitute fulfillment of that deliverable unless the State provides, within ten (10) business days of receipt of the resubmitted deliverable, notice of a continuing deficiency. If notice of a continuing deficiency is given, the State will provide to the contractor a detailed description of the deficiencies that continue.

5.2. As used in Section A. 5.1., the term "continuing deficiency" shall be limited to:

- (a) Inadequate resolution, in the reasonable judgment of the State, of the items raised during the previous State review;
- (b) Related issues which were tied to or created by the method of resolving the previous State comments;
- (c) Items which could not be thoroughly tested or reviewed by the State because of an inadequate, incorrect or incomplete deliverable previously submitted, which was identified as inadequate, incorrect or incomplete in previous written comments by the State; and
- (d) Omissions of parts of a deliverable.

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- 5.3.** The intent of the above paragraph is to preclude the introduction of new and unrelated items during subsequent reviews which could have been identified by a thorough review of a previously submitted deliverable. Such reviews and resubmissions shall not be construed as a waiver of any deliverable or obligation to be performed under this Agreement, nor of any scheduled deliverable date, nor any rights or remedies provided by law or under this Agreement, nor shall the State's comments on any deliverable relieve the contractor from any obligation or requirement of this Agreement.
- 5.4.** In the event the State fails to provide timely review and response for acceptance or rejection of a deliverable in accordance with this Section, the contractor shall notify the State of the late response and proceed with performance as if acceptance had been received from the State. However, such failure by the State to respond shall not constitute acceptance of the deliverable by the State. If, in such circumstances, the State subsequently requires material changes to the deliverable, the parties shall fairly consider and mutually agree as to the effect of the untimely rejection or acceptance on the delivery or implementation schedules. In no event shall the contractor be entitled to any price increase due to the need to correct deficient deliverables, nor shall the contractor be subject to any penalty if the State fails to timely respond.
- 5.5.** The contractor will deliver drafts of deliverables to the State whenever possible to facilitate the State's review process. The parties agree to submit communications regarding deliverables in writing. However, nothing set forth herein with regard to the formal review process for deliverables shall preclude verbal comments by the State to the contractor or its representatives during that process, and those verbal comments may be provided in addition to the formal process set forth herein.
- 6. Medicaid Confidential Data Requirements**
- 6.1.** The contractor and all subcontractors will complete and maintain a NYS Medicaid Data Exchange Application and Agreement (DEAA), and shall not be provided access to Medicaid confidential data without approval of the DEAA.
- 6.2.** Medicaid Confidential Data (MCD) includes, but is not limited to, names and addresses of Medicaid applicants/recipients, the medical services provided, social and economic conditions or circumstances, the DOH's evaluation of personal information, medical data, including diagnosis and past history of disease and disability, any information regarding income eligibility-and amount of medical assistance payment, income information, and/or information regarding the identification of third parties. Income information received from Social Security Administration (SSA) or the Internal Revenue Service must be safeguarded according to the requirements of the agency

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that furnished the data. Also any information received in connection with the identification of legally liable third party resources under 42 CFR 433.138. Each element of MCD is confidential regardless of the document or mode of communication or storage in which it is found.

6.3. This contract involves the MCD of recipients and possibly applicants, both of which are confidential pursuant to Section 367-b(4) of the N.Y. Social Services Law, 42 U.S.C. 1396a(a)(7), Section 1902(a)(7) of the Social Security Act and 42 C.F.R. Section 431.300 et seq.

6.3.1. No disclosure of MCD in the contractor's possession can be made to any other person or entity without the prior written permission of the DOH's Medicaid Confidential Data Review Committee (MCDRC). Likewise, no use(s), other than the use(s) of MCD approved in this data exchange application and agreement, can be made of the MCD without the prior written approval of DOH's MCDRC.

6.4. Pursuant to Section 367-b(4) of the N.Y. Social Services Law, information relating to persons applying for medical assistance shall also be considered confidential and shall not be disclosed to persons or agencies without the prior written approval of the DOH.

6.5. AIDS/HIV Related Confidentiality Restrictions

6.5.1. MCD may contain HIV related confidential information, as defined in Section 2780(7) of the N.Y. Public Health Law. As required by N.Y. Public Health Law Section 2782(5), the DOH hereby provides you with the following notice:

6.5.1.1. HIV/AIDS Notice

This information has been disclosed to you from confidential records which are protected by State law. State law prohibits you from making any further disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. Any unauthorized further disclosure in violation of State law may result in a fine or jail sentence or both. A general authorization for the release of medical or other information is NOT sufficient authorization for further disclosure.

6.5.2. The contractor agrees that any further disclosure of MCD requires the prior, written approval of the DOH's MCDRC. The contractor will require and ensure that any approved agreement, contract or document with a subcontractor contains the above Notice and a statement that the subcontractor or other party may not disclose the MCD without the prior, written approval of the DOH's MCDRC.

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6.6. Alcohol and Substance Abuse Related Confidentiality Restrictions

6.6.1. Alcohol and substance abuse information is confidential pursuant to 42 CFR Part 2. General authorizations are ineffective to obtain the release of such data. The federal regulations provide for a specific release for such data.

6.7. Any agreement, contract or document with a subcontractor must contain all of the above provisions pertaining to confidentiality. It must contain the HIV/AIDS notice as well as a statement that the subcontractor may not use or disclose the MCD without the prior written approval of the DOH's MCDRC.

B. CONTRACTOR'S PERFORMANCE AND BASIS OF PAYMENT

1. Basis of Payment

Consideration for performance by the contractor of the tasks described in the RFP Detailed Specifications will be paid according to the terms and conditions set forth below. The contractor shall submit invoices to the State for payment. Payment shall be made in accordance with Article XI-A of the New York State Finance Law, and are exempt from late payment interest pursuant to the statutory exception for a contractor of third party payment agreements.

1.1. Implementation Payments

The State shall pay the contractor for full and proper completion of all implementation tasks included in the approved implementation plan in the contractor's proposal as modified or supplemented in **Appendix P**, by the terms of this contract and subsequent negotiations.

1.1.1. Upon successful completion of implementation, the contractor shall submit one (1) voucher for payment of approved implementation costs. Payment to the contractor shall be made promptly after receipt of such voucher that is satisfactory to the DOH and the Office of the State Comptroller.

1.1.2. In the event that the contractor fails to achieve milestones related to implementation, or to furnish deliverables, which result in delays of implementation beyond the schedule in the final implementation plan approved by the State, the State may assess penalties for each week the implementation is not achieved beyond the scheduled delivery date. Penalties shall not be assessed for delays attributable to the State or any entity not subject to the contractor's control in the sole judgment of the DOH. Such penalties may be up to thirty percent (30%) of the implementation payment due the contractor at completion of implementation.

1.2. Operations Payments

The State shall pay the contractor for full and proper performance of the administration of disease management functions in the RFP as amended by documented Questions and Answers and in the contractor's proposal as modified or supplemented by the terms of this contract. Payments for the care management functions shall be made monthly, based on the contractor's approved per member cost for each enrolled intervention recipient as specified in **Appendix P** of this Agreement.

- 1.2.1.** The monthly payment will be based on the number of enrolled intervention recipients as of the first business day of the month and the approved per member per month (PMPM). Any disenrollment that occurs during a month will be made effective the first day of the following month in which status change occurred and paid as such. In the case where a former intervention enrollee chooses to re-enroll in the care management program, eligibility for payment will begin the first business day of the following month.
- 1.2.2.** In the event that the contractor fails to meet any milestones, or furnish deliverables related to ongoing administration of care management functions, the portion of payment attributable, in the judgment of the State, to the milestones or deliverables for which the contract is deficient shall be withheld by the State, in its sole discretion, until such time as the milestones or deliverables are determined by the State to have been properly achieved or furnished.
- 1.2.3.** The contractor shall submit a monthly voucher for the administration of care management functions accepted and approved by the State. The State shall, upon receipt of a properly completed voucher, pay the contractor the adjusted payment shown in **Appendix P** of this Agreement.

1.3. Re-negotiations

Under those conditions defined in this Section, the parties agree to enter into good faith negotiations to adjust future payments to reflect associated cost changes as a result of changes in the nature of activities or volume of workload required by the State. It is further agreed that both parties will use their best efforts to finalize negotiations on these matters within sixty (60) calendar days of notification.

- 1.3.1.** In the event that significant changes in projected workload or the contractor's scope of work are required due to changes in Federal or New York State law policy or regulations, the parties agree to immediately enter into negotiations to adjust future payments to reflect associated cost reductions or increases.

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1.3.2. In the event that the State determines significant changes in the scope of this contract or workload are required, the parties agree to immediately enter into negotiations to adjust future payments and terms to reflect such changes in scope.

1.4. Performance

Full payment shall be made on each invoice upon State review and determination that the contractor has performed in accordance with the performance standards and other submitted deliverables as set forth in this Agreement and the RFP.

1.4.1. In the event that the contractor fails, in the reasonable judgment of the State, to properly perform in accordance with the performance standards, full or partial payment for that category for which the contractor is deficient may be withheld by the State until such time as the State reasonably determines that the performance standards are met, or the State may assess liquidated damages.

1.4.2. The determination of the amount withheld shall represent the reasonable value, in the judgment of the State, of the performance standards not met. Notwithstanding the above provisions, the State shall not withhold, within any given month, more than thirty percent (30%) of the total monthly payment due as reflected in **Appendix P** of this Agreement.

1.4.3. The State may assess as liquidated damages a reasonable amount, not to exceed a ten percent (10%) nonrefundable reduction in the total monetary amount of the invoice for the month in which the performance requirement was not met, which the parties hereby agree represents a reasonable measure of the damages incurred by the State for such nonperformance.

1.4.4. The contractor may provide to the State information regarding the circumstances surrounding the deficiency and the measure of damages. The State may consider such information when determining the reasonable measure of damages and when determining whether such assessment will be a nonrefundable deduction and/or a withholding.

1.4.5. Liquidated damages assessments may be repeated each thirty (30) calendar days and further liquidated damages assessed until the performance requirement is determined by the State to have been properly achieved or furnished by the contractor. Assessment of liquidated damages pursuant to the foregoing provisions does not constitute an exclusive remedy, and the State may elect to pursue any other remedies available under the law and the terms of this Agreement.

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- 1.4.6.** If the performance in question is subsequently achieved or furnished as determined by the State, withheld payments (less any liquidated damages assessed) shall be released to the contractor.

1.5. Billing Address

Contractor shall submit standard vouchers to the NYS Department of Health, the State's designated payment office, located at Empire State Plaza, Corning Tower, Room 2019, Albany, New York 12237. Payments to the contractor shall be made promptly after receipt of such vouchers and necessary supporting documentation satisfactory to the DOH and the Comptroller.

2. Contract Procedures

2.1. Subcontracting

- 2.1.1.** Prior written approval by the State shall be required for all subcontracts. This requirement does not apply to individual employer-employee contracts, or management incentives for same, or subcontracts executed prior to the date of release of the RFP. Any subcontract related to performance of this Agreement shall be subject to the provisions of law set forth in Sections 220, 220-d and 220-e of the Labor Law of the State of New York, Article 15 of the Executive Law of the State of New York and to the provisions set forth herein.
- 2.1.2.** All subcontracts shall be in writing and shall contain certain provisions which are functionally identical to, and consistent with, the provisions of this Agreement. Such functionally identical and consistent provisions shall include, but not be limited to, the following provisions of this Agreement: Standard Clauses for all New York State Contracts; HIPAA requirements; Audit; Access Requirements; Medicaid Confidentiality Data Requirements; Employment Practices; Indemnification of the State; Termination; etc.
- 2.1.3.** In addition to furnishing the State with a copy of any proposed subcontract for prior approval, the contractor shall also furnish to the State the following:
- (a)** A description of the supplies or services to be provided under the proposed subcontract;
 - (b)** Identification of the proposed subcontractor;
 - (c)** The proposed subcontract price; and
 - (d)** Any other pertinent information or documentation requested by the State.
- 2.1.4.** A copy of any subcontract, once approved by the State and executed by the contractor and the subcontractor, shall be furnished to the State within thirty (30) calendar days of execution.

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- 2.1.5. The contractor shall give the State immediate notice in writing of any legal action or suit filed, and prompt notice of any claim made, against the contractor by any subcontractor or vendor which may result in litigation related in any way to this Agreement or which may affect the performance of duties under this Agreement.
- 2.1.6. The requirement of prior approval of any subcontract by the State under this Agreement shall not make the State of New York a party to any subcontract or create any right, claim or interest in the subcontractor or proposed subcontractor against the State.
- 2.1.7. The contractor shall not be relieved in any way of any responsibility, duty or obligation of this Agreement by a subcontract.

2.2. **Modification**

- 2.2.1. Scope of Work Alteration - The parties agree that this Agreement, including the RFP as amended in the Questions and Answers, and the Proposal, fairly delineates the scope of work to be performed under this Agreement at the prices presented in **Appendix P** of this Agreement. However, the parties further agree that, in the event the State through change in policy, regulation or law, alters that scope or level of required work or amends the proposed implementation schedule 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.
- 2.2.2. The State may request, or the contractor may propose to the State, enhancements and modifications to support functions not now required to be performed by this Agreement. The contractor shall prepare and submit a proposal to the State in the level of detail requested by the State for each such enhancement or modification specifying the scope of work and the resulting initial and/or operating charges, if any. The contractor will accomplish the work only upon the mutual consent of the parties reduced to writing and approved, as necessary, by the Office of the State Comptroller and all other required State reviewers.
- 2.2.3. This Agreement is subject to modification only upon mutual consent of the parties reduced to writing and approved by the Office of the State Comptroller and all other required State reviewers.

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2.3. Termination

2.3.1. Basis for Termination - The Agreement may be terminated:

2.3.1.1. By mutual written agreement of the contracting parties.

2.3.1.2. By the State, in whole, or, from time to time, in part whenever the contractor shall materially default in performance of the Agreement in accordance with its terms and shall fail to cure such default within a period of thirty (30) calendar days (or such longer period as the State may allow) after receipt from the State of a written notice specifying the default. If it is subsequently determined for any reason that the contractor was not in material default or that the contractor's failure to perform or make progress in performances was due to causes beyond the control and without the fault or negligence of the contractor, the State shall have the option to either deem the Notice of Termination to have been issued under Section B, 2.3.1.3. herein as a termination for convenience of the State, and the rights and obligations of the parties shall be governed accordingly, or allow the contractor to resume performance under this Agreement, with any price adjustment for new start-up, etc. made pursuant to the procedure set forth in Section B, 2.2.1. herein. In the event of a termination for default, the contractor shall be paid the following:

- (a) For operating costs and charges, the calculated monthly payment prorated to the date of termination
- (b) Costs allowable in the reasonable judgment of the State incurred in providing continuity of services; and
- (c) Costs allowable in the reasonable judgment of the State for settling and paying subcontractor and supplier claims arising out of the termination of work when costs were incurred prior to termination and such claims are properly chargeable to the terminated portion of this Agreement.

2.3.1.3. By the State, in whole, or from time to time in part, whenever for any reason the State shall determine that such termination is in the best interest of the State. Such termination shall be referred to herein as "termination for convenience." Upon receipt of thirty (30) calendar days (or such longer period as the State may allow) notice of termination for convenience, the contractor shall be paid the following:

- (a) For operating cost and charges, the calculated monthly payment prorated to the date of termination.
- (b) For the undepreciated value of equipment to be turned over to the State;
- (c) Costs allowable in the reasonable judgment of the State incurred in providing continuity of services;
- (d) All other ongoing expenses allowable in the reasonable judgment of the State incurred by the contractor in performance under this Agreement;

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- (e) Costs allowable in the reasonable judgment of the State of settling and paying subcontractor and supplier claims arising out of the termination of work when such costs were incurred prior to termination and such claims are properly chargeable to the terminated portion of this Agreement; and
- (f) Reasonable costs in the reasonable judgment of the State, arising from the settlement process, including accounting, legal, clerical and other justifiable expenses, necessary for the preparation of settlement claims and supporting data with respect to the terminated portion of this Agreement, and for the termination and settlement of subcontracts thereunder.

2.3.1.4. Upon filing of a petition in bankruptcy or insolvency by or against the contractor, if such petition is not vacated within thirty (30) calendar days of its filing, the State may deem this Agreement terminated without termination services or costs, but payments for services rendered, subject to the status of the State as a creditor in possession, shall be made as provided in Section B, 2.3.1.3. herein. The State shall not be precluded during the thirty (30) calendar day vacated period from terminating this Agreement under other bases provided for in Section B, 2.3.1. herein.

2.3.1.5. Should State funds for this Agreement not be appropriated in the approved State budget the State may deem this Agreement terminated.

2.3.1.6. If this Agreement terminates under Section B, 2.3.1.5. herein, no special termination arrangements or special remuneration are necessary.

2.3.2. Procedures on Termination

Upon receipt of a written notice of termination in the exercise of any bases for termination pursuant to Section B, 2.3.1. herein, and except as otherwise directed by the Deputy Commissioner of the Office of Medicaid Management, the contractor shall:

2.3.2.1. Immediately provide to the State or, at the State's option, to a successor contractor in conformance with Section A, 3. herein, all assets which under Section A, 3. are the property of the State or which the State is entitled to use under this Section as well as all information necessary for the completion of disease management functions underway. The contractor shall also make provision for turning over any remaining records to the State which are held after the completion of the final accounting as provided for in Section B, 2.3.2. herein. Additionally, the contractor shall assist the State or a successor contractor in completing any activities undertaken before the termination of the Agreement.

2.3.2.2. Stop work under this Agreement on the date and to the extent specified in the notice of termination.

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- 2.3.2.3.** Place no further orders or subcontracts for materials, services or facilities, except as may be necessary for completion of such portion of the work under this Agreement as is not terminated.
- 2.3.2.4.** Terminate all orders and subcontracts to the extent that they relate to the performance of work terminated by the notice of termination.
- 2.3.2.5.** Assign to the State, in the manner and to the extent directed by the State, all of the rights, title and interests of the contractor under the orders of subcontracts so terminated, in which case the State shall have the right, in its reasonable judgment, to settle or pay any or all claims arising out of termination of such orders and subcontracts.
- 2.3.2.6.** With the approval or ratification of the State, to the extent it may require, which approval or ratification shall be final and conclusive for all purposes of this clause, settle all outstanding liabilities and all claims rising out of such termination or orders or subcontracts, the cost of which would be reimbursable in whole or in part, in accordance with the provisions of this Agreement.
- 2.3.2.7.** Complete the performance of such part of the work as shall not have been terminated by the notice of termination.
- 2.3.2.8.** Take such action as may be necessary, or as the State may direct, for the protection and preservation of the property related to this Agreement which is in the possession or control of the contractor and in which the State has or may acquire an interest.
- 2.3.2.9.** After receipt of a notice of termination, the contractor shall submit to the State its termination claim in the form and with the certification prescribed by the State. Such claim shall be submitted promptly but in no event later than six (6) months from the effective date of termination, unless one or more extensions in writing are granted by the State upon request of the contractor made in writing within such six (6) month period or authorized extension thereof. However, if the State determines that the facts justify such action, it may receive and act upon any such termination claim within any reasonable time after such six (6) month period or any extension thereof. Upon failure of the contractor to submit its termination claims within the time allowed, the State may, subject to any review required by the State's procedures in effect as of the date of execution of this Agreement, determine, on the basis of information available to it, the amount, if any, due to the contractor by reason of the termination and shall thereupon cause to be paid to the contractor the amount so determined.
- 2.3.2.10.** Subject to the provisions of Section B, 2.3.2.10. herein, and subject to any review required by the State's procedures in effect as of the date of execution

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- of this Agreement, the contractor and the State may agree upon the whole or any part of the amount or amounts to be paid to the contractor by reason of the total or partial termination of work pursuant to Section B, 2.3. herein. This Agreement shall be amended accordingly, and the contractor shall be paid the agreed amount.
- 2.3.2.11.** In the event of the failure of the contractor and the State to agree in whole or in part, as provided in Section B, 2.3.2.11. herein, as to the amounts with respect to charges to be paid to the contractor in connection with the termination of work pursuant to Section B, 2.3. herein, the State shall determine, on the basis of information available to it and as provided in Section B, 2.3., the amount if any, due to the contractor by reason of termination and shall pay to the contractor the amount so determined.
- 2.3.2.12.** The contractor shall have the right to appeal under Section B, 2.5. of this Agreement, entitled "Disputes," from any such determination made by the State, except that, if the contractor has failed to submit its claim within the time provided in Section B, 2.3.2.9. above, and has failed to duly request extension of such time, it shall have no such right of appeal.
- 2.3.2.13.** In any case where the State has made such determination of the amount due, the State shall pay to the contractor the following:
- (a) If no timely appeal has been taken, the amount so determined by the State; or
 - (b) If an appeal has been timely taken, the amount finally determined on such appeal.
- 2.3.2.14.** In arriving at the amount due the contractor under Section B, 2.3.2.10. through Section B, 2.3.2.12. herein, there shall be deducted:
- (a) Any documented claim which the State may have against the contractor in connection with this Agreement; and
 - (b) The agreed price for, or the proceeds of sale of, any materials supplied, or other things acquired by the contractor or sold pursuant to the provisions of Section B, 2.3. herein and not otherwise recovered by or credited to the State.
- 2.3.2.15.** The State may from time to time, under such terms and conditions as it may prescribe, make partial payments and payments on account against costs incurred by the contractor in connection with the termination portion of this Agreement whenever, in the opinion of the State, the aggregate of such payments shall be within the amount to which the contractor will be entitled hereunder. If the total of payments is in excess of the amount finally determined to be due under Section B, 2.3.2. herein, such excess shall be payable by the contractor to the State upon demand. Simple interest, shall

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accrue at the rate of ten percent (10%) per year, for the period from the receipt of the first invoice and demand for payment, to the date on which such excess is repaid to the State.

2.4. Agreement Duration

2.4.1. Term of the Agreement

The term of this Agreement shall be for up to twenty-four (24) months following contract approval by the OSC.

2.4.2. Extension of Term of Agreement

The State has the option, under one hundred fifty (150) calendar days written notice, to extend the end-date of this Agreement for a period not to exceed two (2) years, in one-year increments. Payments for the extension period(s) shall be in the amounts identified in **Appendix P** of this Agreement, which shall be based upon the rates contained in the contractor's proposal and subsequent negotiations with the State adjusted by the lesser of a) the consumer price index rate of increase or b) three percent (3%).

2.5. Disputes

This Disputes provision shall apply to any dispute of the parties relating to performance under this Agreement. Any dispute concerning any question of fact or law arising under this Agreement which is not disposed of by mutual agreement of the parties shall be initially decided by the State. A copy of the written decision shall be furnished to the contractor. Upon issuance of such decision, the parties shall proceed diligently with the performance of this Agreement and shall comply with the provisions of such decision and continue to so comply pending further resolution of such dispute as provided herein. The decision of the State shall be final and conclusive unless, within ten (10) calendar days from the receipt of such decision, the contractor furnishes a written appeal to the State. In the event of an appeal, the State shall promptly review the initial decision, and confirm, annul or modify it. The decision of the State shall be final and conclusive unless it is determined by a court of competent jurisdiction to concern one of the questions addressed in Section 7803 of the Civil Practice Law and Rules. In connection with any appeal as provided herein, the contractor shall be afforded an opportunity to be heard de novo and to offer evidence in support of its appeal. Pending final decision of any Article 78 proceeding hereunder, both parties shall proceed diligently with the performance of this Agreement in accordance with the State's decision.

2.6. Access Requirements

2.6.1. Access to Premises

To assure compliance with this Agreement and for any other reason the State deems appropriate for the effective and continuing operation of the Medicaid program, the DOH, the Office of the State Comptroller, and their authorized representatives and designees, shall at all times during normal business hours have the right to enter into the contractor's premises, including the contractor's Medicaid Care Management operation site, or such other place where duties under this Agreement are performed, to inspect, monitor or otherwise evaluate the work performed or being performed therein, or to elicit information concerning the operation of the Medicaid program. Provisions shall be made by the contractor to provide permanent identification cards for all on-site personnel and a limited number of other State personnel. No additional access requirements will be imposed on State personnel that are not required of the contractor's employees. The State shall have final authority in determining the extent of access to the contractor's facilities for all on-site personnel, State personnel, key personnel and any other individuals whom the State deems appropriate.

2.6.1.2. For any instance of access by authorized representatives or designees of any State agency or successor contractor for the Medicaid program, 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. The right of access provided for herein shall include on-site visits, as directed and limited by the State, by representatives of competitors in the process of procurement of a successor contractor.

2.6.1.3. The contractor shall be responsible for assuring that the provisions of Section B.2.6.1. shall apply to any subcontract related to performance under this Agreement.

2.6.2. Access to and Audit of Agreement Records

At all times during the period that this Agreement is in force and for a period of six (6) years thereafter, the contractor shall provide all authorized representatives of the State government with full access to all its financial records that pertain to services performed and determination amounts payable under this Agreement, including access to appropriate individuals with knowledge of financial records (including the contractor's independent public auditors) and full access to all additional records that pertain to

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services performed and determination of amounts payable under this Agreement, permitting such representatives to examine, audit and copy such records at the site at which they are located. Such access shall be consistent with **Appendix A**, Item 10.

- 2.6.2.1.** All records and information obtained by the State pursuant to the provisions of this Agreement, whether by audit or otherwise, shall be usable by the State in any manner, in its sole discretion, it deems appropriate and the contractor shall have no right of confidentiality or proprietary interest in such records or information.
- 2.6.2.2.** The State will give the contractor at least ten (10) calendar days written notice (subject to its obligations under Section 89 (subd. 3) of the New York State Public Officer's Law) of its intent to disclose outside government financial data provided by or obtained from the contractor relating to the contractor's performance under this Agreement. The preceding sentence is intended to set forth a notice provision only; it does not, nor is it intended, to derogate or qualify any rights of the State set forth in the first sentence of Section B, 2.6.2.1. above.
- 2.6.2.3.** The contractor shall promptly notify the State of any request by a third-party for access to any records maintained pursuant to this Agreement.
- 2.6.2.4.** The contractor shall be responsible for assuring that the provisions of Sections B, 2.6.2.1. and 2.6.2.2. above shall apply to any subcontract related to performance under this Agreement.

2.6.3. 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, with disposal by the contractor of any records during said period permitted only upon prior written approval by the State. 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 file archived of any Agreement-related documents may be substituted for the originals with the prior written approval of the State, provided that the microfilming procedures are accepted by the State as reliable and are supported by an adequate retrieval system.

- 2.6.3.1.** The contractor shall be responsible for assuring that the provisions of Section B, 2.6.3. herein shall apply to any subcontract related to performance under this Agreement.

3. Fiscal Safeguards

3.1. Indemnification of the State

The contractor shall indemnify, defend and hold harmless the Medicaid program, the State, its officers, agents or employees from any and all claims and losses accruing or resulting to any and all contractors, subcontractors, material men, laborers and any other person, firm or corporation furnishing or supplying work, services, materials or supplies in connection with the performance of this Agreement, and from all claims and losses accruing or resulting to any person, firm or corporation who may be injured or damaged by the negligence of the contractor, its officers, agents or employees or subcontractors in the performance of this Agreement and against any liability, including costs and expenses, for violation of proprietary rights, copyrights, or rights of privacy, arising out of the publication, translation, reproduction, delivery, performance, use or disposition of an data furnished under this Agreement or based on any libelous or otherwise unlawful matter contained in such data.

3.2. Cure of Payment Defaults

If the State defaults in payments to the contractor under this Agreement, the subsequent acceptance of such past due charges by the contractor or any of its duly authorized agents, when such payment is specifically identified as being payment in full, shall fully reinstate this Agreement.

3.3. Availability of Key Personnel

The contractor is required to commit key personnel solely to the operation of the Medicaid Care Management Program as noted in the contractor's proposal contained in **Appendix C**. Any changes in the key personnel must be approved in advance by the State. In the event that any of the key personnel will be or are unavailable for extended periods for the regular performance of their duties, the contractor will designate and propose to the State, subject to the State's prior approval, an equally qualified alternate with full authority to act for the key person for the duration of the absences.

4. General Provisions

4.1. Document Incorporation and Order of Precedence

In the event of any inconsistency in or conflict among the document elements of this Agreement identified in this Section, such inconsistency or conflict shall be resolved by giving precedence to the document elements in the following order:

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- (a) First, Appendix A (Standard Clauses for all New York State Contracts);
- (b) Second, body of this Agreement;
- (c) Third, Appendices other than A, B, and C attached to the body of this Agreement;
- (d) Fourth, **Appendix B** (the RFP, as amended by the Questions and Answers); and
- (e) Fifth, **Appendix C** (the contractor's Proposal, as amended and supplemented.)

4.2. **Independent Capacity of Contractor**

The parties hereto agree that the contractor is an independent contractor, and the contractor, its agents, officers and employees, in the performance of this Agreement, shall act in an independent capacity and not as officers or employees of the State.

4.3. **No Third Party Beneficiaries**

Nothing contained in this Agreement, expressed or implied, is intended to confer upon any person, corporation or other entity, other than the parties hereto and their successors in interest and assigns, any rights or remedies under or by reason of this Agreement.

4.4. **Non-Assignability**

Neither the rights nor the obligations of this Agreement may be conveyed, assigned, delegated, novated or otherwise transferred in any manner whatsoever by the contractor, either in whole or in part, without the prior written approval of the State. Such approval to the contractor subsidiaries or affiliates shall not be unreasonably withheld.

4.5. **Contractor Personnel**

The State reserves the right to require the contractor to discharge, from performance of any or all duties under this Agreement, specified contractor employees. The State will not exercise this authority unreasonably. The contractor agrees to replace any employee so discharged with an employee of equal or better qualifications. If the State exercises its rights under this provision, it agrees to provide written notice to the contractor setting forth its reasons with specificity.

4.6. **Employment Practices**

The contractor shall comply with the nondiscrimination clause contained in Federal Executive Order 11246, as amended by Federal Executive Order 11375, Americans with Disabilities Act of 1990 and 42 USC Sec. 12101 et seq. relating to Equal Employment Opportunity for all persons without regard to race, color, religion, disability, sex or national origin, and the implementing rules and regulations prescribed by the Secretary of Labor and with 41 Code of Federal Regulations, Chapter 60. The contractor and any of its subcontractors shall comply with the Executive Law of the State of New York,

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Sections 290-299 thereof and any rules or regulations promulgated in accordance therewith.

4.6.1. The contractor shall comply with regulations issued by the Secretary of Labor of the United States in 41 Code of Federal Regulations, Chapter 60, pursuant to the provisions of Executive Order 11758 and the Federal Rehabilitation Act of 1973 and Americans with Disabilities Act of 1990. The contractor shall likewise be responsible for compliance with the above-mentioned regulations by subcontractors with whom the contractor enters into a contractual relationship in furtherance of this Agreement.

4.6.2. Employment practices of the contractor shall be consistent with corporate personnel policy and shall be uniformly applied to all contract staff.

4.6.3. The contractor agrees to cooperate in implementing State policies intended to achieve equal opportunity employment and, accordingly, warrants that it will not discriminate against employees or applicants for employment because of race, creed, color, national origin, sex, age, disability or marital status. The contractor will state, in all solicitations, or advertisements for employees placed by or on behalf of the contractor, that all qualified applicants will be afforded equal employment opportunities without discrimination because of race, creed, color, national origin, sex, age, disability or marital status.

4.7. Confidentiality of Client and Provider Information

The contractor, its officers, agents and employees and subcontractors, shall treat all information, with particular emphasis on information relating to participants and providers and information determined by the State to be trade secret information, which is obtained through performance under this Agreement, as confidential information to the extent required by the laws of the State of New York and the United States and any regulations promulgated thereunder.

4.7.1. Except as provided in Section B, 4.7.2. herein, all individually identifiable or trade secret information relating to any eligible participant or provider shall be held confidential and shall not be disclosed by the contractor, its officers, agents and employees or subcontractors, to any outside party without the prior written approval of the State.

4.7.2. The use of information obtained by the contractor in the performance of its duties under this Agreement shall be limited to purposes directly connected with such duties.

4.7.3. The contractor shall promptly advise the State of all requests made to contractor for information described in herein.

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4.7.4. The contractor shall be responsible for assuring that any agreement between the contractor and any of its officers, agents and employees or subcontractors contains a provision which strictly conforms to the provisions of this Section.

4.8. Legal Assurance of Authority to Perform

In consideration of the within premises, the contractor represents to the State that:

- (a) the contractor has corporate authority to perform all duties required of it by this Agreement; and
- (b) the contractor is qualified to do business in the State of New York.

4.8.1. The contractor shall give immediate notice to the State of any event or circumstances which may affect the validity of the representations herein contained and shall take any and all actions required to preserve its legal authority to perform this Agreement.

4.9. Force Majeure

Neither party shall be liable or deemed to be in default for any delay or failure in performance under this Agreement resulting directly or indirectly from acts of God, civil or military authority, acts of public enemy, wars, riots, civil disturbances, insurrections, accidents, fire, explosions, earthquakes or flood. The parties are required to use best efforts to eliminate or minimize the effect of such events during performance of this Agreement.

4.10. Notification

Any notice required by this Agreement to be given between the contractor and the State shall be sent to the designated DOH Medicaid Project Director or the contractor's designated Medicaid Care Management Project Director by registered or certified mail, return receipt requested, or shall be delivered in hand and a receipt granted.

4.11. Patent or Copyright Infringement

The contractor, solely at its expense, shall defend any claim or suit which may be brought against the Medicaid program or the State for the infringement of United States patents or copyrights arising from the contractor's or the State's use of any equipment, materials or information prepared, developed or furnished by the contractor in connection with performance of this Agreement, and in any such suit shall satisfy any final judgment for such infringement. The State will give the contractor written notice of such claim or suit and full right and opportunity to conduct the defense thereof, together with full information and all reasonable cooperation.

4.11.1. If principles of governmental or public law are involved, the State may participate in the defense of any action identified in Section B, 4.11. herein,

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but no costs or expenses shall be incurred upon the account of the contractor without the contractor's written consent.

- 4.11.2.** If, in the contractor's opinion, any equipment, materials or information likely to or does become the subject of a claim of infringement of a United States patent or copyright, then, without diminishing the contractor's obligation to satisfy any final award, the contractor may, with the State's prior written approval, substitute other equally suitable equipment, materials and information, or at the contractor's option and expense, obtain the right for the State to continue the use of such equipment, materials and information.
- 4.11.3.** In the event that an action at law or in equity is commenced against the State arising out of a claim that the State's use of the software under this Agreement infringes on any patent, copyright or proprietary right, and such action is forwarded by the State to the contractor for defense and indemnification pursuant to Section B, 4.11. herein, the State shall copy all pleadings and documents forwarded to the contractor, together with the forwarding correspondence, to the Office of the Attorney General of the State of New York, together with a copy of this Agreement. If upon receipt of such request for defense, or at any time thereafter, the contractor is of the opinion that the allegations in such action, in whole or in part, not covered by the indemnification set forth in Section B, 4.11. herein, the contractor shall immediately notify the DOH and the Office of the Attorney General of the State of New York in writing and shall specify to what extent the contractor believes they are and are not obligated to defend and indemnify under the terms and conditions of this Agreement.
- 4.11.4.** The contractor shall in such event protect the interests of the State of New York and secure a continuance to permit the State of New York to appear and defend its interest in cooperation with the contractor as is appropriate, including any jurisdictional defenses which the State shall have.

4.12. Conflict of Interest

If during the term of this Agreement and any extension thereof the contractor or subcontractor becomes aware of an actual or potential affiliation or relationship which may be considered a conflict of interest, the contractor shall notify the State in writing immediately.

- 4.12.1.** Should the contractor engage any current or former New York State employee as its own employee or as an independent contractor because of such employee's knowledge of New York State finances, operations or knowledge of the State's operation, or any current or former State employee who in the course of their State employment had frequent contact with management level contractor employees, the contractor shall notify the State, in writing, immediately; should the State thereafter determine that such employment is inconsistent with State or Federal Law, the State shall so

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advise the contractor, in writing, specifying its basis for so determining, and may request that the contractual or employment relationship be terminated.

- 4.12.2.** Should the contractor or its related corporate entities wish to contract with Medicaid provider(s) to provide services or products, the contractor must satisfactorily demonstrate that no conflict of interest exists, and must receive prior approval of such activity from the State, which approval shall not be unreasonably withheld.
- 4.12.3.** The contractor must notify the State in writing of the existence and nature of all affiliations, relationships or other financial arrangements (contractual or otherwise) that it has with any individual, group or any other entity, including a health care organization provider group, pharmaceutical manufacturer, or other health care related entity, as of the date of execution of this contract. Such relationships include those which the contractor, the contractor's parent company or companies or any subcontractors under this contract have with the pharmaceutical industry. The contractor must also notify the State in writing of any new affiliations, relationships or financial arrangements that develop during the term of this contract at the time that such relationships develop. If the State determines that the relationship(s) are inappropriate, the State has the authority to request that the relationships be terminated or request written assurances from the contractor to be provided to the State regarding the impact of the relationships on the New York State Medicaid program. The State shall be the sole source of remuneration under this contract and any financial arrangements made between the contractor and any health care organization provider group, pharmaceutical manufacturer, or other health care related entity, particularly those which are for the promotion of specific drugs or medical products, without State approval are strictly prohibited. Information which the contractor provides to the State which is considered a trade secret will be kept confidential as permitted by the New York State Public Officer's Law.

4.13. Standard of Interpretation

This Agreement shall be subject to liberal interpretation to accomplish the parties' evident purpose. The contractor and the State shall perform under this Agreement in a manner to fully ensure smooth, non-disruptive operation of the Medicaid program, whether such operation is by the contractor or by the State or a successor contractor, consistent with the terms of this Agreement. Performance by the contractor and the State, under this Agreement shall at all times be consistent with this fundamental premise and this Agreement shall be construed accordingly. Disagreement between the parties concerning interpretation of this Agreement shall be subject to the "Disputes" provision set forth in Section B, 2.5. herein.

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4.14. Waiver of Breach

Except as provided in Section B, 3.3. herein, no term or provision of this Agreement shall be deemed waived and no breach excused, unless such waiver or consent shall be in writing and signed by the party claimed to have waived or consented. Any consent by a party to, or waiver of, a breach under this Agreement shall not constitute or consent to, a waiver of, or excuse for any other, different or subsequent breach.

4.15. Agreement Approval

The State Finance Law of the State of New York, Section 112, requires that any contract made by a State department which exceeds fifteen thousand dollars (\$15,000) in amount be first approved by the Comptroller of the State of New York before becoming effective. The parties recognize that this Agreement is wholly executory and not binding until and unless approved by the Department of Law and the Comptroller of the State of New York.

4.16. Choice of Law

The parties agree that this Agreement shall be interpreted according to the laws of the State of New York. The contractor shall be required to bring any legal proceeding against the State arising from this Agreement in New York State courts.

4.17. Standard New York State Contract Clauses

Standard Clauses for all New York State Contracts, attached hereto as **Appendix A**, is hereby fully incorporated into this Agreement.

4.18. Severability

Should any provision of this Agreement be declared or found to be illegal, unenforceable, ineffective, or void, then each party shall be relieved of any obligation arising from such provision; the balance of this Agreement, if capable of performance, shall remain in full force and effect.

APPENDIX A

Standard Clauses For All New York State Contracts

APPENDIX A

STANDARD CLAUSES FOR ALL NEW YORK STATE 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, licensor, 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 \$15,000 (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.

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. In accordance with 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, age, disability 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 REQUIREMENT. In accordance with Section 139-d of the State Finance Law, if this contract was awarded based upon the submission of bids, Contractor warrants, under penalty of perjury, that its bid was arrived at independently and without collusion aimed at restricting competition. Contractor further warrants 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 contractors 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 purpose 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, AESOB, 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 Division 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 XI-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:

Department of Economic Development
Division for Small Business
30 South Pearl Street
Albany, New York 12245
Tel. 518-292-5220

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

Department of Economic Development
Minority and Women's Business Development Division
30 South Pearl Street
Albany, New York 12245
<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. Contact the Department of Economic Development, Division for Small Business, 30 South Pearl Street; Albany New York 12245, 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.

APPENDIX B

Request for Proposals "Medicaid Disease and Care Management Demonstration Programs" March 2005

APPENDIX C

Contractor's Proposal

APPENDIX D

General Specifications

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. The services to be performed by the Contractor shall be at all times subject to the direction and control of the Department as to all matters arising in connection with or relating to this Agreement.
2. 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

3. 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:

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

- a. 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:
 1. 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).
 2. 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.

- a. 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.
- b. 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.
- c. 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:
 1. that the work performed by the subcontractor must be in accordance with the terms of this AGREEMENT, and

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

AA. Provisions Related to New York State Executive Order Number 127

1. The CONTRACTOR certifies that all information provided to the STATE with respect to New York State Executive Order Number 127, signed by Governor Pataki on June 16, 2003, is complete, true, and accurate.

2. 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 Executive Order Number 127, 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.

APPENDIX E

Worker's Compensation (Appendix E-1)
Disability Benefits (Appendix E-2)

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

1. Workers' Compensation, for which one of the following is incorporated into this contract as Appendix E-1:

- a. WC/DB-100 or WC/DB-101 Business Does Not Require Workers' Compensation and/or Disability Benefits Coverage, or
- b. C-105.2 Certificate of Workers' Compensation Insurance Coverage, or
- c. U-26.3 State Insurance Fund Version of Certificate of Workers' Compensation Insurance Coverage, or
- d. SI-12 Certificate of Workers' Compensation Self-Insurance or GSI-105.2 Certificate of Workers' Compensation Group Self-Insurance; and

2. Disability Benefits coverage, for which one of the following is incorporated into this contract as Appendix E-2:

- a. WC/DB-100 or WC/DB-101 Business Does Not Require Workers' Compensation and/or Disability Benefits Coverage, or
- b. DB-120.1 Certificate of Disability Benefits Insurance Coverage or the DB-820/829 Certificate/Cancellation of Insurance, or
- c. DB-155 Certificate of Disability Benefits Self-Insurance.

APPENDIX F

Fair Hearings

Fair Hearings:

The fair hearing process is a procedure by which the recipient may appeal a denial of program benefits. Fair hearings are held at a time and location convenient to the recipient and easily accessible to the recipient, allowing for age and disabling conditions.

Once a fair hearing is requested, a notice of hearing is issued by the State OTDA advising the recipient of the date, time and place of the hearing, his/her rights with respect to the hearing, procedure for requesting an adjournment or relocation of the hearing, the issue to be determined and the manner in which the hearing is to be conducted. The notice of hearing will be issued only after the OTDA has received notice that the decision was adverse to the recipient and the recipient had filed a timely request for hearing. The notice of hearing is to be issued at least ten (10) days prior to the scheduled hearing date. The contractor may be required to send the recipient or his/her representative copies of all documents to be submitted into evidence at the hearing in support of the contractor's action.

The hearing shall be conducted by employees of the OTDA pursuant to all applicable federal and State laws, regulations and policy. In addition to having all the powers conferred by law, the hearing officer would be empowered to hear and determine the issues raised and to conduct the hearing in a manner to afford the recipient a full opportunity to present his objections to the action taken. The parties to the hearing would be the recipient seeking review of a denial determination and the contractor. The contractor shall prepare the hearing summary for all requests for hearings involving decisions made under this contract. The contractor would be required to be represented by an employee who has the ability and authority to reverse a determination made.

On the scheduled hearing date, the parties, their representatives and the hearing officer will meet at the time and place designated in the notice. The hearing officer will state the issues to be decided and obtain agreement from the parties as to those issues in dispute. The contractor's representative would provide a brief written summary including, but not limited to, the decision which resulted in the hearing request, a brief description of the facts and evidence supporting the action, including the specific provision of the law or regulations which support the action taken and a copy of the determination after reconsideration. The contractor shall be solely responsible for presenting its position at the recipient's fair hearing.

Both parties would be permitted to present relevant evidence and witnesses on their behalf, to cross-examine witnesses of the other party, and offer evidence in rebuttal. The hearing officer will preside and assure an orderly hearing, ruling on evidence, objections and points of law; he/she will also assume responsibility for assuring that all relevant evidence on the issue was brought out, either by the parties or by direct questioning of the parties and their witnesses.

Upon completion of the hearing, the hearing officer will consider the record and issue his decision. Where the issue involved a policy or procedure of the contractor or the State, the hearing officer will be permitted to reserve decision until such time as he/she had been able to review the record and the evidence presented. In cases where a decision was reserved, the written decision of the hearing officer would be issued in a timely manner. This written decision should describe the issues, recite the relevant facts as found by the hearing officer, describe the applicable law, regulations and policies, make appropriate findings and determinations, stating the reasons therefore, and direct the contractor to take specific action with respect to the issue decided. A copy of the written decision would be mailed to both parties.

Where any decision of the hearing officer was adverse to the recipient, in whole or in part, the recipient would be advised of his/her right to seek judicial review pursuant to Article 78 of the Civil Practice Law and Rules. The notice of this right would accompany the written decision of the hearing officer. The contractor would be required to assist the Department in the defense of any such Article 78 proceeding or other legal action based on the contractor's determination including, but not limited to, preparation of affidavits and presentation of evidence or testimony.

APPENDIX G

Institutional Review Board Protocol Review Request Form (DOH-1871)

**DOH-1871 Instructions
DOH-1871 Form
Checklist of Materials to Submit to the IRB**

PROTOCOL REVIEW REQUEST FORM

APPLICATION INSTRUCTIONS

Complete the DOH 1871 form using the instructions below. Be sure the DOH 1871 form is endorsed by your Center Director or appropriate Higher-Up. If you are not from DOH, the signature line for AYCenter Director or Other Authorized Institutional Official@ can be endorsed by your IRB Chair.

Study Title: indicate the actual title of the research study being submitted for review and approval.

Grant Title: indicate the title of the grant which funds the study, if applicable.

Principle Investigator(s): list all Investigators who will be responsible for the overall conduct of the study.

IRB Training Completed: indicate whether the Investigators have completed an approved course in the protection of human subjects in research.

List Other Institutions Involved: indicate No or Yes plus the name of the collaborating institution(s) in the space provided.

IRB Approval: indicate No, Yes, or In Progress based on the status of such approval at the collaborating institution at the time of submission. Note that this approval must be provided prior to the initiation of approved study activities.

Sponsor: provide the name of the sponsor for the research, ex. CDC, NIH.

Grant Number: provide the Grant Number corresponding to the Grant Title requested above.

Employee Of: check the box corresponding to the Principal Investigator=s employer and be sure to mark all that apply.

Anticipated Start Date: indicate the date on which the study is expected to commence.

Reason for Applying to the IRB: indicate the level/type of review that is being sought. It is strongly suggested that you indicate the proper level of review in order to avoid delay in the processing of your request.

Check all that apply to your research study: check the appropriate categories that identify populations to be included in the research. The IRB is made aware of the need to invoke any additional protections such as in the case of research with either prisoners, minors, the mentally incapacitated, or pregnant women. **Investigational Drugs and Devices:** INDs/Investigational

Drug name(s) and IDEs/Investigational Device name(s). Indicate in this section the numbers and names of any investigational new drugs (INDs) or Investigational Device Exemptions (IDEs) involved in the research.

If your study is a Drug/Biologic study, a copy of the following is required:

- Y Investigator=s Drug Brochure
- Y Background Information for Food Supplements
- Y FDA Form 1572 (if applicable)

If your study is a Device study, a copy of the signed Investigator Agreement for protocols with an IDE, and ONE of the following:

- Y FDA letter granting the Investigational Device Exemption (IDE) or
- Y Letter from sponsor stating that the study is a non-significant risk device study or
- Y Letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2 or otherwise exempt.

A. EXEMPT

Mark the checkbox that is appropriate for your study in Section A. Attach a short description of the protocol and any other supporting documents. This type of study can be submitted for review at any time and will be reviewed by the IRB Chair or Executive Secretary.

One copy and an original document are needed for IRB review.

B. EXPEDITED REVIEW

Research activities involving no more than minimal risk to human subjects, and that involve only procedures listed in one or more of the categories listed in Section B may be eligible for the Expedited Review procedure. The Expedited Review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Attach the protocol, informed consent form(s), a brief description of how consent will be obtained, a copy (or copies) of other IRB approval(s) and any other necessary documents to the form.

An original and three (3) copies of the entire package must be submitted to the IRB to be reviewed. Expedited proposals are accepted and reviewed as received.

C. FULL REVIEW

Any study involving greater than minimal risk must receive Full Review by a quorum of all IRB members in attendance at a full Board meeting. Studies involving one or more of the protected classes will automatically qualify for a full Board review.

Attach the protocol, informed consent form(s), child assent form (if applicable), a brief description of how consent will be obtained, a copy (or copies) of other IRB approval(s) and any other necessary documents to the form.

An original and 18 copies of the entire package should be submitted to the IRB to be reviewed at the next scheduled monthly IRB meeting. Refer to the Board schedule for deadlines and meeting dates.

D. FIVE YEAR REVIEW

In addition to the annual continuation review, studies must reapply to the IRB for approval every five years. Apply to the IRB using the DOH 1871 form as if applying for a new study and follow the instructions that are appropriate to the level of review (Section A,B,C). The following must be included:

- Y A summary description of subjects= experience: benefits, adverse events or unanticipated problems. The number and reasons for withdrawal of subjects, and/or complaints about the research.
- Y A summary of study results thus far.
- Y Attach any new literature, findings, or other relevant information.
- Y A copy of the current informed consent document(s).
- Y Any planned changes in the conduct of the study.

E, F, & G REGISTRY REQUESTS

Each registry has its own procedures for information/data requests. Check with the contact person listed in the DOH Guidelines to determine where to apply for information/data from a particular registry. Vital Records requires IRB full Board approval for proposals seeking birth and death certificate information. Follow the instructions for Full Board approval for Vital Records requests and mail your package to them.

**NYS DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD**

IRB# _____ - _____

PROTOCOL REVIEW REQUEST FORM

| | | |
|---|---|---|
| Study Title: <hr/> <hr/> <hr/> | <u>Date Received</u> | <u>Date Approved</u> |
| <hr/> | List Other Institutions Involved: <input type="checkbox"/> NO <input type="checkbox"/> YES (If yes, specify the institution(s)) <hr/> <hr/> | |
| Grant Title (if different): <hr/> <hr/> <hr/> | IRB approval: <input type="checkbox"/> NO <input type="checkbox"/> YES <input type="checkbox"/> In Progress | |
| <hr/> <hr/> | Sponsor: | Grant Number: |
| Principal Investigator(s): <hr/> <hr/> <hr/> <hr/> | IRB Training Completed No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> | Employee of: (check all that apply) <input type="checkbox"/> NYS DOH <input type="checkbox"/> Health Research, Inc. <input type="checkbox"/> Wadsworth Center <input type="checkbox"/> Albany Medical Center <input type="checkbox"/> Other |
| (Attach copy of training certificate) | Anticipated Start Date: (__ / __ / __) | |

Reason for applying to the IRB: (check all that apply)

A. Exempt

B. Expedited Review

C. Full Review

E. Cancer Registry Request

F. Other Registry Request

D. Vital
Records Data Request
G. 5 Year
Review

Check all that apply to your research study:

- Children and Minors (Expedited/Full)
- Cognitively Impaired (Expedited/Full)
- Incapacitated Adults (Expedited/Full)

- Fetuses, in vitro fertilization (Expedited/Full)
- International Research (Exempt/Expedited/Full)

NEW YORK STATE DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD PROTOCOL REVIEW REQUEST FORM

- Normal Volunteers (Exempt/Expedited/Full)
- Pregnant Women (Expedited/Full)
- Prisoners (Expedited/Full)

- Students, Employees (Exempt/Expedited/Full)
- Blood Spots (Exempt/Expedited/Full)

Investigational Drugs and Devices:

INDs: _____ Investigational Drug names:

IDEs: _____ Investigational Device names:

Does anyone listed as an Investigator on this study have a financial or ethical conflict of interest?
YES NO

A COPY OF THE PROTOCOL AND ANY SUPPORTING DOCUMENTATION MUST ACCOMPANY THIS APPLICATION

A. EXEMPT

Check the appropriate criteria for an Exemption:

| | |
|--------------------------|--|
| <input type="checkbox"/> | Normal Educational Practices and Settings (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: <ul style="list-style-type: none"><input type="checkbox"/> (a) research on regular and special education instructional strategies or<input type="checkbox"/> (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |
| <input type="checkbox"/> | Anonymous Educational Tests, Surveys, Interviews or Observations (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects AND (b) any disclosure of the human subjects= responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, or reputation. |
| <input type="checkbox"/> | Identifiable Subjects in Special Circumstances (3) Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2, if: <ul style="list-style-type: none"><input type="checkbox"/> (a) the human subjects are elected or appointed public officials or candidates for public office or<input type="checkbox"/> (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. |
| <input type="checkbox"/> | Collection or Study of Existing Data (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. |
| <input type="checkbox"/> | Taste and Food Evaluation and Acceptance Studies (6) Taste and food quality evaluation and consumer acceptance studies: <ul style="list-style-type: none"><input type="checkbox"/> (a) if wholesome foods without additives are consumed, or<input type="checkbox"/> (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. |

Attach a short description of the protocol and any other supporting documents. **An original and one copy** is required for IRB review.

B. EXPEDITED REVIEW

Research activities involving no more than minimal risk¹ to human subjects, and involve only procedures listed in one or more of the following categories **MAY** be eligible for the Expedited Review procedure. The Expedited Review procedure **MAY NOT** be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and

¹When the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Attach the protocol, informed consent form(s), a brief description of how consent will be obtained, copies of other IRB approval(s) (if available) and any other necessary documents to this form. **An original and three copies of the entire package** should be submitted to the IRB.

Check appropriate criteria for Expedited Review:

| | |
|--------------------------|---|
| <input type="checkbox"/> | <p>(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.</p> <ul style="list-style-type: none"><input type="checkbox"/> (a) research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)<input type="checkbox"/> (b) Research on medical devices for which<ul style="list-style-type: none"><input type="checkbox"/> (i) an investigational device exemption application (21 CFR Part 812) is not required; or<input type="checkbox"/> (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. |
| <input type="checkbox"/> | <p>(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:</p> <ul style="list-style-type: none"><input type="checkbox"/> (a) from healthy, nonpregnant adults who weigh at least 110 lbs. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or<input type="checkbox"/> (b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week. |
| <input type="checkbox"/> | <p>(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:</p> <ul style="list-style-type: none"><input type="checkbox"/> (a) hair and nail clippings in a nondisfiguring manner;<input type="checkbox"/> (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;<input type="checkbox"/> (c) permanent teeth if routine patient care indicates a need for extraction;<input type="checkbox"/> (d) excreta and external secretions (including sweat);<input type="checkbox"/> (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;<input type="checkbox"/> (f) placenta removed at delivery;<input type="checkbox"/> (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;<input type="checkbox"/> (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;<input type="checkbox"/> (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;<input type="checkbox"/> (j) sputum collected after saline mist nebulization. |
| <input type="checkbox"/> | <p>(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:</p> |

²Children are defined in the HHS regulations as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. @ 45 CFR 46.402(a)

| |
|--|
| <ul style="list-style-type: none"> <input type="checkbox"/> (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; <input type="checkbox"/> (b) weighing or testing sensory acuity; <input type="checkbox"/> (c) magnetic resonance imaging; <input type="checkbox"/> (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; <input type="checkbox"/> (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. |
| <p><input type="checkbox"/> (5) Research involving materials (data, documents, records, or specimens) that have been collected for any reason, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4) This listing refers only to research that is not exempt.)</p> |
| <p><input type="checkbox"/> (6) Collection of data from voice, video, digital, or image recordings made for research purposes.</p> |
| <p><input type="checkbox"/> (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)</p> |
| <p><input type="checkbox"/> (8) Continuing review of research previously approved by a convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for the long term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified or (c) where the remaining research activities are limited to data analysis.</p> |
| <p><input type="checkbox"/> (9) Continuing review of research not conducted under an investigational new drug application or investigational drug exemption where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.</p> |

C. FULL REVIEW

Any study involving greater than minimal risk or not meeting the exempt or expedited status must receive Full Review by a quorum of all IRB members in attendance at a full board meeting.

Submit an original and **25** copies of entire packet of IRB materials by the deadline for the next IRB full board meeting.

D. 5 YEAR REVIEW

If your original submission was approved as an exemption and still qualifies as an exemption, complete section A. If your original submission was approved as an expedited review and still qualifies as an expedited review, complete section B. If your original submission was approved as a full review, you must complete section C. and submit to the full Board meeting that falls **BEFORE** your five-year review due date.

E,F,G REGISTRY REQUESTS

NEW YORK STATE DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD PROTOCOL REVIEW REQUEST FORM

Requests for registry data requiring IRB approval must submit an original and eighteen (18) copies of the entire package to be reviewed at the scheduled bi-monthly IRB meeting.

As Principal Investigator of this study, I assure the IRB that, as required by federal regulations:

Proposed changes in approved studies will be presented to the IRB for review and approval prior to initiation except where necessary to eliminate apparent immediate hazards to the subjects.

The IRB, appropriate institutional officials, the Office for Human Research Protections (OHRP) and the FDA, if applicable, will be promptly informed of any unanticipated problems involving risks to subjects or others and research related injuries.

The informed consent of the subject will be obtained by the investigator in the manner and format approved by the IRB prior to the initiation of the study.

The study will be resubmitted to the IRB for continuing review at the interval determined by the IRB to be appropriate to the risk, but not less than once a year.

All protocols involving human subjects or specimens obtained from human subjects, whether performed at DOH or elsewhere, in the grant listed on this application, have been described in this application or have already been approved by the IRB.

Signature of Principal Investigator

Date

Signature of Center Director or

Date

Other Authorized Institutional Official

Signature of Chair or Executive Secretary

Date

Send Completed Forms to:

**NYS DOH Institutional Review Board
ESP Corning Tower - Room 474
Albany, NY 12237**

For Questions send E-Mail to:

irbbml@health.state.ny.us

NEW YORK STATE DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD PROTOCOL REVIEW REQUEST FORM

Principal Investigator Name: _____

Address: _____

Phone Number (_____) _____ - _____

E-mail: _____

Co-Investigator Name: _____

Address: _____

Phone Number: (_____) _____ - _____

E-mail: _____

Co-Investigator Name: _____

Address: _____

Phone Number: (_____) _____ - _____

E-mail: _____

Co-Investigator Name: _____

Address: _____

Phone Number: (_____) _____ - _____

E-mail: _____

Co-Investigator Name: _____

Address: _____

Phone Number: (_____) _____ - _____

E-mail: _____

Study Coordinator: _____

Address: _____

Phone Number: (_____) _____ - _____

E-mail: _____

CHECKLIST OF MATERIALS TO SUBMIT TO THE IRB

- √ **Professional qualifications to do the research** (including a description of necessary support services and facilities)
- √ **Training** (include a current certificate of completion from a workshop on Human Subjects Protection)
- √ **Title of the study**
- √ **Purpose of the study** (including the benefit obtained by doing the study)
- √ **Sponsor of the study**
- √ **Results of previously related research**
- √ **Subject selection criteria**
- √ **Subject exclusion criteria**
- √ **Justification for use of special subject populations** (e.g. the mentally retarded, children, etc.)
- √ **Study design** (including as needed a discussion of the appropriateness of research methods)
- √ **Description of procedures to be performed**
- √ **Provisions for managing adverse reactions**
- √ **Description of how confidentiality will be protected**
- √ **The circumstances surrounding a consent procedure:**
 - Environment
 - Time
 - Condition of subject
 - Subject's autonomy
- √ **Elements of Informed Consent:**
 - A statement that the study involves research
 - An explanation of the purpose of the research and the expected duration of the subject's participation

- A description of the procedures to be followed and identification of any procedures which are experimental
- A description of any foreseeable risks or discomforts to the subjects
- A description of any benefits to the subject or others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained (also note that the study sponsor, staff from DHHS or staff from the approving IRB may inspect the records)
- An explanation of whether compensation or medical treatment is available if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

√ **Additional elements of informed consent that may be included:**

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research may be related to the subject's willingness to continue participation
- The approximate number of subjects involved in the study.

√ **The documentation of informed consent:**

- use of oral consent procedures
- use of abbreviated written consent
- written narrative of information to be provided orally
- use of long written consent
- providing the subject a copy of the consent information

- who will obtain informed consent
 - provision for witness as needed
 - signature of subject or subject's representative
 - signature by investigator
 - signature by person obtaining consent
 - signature by witness
 - compensation to subject for his participation in the study
 - protection of subject's privacy
 - extra costs to subject because of his participation in the study
 - extra costs to third party payers because of subject's participation.
- √ **Proposed survey instruments, questionnaires or recruitment notices**
- √ **Changes in study after initiation**
- √ **Unexpected serious adverse reactions**
- √ **Progress reports**
- √ **Final reports**

APPENDIX H

Federal Health Insurance Portability and Accountability Act
("HIPAA")
Business Associate Agreement ("Agreement")

Appendix H

Federal Health Insurance Portability and Accountability Act (“HIPAA”) Business Associate Agreement (“Agreement”)

I. Definitions:

- (a) A Business Associate shall mean the CONTRACTOR.
- (b) A 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.
- (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.
- (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. No such disclosures shall be made without the prior written permission of the New York State Department of Health, Office of Medicaid Management.
- (j) The Business Associate agrees to provide to the Covered Program or an Individual, in a 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. Permitted Uses and Disclosures by Business Associate

(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, and only with the prior written permission of the Department, 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, the 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. Such Medicaid Protected Health Data may not be in any way permanently combined with other information gained from other sources.

VI. Term and Termination

- (a) *Term.* Effective April 14, 2003 in the event of termination for any reason, 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 not possible, for so long as Business Associate maintains such Protected Health Information.

VII. Violations

- (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 Covered Program 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. This provision shall survive the expiration or termination of this Agreement.

VIII. 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.

Name _____

Signature _____

Date _____

Name _____

Signature _____

Date _____

APPENDIX N

Data Exchange Application and Agreement



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York
12237

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

To:

Enclosed please find a copy of the NYSDOH Office of Medicaid Management's Data Exchange Application and Agreement. Please fill out this application completely and attach any other supporting documentation.

Please contact me at (518) 473-4848 if you have any additional questions about this application or Medicaid's data security procedures.

Sincerely,

Jim Botta
Data Security Coordinator
Office of Medicaid Management

Data Exchange Application and Agreement

11/19/04

Log # _____

New York State Department of Health

Office of Medicaid Management

Medicaid Confidential Data Review Committee

Assigned to Committee Member _____

Bureau/ Office _____

Telephone # _____

Data Exchange Application and Agreement

Purpose:

The purpose of this Data Exchange Application and Agreement (DEAA) is to provide information supporting the applicant's request for the release of Medicaid confidential data (MCD) and to serve as the basis for assessing the appropriateness of releasing MCD. In addition, the DEAA, when approved by the Medicaid Confidential Data Review Committee, forms an agreement between the applicant and the New York State Department of Health as to the terms and conditions under which the release will be made.

Pursuant to the New York State Medicaid State Plan requirements, Social Security Act, Section 1902(a) (7), 42 USC 1396a (a) (7) a.d.; and federal regulations at 42 CFR 431.302, no release of MCD is permitted unless such release is directly related to the administration of the Medicaid state plan.

MCD is also protected by Social Services Law Section 369 (4), which states:

Also, pursuant to Section 367b(4) of the NY Social Services Law, information relating to persons Applying For medical assistance shall also be considered confidential and shall not be disclosed to persons or agencies without the prior written approval of the New York State Department of Health.

Any inconsistent provision of this chapter or other law notwithstanding, all information received by public welfare officers concerning applicants for and recipients of medical assistance may be disclosed or used only for purposes directly connected with the administration of medical assistance for needy persons.

Please note that Medicaid Confidential Data released to you may contain AIDS/HIV related confidential information as defined in Section 2780(7) of the New York Public Health Law. As required by N.Y. Pub. Health Law Section 2782(5), the New York Department of Health hereby provides the following notice:

“This information has been disclosed to you from confidential records which are protected by state law. State law prohibits you from making any further disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. Any unauthorized further disclosure in violation of state law may result in a fine or jail sentence or both. A general authorization for the release of medical or other information is NOT sufficient authorization for the release for further disclosure.”

The applicant agrees to include the notice preceding, as well as references to statutory and regulatory citations set forth under “**Purpose**” in the DEA, in any agreement, contract or Document the Applicant enters into that involves Medicaid Confidential Data. Further, the Applicant agrees to state in any such agreement, contract or document that the subcontractor(s) or other party may not further disclose the Medicaid confidential data without the prior written approval of the New York State Department of Health.

Data Exchange Application and Agreement

I. APPLICANT INFORMATION:

Requester Name: _____
Title: _____
Agency: _____ Telephone: () -
Address: _____

A. List the agencies, departments, organizations, data contractors or other entities that will see the Medicaid Confidential Data. For each entity, list names and telephone numbers of each and every individual having access to Medicaid Confidential data. Access to the data covered by this agreement shall be limited to the individuals listed below

- 1) _____
- 2) _____
- 3) _____
- 4) _____

Please note that you must submit copies of contracts, memoranda of understanding, letters of agreement and any other documents you have or will enter into with each of these entities that will be working with Medicaid confidential data. Such documents must contain the language describing responsibility for Medicaid and HIV/AIDS confidential data as contained in the purpose section of this Data Exchange Application and Agreement and must be labeled as an attachment, starting with Attachment E, in alphabetical order. All attachments and any documents submitted by the applicant(s) are considered part of this data exchange agreement.

II. PURPOSE OF PROJECT AND DATA USE:

A. Please describe the nature and type of work for which Medicaid confidential data information is needed. In this section the applicant must state in non-technical language the purpose(s) of the project for which the Medicaid confidential data will be used. Provide specific details of how the data will be used to accomplish the purpose set forth in this section.

III. DELIVERABLES:

Proposed publications require review and approval by the New York State Department of Health prior to publication and no review, comment, or approval of proposed publications will be forthcoming until deliverables have been reviewed and approved by the New York State Department of Health. The data source (New York State Department of Health, Office of Medicaid Management) shall be acknowledged on all labels, reports and any other documents developed, along with a provision stating that all conclusions derived in the proposed policy analysis/evaluation are those of the author and not of the New York State Department of Health.

A. Please describe the reports, evaluation or other documentation to be produced as a result of obtaining Medicaid confidential data.

B. Also, indicate the date that such draft reports of this project will be transmitted to NYSDOH for review:

IV. DATA ELEMENTS AND CLAIM FILES REQUESTED:

A. Specify what individual Medicaid record level data elements are needed for this request:

B. Specify the dates of the claim files requested: _____

NOTE: ALL RECIPIENT NAMES AND IDs MAY BE ENCRYPTED ON NON-MEDICAID AGENCY REQUEST.

V. DATA OUTPUT FORMAT:

A. Describe the media format (paper printout or datatape or cartridge) that you require:

B. No individual claim specific data in any form shall be combined or become part of another database or information sharing and retrieval system. Any use of individual recipient record data beyond this application must have NYSDOH Office of Medicaid Management approval in writing.

VI. DATES OF APPLICATION:

List the beginning and end date of this project:

VII. STORAGE & DISPOSAL OF MEDICAID CLAIMS DATA:

A. Storage of Data- No matching with any other data is permissible.

The applicant agrees that it is designated as Custodian of the Medicaid confidential data released under this DEAA and will be responsible for, in its hands or in the hands of its subcontractors, the observation of all conditions for use, establishment and maintenance of security as specified in this agreement to prevent unauthorized use. The applicant represents and warrants that such data will not be disclosed, released, revealed, showed, sold, rented or loaned and no access to the data will be granted to any person or entity other than those listed in Section I.

The applicant agrees to establish and to insure that its subcontractors, if any establish appropriate administrative, technical and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use of or access to the data. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by the Health Insurance Portability and Accountability Act of 1996.

(Attach a labeled copy of the applicant's data storage access and security policy. If there is another entity with access to the data, attach a copy of the pertinent data storage access and security policy.)

Data Exchange Application and Agreement

B. Disposal of data:

1. Specify whether Medicaid confidential data will be returned or destroyed upon completion of the project:

2. If data is to be destroyed, specify method and date of destruction:

3. Date that the datafiles will be returned:

4. If the data is to be destroyed, the applicant agrees to submit an affidavit specifying the date of destruction and the method of destruction. Further, the applicant agrees to accomplish the destruction of the data and the submission of the affidavit within 30 days of the date set forth in **B.2** preceding.

C. Name of person(s) / staff who are charged with the administration of and technical handling of the storage and retrieval facility:

| | <u>Name</u> | <u>Telephone</u> |
|----|-------------|------------------|
| 1. | _____ | _____ |
| 2. | _____ | _____ |
| 3. | _____ | _____ |
| 4. | _____ | _____ |
| 5. | _____ | _____ |

- D. The New York State Department of Health requires all agencies handling individual recipient data records to keep a record of data use. Additionally, NYSDOH reserves the right to audit requesting agency records on data outlined in this request to ensure compliance with this application.

- E. This application shall be terminated if any of the specified terms and conditions are not adhered to.

VIII. DISCLAIMERS & MODIFICATIONS:

- A. All modifications to this agreement must be submitted in writing to and approved by the New York State of Health, Office of Medicaid Management.

IX. LIMITATIONS & LIABILITIES:

- A. The New York State Department of Health will not be responsible for any loss due to data exchange.
- B. Please send your completed copy of this application to:

James Botta
Chairman, Medicaid Confidential Data Review Committee
NYSDOH/OMM
Corning Tower, Room 2038
Albany, New York 12237

Data Exchange Application and Agreement

X. EXECUTORY CLAUSE: (MUST BE SIGNED):

CONFIDENTIALITY CERTIFICATION BY

("Applicant"):

(Executory Clause)

It is understood by and between the parties that this Agreement shall be deemed executory to the extent of the resources available to NYSDOH Medicaid program and no liability on account thereof shall be incurred by the NYSDOH Medicaid beyond the resources available thereof.

To

New York State Department of Health ("Department")

The Applicant has requested the following Medicaid confidential data (describe data): _____ ("the data")

to (state purpose and legal authority): _____

for periods (dates): _____, and application will expire on (date): _____.

Section 1902(a) (7) of the federal Social Security Act and Section 369 (4) of the Assistance Social Services Law, require that Medicaid confidential data be treated as confidential and used or disclosed only for a purpose directly connected with the administration of the Medical Assistance program.

The Applicant certifies to the Department that the Applicant, its officers, employees, agents or subcontractors will adhere to these MA confidentiality standards and provisions of the legal authority cited by the applicant. The Applicant will provide the following controls to ensure confidentiality of the data:

1. The data may be used only for the purpose listed in this Application.
2. Only listed Applicant staff who require the data to perform functions listed in this Application may be given access to the data. Such staff will be instructed by the Applicant in the confidential nature of the data and its proper handling.

Data Exchange Application and Agreement

3. The data will be secured in locked storage receptacles when the data are not under the direct and immediate control of an authorized Applicant staff member engaged in work under this Application.
4. The data, including any copies made by the Applicant, will be returned to the Department by the Applicant upon completion the Application purpose, or with prior written Department approval, the data may be destroyed by the Applicant after its use and a written confirmation provided by the Applicant to the Department of such destruction

(Applicant)_____ makes this Confidentiality Certification and Executory Clause as a condition for receipt of confidential MA information and to ensure maintenance of confidentiality and security of the data pursuant to the aforementioned laws.

Date: _____
Signature of Commissioner / CEO: _____
Organization: _____
Address: _____

State of _____

}ss.:

County of _____

Subscribed and sworn to before me on this _____ day of _____, 20_____

Notary Public

XI. ATTACHMENTS:

Attachment A: Policy Analysis/Evaluation Outline Requirements.

Attachment B: Guidelines pertaining to HIV/AIDS related data.

Attachment C: Federal Guidelines on Confidentiality of Medicaid AIDS Data.

Attachment D: Third Party Contractor Language

ATTACHMENT A

INFORMATION REQUIRED FOR MEDICAID POLICY ANALYSIS/EVALUATION PROJECTS MUST BE FILLED OUT. REFERENCES TO OTHER ATTACHMENTS ARE NOT SUFFICIENT.

I. Title

II. Source of Request

III. Project Purpose, Objectives and Policy Analysis/Evaluation Questions

IV. Background and Importance of Project

- A. Literature review (sufficient to document that policy analysis/evaluation questions have not been answered elsewhere sufficiently for Department's needs).
- B. Knowledge to be gained
- C. Who/what will benefit

V. Policy Analysis/Evaluation/Methodology and design

- A. Hypotheses to be tested
- B. Data to be acquired

VI. Workplan

VII. Project Staff

- A. Persons to work on project;
- B. Identification of study director;
- C. Names, titles and telephone numbers of each person with access to the individual level data.

VIII. Other Issues

- A. Whether recipient and/or provider specific information are required. If yes, why hypotheses cannot be tested with aggregate level data.
- B. Procedures for ensuring confidentiality, security, and identification of staff who will have access.

ATTACHMENT B

INDIVIDUAL LEVEL MEDICAID AIDS DATA PROVISIONS

I. GENERAL PROVISIONS

Applicants must be aware that Medicaid data may include HIV/AIDS related data and information.

AIDS confidentiality is provided for in Article 27-F of the Public Health Law, Sections 2780 through 2787. Section 2782 (subd. 6, par.b) provides in part: "Confidential HIV related information relating to a recipient of [health or social] services may be disclosed in accordance with regulations promulgated pursuant to [Section 2786(2)(a)] of this article to an authorized employee or agent of [a provider of health or Health] or [a federal, state or local government agency supervising or monitoring the provider or administering the program under which the service is provided], when reasonably necessary for such supervision, monitoring, administration, or provision of such service. Section 2782 (sub 5. Para.) provides in part: "Whenever disclosure of confidential HIV related information is made pursuant to this article, except for disclosures made pursuant to paragraph (a) of this subdivision one of this section or paragraph (a) or (e) of subdivision four of this section, such disclosure shall be accompanied or followed by a statement in writing which includes the following or substantially similar language: "This information has been disclosed to you from confidential records which are protected by state law. State law prohibits you from making any further disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. Any unauthorized disclosure in violation of state law may result in a fine or jail sentence or both. A general authorization for the release of medical or other information is NOT sufficient authorization for further disclosure." An oral disclosure shall be accompanied or followed by such a notice within ten days.

In response to the requirements of Section 2786 of the Public Health Law, the New York State Department of Social Services has promulgated a regulation at 18 NYCRR 360-8.1 entitled "Confidentiality of HIV and AIDS related information." This section applies to confidential HIV related information obtained in the course of administering the Medicaid program. Section 360-8.1(c) provides in part:

"Confidential HIV related information can be used or disclosed only for a purpose which is directly connected with the administration of the MA program and consistent with the limitations of section 2782 of the Public Health Law relating to persons to whom or entities to which confidential HIV related information may be disclosed. As applied to this section, such a purpose may include supervision, monitoring, administration or provision of MA care, services and supplies."

Data Exchange Application and Agreement

Bringing these standards together, then, disclosure of recipient identifiable Medicaid AIDS data is only permissible for a purpose directly connected with Medicaid administration which may include supervision, monitoring, administration or provision of Medicaid care, services and supplies. These requirements were emphasized in an April 23, 1991 directive from the CMS (HCFA) Region 2 Administrator (Attachment C).

II. PRACTICAL CONSIDERATIONS AND CONSTRAINTS

- A. In supplying individual AIDS data records extracts may be used rather than all claims records/files.
- B. Only encrypted person level data will be shared (no name, scrambled ID), and all records must be handled as confidential because enough information exists on records to compromise recipients identity.
- C. No files will be released until the New York State Department of Health has tested them to assure accuracy.

Data Exchange Application and Agreement

ATTACHMENT C FEDERAL RULING ON CONFIDENTIALITY OF MEDICAID AIDS DATA



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Refer to DMD:SOB-3

APR 23 1991

Region II
Federal Building
26 Federal Plaza
New York NY 10278

MEDICAID STATE OPERATIONS LETTER #91-32

FROM: Associate Regional Administrator
Division of Medicaid

TO: State Agencies Administering the Medicaid Program

SUBJECT: Confidentiality and Release of Medicaid Data Concerning
Persons with Acquired Immune Deficiency Syndrome (AIDS)

The purpose of this letter is to clarify Federal policy regarding the sharing of claims data regarding Persons Living With AIDS (PLWA) by State Medicaid agencies with other State agencies. Such a practice is in violation of Federal privacy safeguards. Some State health departments, for example, have negotiated data exchanges with State Medicaid agencies to assure complete reporting of AIDS cases to the Centers for Disease Control, Public Health Service (PHS), in order to maximize State allocations under certain Federal AIDS grant programs.

While surveillance of disease prevalence is a legitimate public health concern, section 1902(a)(7) of the Social Security Act and 42 CFR 431, subpart F, permit disclosure of information concerning Medicaid applicants or recipients only for purposes directly related to administration of the State Medicaid plan. These purposes include establishing eligibility, determining the amount of medical assistance, providing Medicaid services for recipients, and participating in certain investigations and legal proceedings. Regulations at 42 CFR 431.306 further require that individual consent be obtained, whenever possible, before responding to requests for information from outside sources.

We have previously advised states that State Medicaid agencies may not furnish the Special Supplemental Program for Women, Infants, and Children (WIC) with Medicaid recipient lists to facilitate WIC outreach efforts. Section 6406 of the Omnibus Budget Reconciliation Act of 1989 subsequently mandated that States notify certain Medicaid eligible women of the availability of WIC benefits, refer such women to the responsible WIC agency and coordinate Medicaid and WIC operations. However, the principle stressed by our previous clarification remains applicable with regard to disclosure of AIDS-related, recipient-specific data.

We wish to remind you, therefore, that confidential information concerning ANY Medicaid recipient, including any PLWA, is to be released only under very limited circumstances, and then only to very limited categories of requestors. However, as an alternative to the release of patient identifying information, Medicaid agencies may provide others with summary data, including recipient counts and expenditures. Medicaid agencies may also disseminate

information directly related to the health and welfare of recipients in regular mailings or through Medicaid participating providers. However, State health departments seeking recipient information for reasons unrelated to administration of the Medicaid program should be advised that accurate counting of AIDS cases must rely on provider compliance with State reporting requirements. Medicaid data is not available for such purposes.

If you have questions, please contact your Medicaid State Representative at 212-264-2775.

Arthur J. O'Leary

Data Exchange Application and Agreement

ATTACHMENT C
FEDERAL RULING ON CONFIDENTIALITY OF
MEDICAID AIDS DATA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Refer to DMD: SOB-2

Region II
Federal Building
26 Federal Plaza
New York, NY 10278

MEDICAID STATE OPERATIONS LETTER # 91-32

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If you have questions, please contact your Medicaid State Representative at (212) 264-2775.

Arthur J. O'Leary

ATTACHMENT D
CONFIDENTIALITY LANGUAGE FOR THIRD PARTY CONTRACTS

To DEAA Applicant:

The federal Center for Medicare and Medicaid Services (CMS) requires that all contracts and/or agreements executed between the Department of Health and any second party that will receive Medicaid Confidential Data must include contract language that will bind the applicant(s) to ensure that contractor(s) abide by the regulations and laws that govern the protection of individual, Medicaid confidential level data. This notification requires that your office include the following language in all future contracts that will govern the release such confidential data:

Medicaid Confidential Data includes, but is not limited to, names and addresses of Medicaid applicants/recipients, the medical services provided, social and economic conditions or circumstances, the Department's evaluation of personal information, medical data, including diagnosis and past history of disease and disability, any information regarding income eligibility-and amount of medical assistance payment, income information, and/or information regarding the identification of third parties, Income information received from SSA or the Internal Revenue Service must be safeguarded according to the requirements of the agency that furnished the data. Also any information received in connection with the identification of legally liable third party resources under 433.138 of this chapter. Each element of Medicaid confidential data is confidential regardless of the document or mode of communication or storage in which it is found.

Note that this contract involves the Medicaid Confidential Data (MCD) of recipients and possibly applicants, both of which are confidential pursuant to Section 367b(4) of the N.Y. Social Services Law, 42 U.S.C. Section 1396(a)(7), Section 1902(a)(7) of the Social Security Act and 42 C.F.R. Section 431.300 et seq.

NO DISCLOSURE OF MCD IN YOUR POSSESSION CAN BE MADE TO ANY OTHER PERSON OR ENTITY WITHOUT THE PRIOR WRITTEN PERMISSION OF THE NEW YORK STATE DEPARTMENT OF HEALTH (NYSDOH), MEDICAID CONFIDENTIAL DATA REVIEW COMMITTEE (MCDRC). LIKEWISE, NO USE(S), OTHER THAN THE USE(S) OF MCD APPROVED IN THIS DATA EXCHANGE APPLICATION AND AGREEMENT, CAN BE MADE OF THE MCD WITHOUT THE PRIOR WRITTEN APPROVAL OF NYSDOH, MCDRC.

Also, pursuant to Section 367b(4) of the NY Social Services Law, information relating to persons APPLYING FOR medical assistance shall also be considered confidential and shall not be disclosed to persons or agencies without the prior written approval of the New York State Department of Health.

Data Exchange Application and Agreement

AIDS/HIV Related Confidentiality Restrictions:

Also note that Medicaid Confidential Data (MCD) may contain HIV related confidential information, as defined in Section 2780(7) of the N.Y. Pub. Health Law. As required by N.Y. Pub. Health Law Section 2782(5). The New York Department of Health hereby provides you with the following notice:

HIV/AIDS NOTICE

This information has been disclosed to you from confidential records which are protected by state law. State law prohibits you from making any further disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. Any unauthorized further disclosure in violation of state law may result in a fine or jail sentence or both. A general authorization for the release of medical or other information is NOT sufficient authorization for further disclosure.

The contractor agrees that any further disclosure of MCD requires the prior, written approval of the New York State Department of Health (NYSDOH), Medicaid Confidential Data Review Committee (MCDRC). The Contractor will require and ensure that any approved agreement, contract or document with a subcontractor contains the above Notice and a statement that the subcontractor or other party may not disclose the MCD without the prior, written approval of the NYSDOH MCDRC.

Alcohol and Substance Abuse Related Confidentiality Restrictions

Alcohol and substance abuse information is confidential pursuant to 42 C.F.R. Part 2. General authorizations are ineffective to obtain the release of such data. The federal regulations provide for a specific release for such data.

ANY AGREEMENT, CONTRACT OR DOCUMENT WITH A SUBCONTRACTOR MUST CONTAIN ALL OF THE ABOVE PROVISIONS PERTAINING TO CONFIDENTIALITY. IT MUST CONTAIN THE HIV/AIDS NOTICE AS WELL AS A STATEMENT THAT THE SUBCONTRACTOR MAY NOT USE OR DISCLOSE THE MCD WITHOUT THE PRIOR WRITTEN APPROVAL OF THE NYSDOH, MCDRC.

Data Exchange Application and Agreement

Applicant/Contractor

Signature.....Date...../...../.....

Name Printed.....

Company.....

Second Applicant/Contractor

Signature.....Date...../...../.....

Name Printed.....

Company.....

APPENDIX O

RFP Acronyms/Definitions

For the purposes of this contract, the following terms, abbreviations, and acronyms are defined as follows:

ACRONYMS

| | |
|--------------|---|
| CDC | Center for Disease Control |
| CFR | Code of Federal Regulation |
| CM | Care Management |
| CMD | Disease and Care Management Demonstration |
| CMO | Care Management Organization |
| CMS | Centers for Medicare and Medicaid Services |
| DEAA | Data Exchange Application and Agreement |
| DME | Durable Medical Equipment |
| DOH | New York State Department of Health |
| DSI | Disease Severity Indicator |
| DUR | Drug Utilization Review |
| ED | Emergency Department |
| EMEVS | Electronic Medicaid Eligibility Verification System |
| FET | Financial Evaluation Team |
| FFP | Federal Financial Participation |
| FFS | Fee-for-Service |
| HIPAA | Health Insurance Portability and Accountability Act |
| IPRO | Island Peer Review Organization |
| LDSS | Local District Social Services |

| | |
|---------------|--|
| MCD | Medicaid Confidential Data |
| MCDRC | Medicaid Confidential Data Review Committee |
| MMIS | Medicaid Management Information System |
| NYS | New York State |
| OASAS | Office of Alcohol and Substance Abuse Services |
| OMH | Office of Mental Health |
| OMM | Office of Medicaid Management |
| OMRDD | Office of Mental Retardation Development Disabilities |
| PMPM | Per Member Per Month |
| QIP | Quality Improvement Project |
| RFP | Request For Proposal |
| SFY | State Fiscal Year |
| SURS | Surveillance & Utilization Review System |
| TET | Technical Evaluation Team |
| Vendor | An organization, agency or other entity that provides specialized or unique services to the State of New York. |

RFP DEFINITIONS

AGREEMENT - The legal arrangement between the State of New York and the party to which the contract is awarded.

BIDDER/OFFEROR - Any company, firm, individual or other entity who can demonstrate an ability to perform the duties and responsibilities outlined in the RFP.

CARE MANAGEMENT (CM) - An approach or process for managing persons with chronic illness focused on prevention and treatment based on evidence-based standards of care to provide high quality cost effective health care. CM services may include care coordination, access to care managers skilled in monitoring of disease symptoms and medication questions, patient education in self-management, and physician-coordinated care plans.

CARE MANAGEMENT ORGANIZATION (CMO) - An entity that has contracted with OMM to provide care management services for CMD eligible enrollees.

CARE PLAN - A written plan developed describing the treatment proposed for each CMD intervention enrollee.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) - The federal agency responsible for the administration of the Medicaid and Medicare programs.

CMD MANAGER - A state employed staff person designated to coordinate the activities of the CMD contract and to resolve questions and perform other functions as necessary to ensure the contract is appropriately administered.

CMD ELIGIBLE ENROLLEE - A Medicaid recipient who has been determined eligible by OMM to participate in a CMD.

CMD INTERVENTION ENROLLEE - A Medicaid recipient who is an actively receiving CM services and interventions and is selecting to participate in the CMD.

CMD OPT-OUT - CMD eligibles that have been contacted by the CMO or its subcontractor and have stated that they do not wish to participate in the CMD.

CMD REACTIVATED (OPT-IN) ENROLLEE - A Medicaid recipient who had previously opted-out of the CMD and at a later time selects to opt-in or become an active intervention enrollee receiving CM services and interventions.

CODE OF FEDERAL REGULATION (CFR) - A codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government.

COMMISSIONER - The New York State Commissioner of Health.

CONTRACT - The written, signed agreement resulting from this RFP for contractor services to review medical necessity and quality of selected services for the Office of Medicaid Management.

CONTRACT MANAGER - A contractor representative that is the primary point of contact for the contractor's performance and who has the authority to make decisions that are binding on the contractor. This representative will also manage the contract on a day-to-day basis and be the primary liaison between DOH and the contractor.

CONTRACTOR - An organization which successfully completes the bidding process and is approved to contract directly with the DOH for the work specified herein.

CONTROL GROUP – A group of prospective CM enrollees that have been randomly selected by DOH.

DELIVERABLES - Reports, tables, documentation, etc., that are necessary parts of this contract and indicate that progress and contractual requirements are being met.

DEPARTMENT - New York State Department of Health.

DISEASE MANAGEMENT – The utilization of current, evidence-based interventions to improve the management of a disease state, provide high quality, preventive care and reduce the costs of providing health care.

DISEASE SEVERITY - This may include health care utilization, the presence of more than one chronic disease, the presence of other acute diseases, or other relevant criteria and ranked from a less severe to a most severe category to each CM enrollee.

DISEASE SEVERITY INDICATOR (DSI) - An indicator which reflects the complexity of a disease and a patient's level of risk (high, medium, low) of developing complications attributable to that disease.

“EMERGENCY MEDICAL CONDITION” - A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in placing the health of the individual (or with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to body functions or serious dysfunction of any bodily organ or part. Section 1932(b) (2) to the Social Security Act.

FEDERAL FINANCIAL PARTICIPATION (FFP) - A percentage of expenditures to be reimbursed by the federal government for medical assistance and administrative costs to a State Medicaid program.

FISCAL YEAR - (Federal) - October 1st through September 30th.
(State) - April 1st through March 31st.

HEALTH CARE FACILITY - An organization involved in the delivery of health care services for which reimbursement may be made in whole or part under Title XIX of the Act.

IMPLEMENTATION - The successful installation of services as specified in the contract resulting from this RFP.

INTERVENTION ENROLLEE - A CMD enrollee who has been selected and/or agreed to participate in the CMD and is actively receiving CM services from the vendor.

INTERVENTION GROUP - A group of prospective CM enrollees that have been randomly selected by the DOH to be actively managed by the contractor.

LOCAL GOVERNMENT ORGANIZATION - A governmental organization such as a County, Local District of Social Services or a regional health office.

MEDICAID - The joint federal and state medical assistance program that is described in Title XIX of the Social Security Act.

MEDICAID DISEASE AND CARE MANAGEMENT DEMONSTRATION (CMD) - A program designed to test state of the art technologies, techniques and different models in conducting care management services.

MEDICAID MANAGEMENT INFORMATION SYSTEM (MMIS) - A complex data warehouse system that processes and stores Medicaid medical claims data.

MEDICAL HOME - The provision of health care by a known resource (clinic or physician) to an individual patient for all primary and preventive care services to assure continuity of care and a linkage for necessary consultative, specialty and health-related services.

OFFICE OF MEDICAID MANAGEMENT (OMM) - The Office of Medicaid Management in the Department of Health; the single state agency that is responsible for the administration of the Medicaid program in New York State.

OPT-OUT - An intervention enrollee that has been contacted by the CMO or its subcontractor and has selected not to participate in the CMD.

PERFORMANCE STANDARDS - The criteria by which performance is measured.

POTENTIAL CM ENROLLEE – A Medicaid recipient which has been screened and found to demonstrate the general indications for requiring an intervention.

PRACTITIONER - An individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

PROSPECTIVE CM ENROLLEE - A Medicaid recipient who have been assigned a disease severity indicator by the vendor, and whose records are returned to the DOH for consideration as an intervention enrollee.

PROVIDER - Person, entity or facility enrolled in the Medicaid program and renders services to Medicaid beneficiaries and bills Medicaid for services.

RE-ACTIVATED (OPT-IN) - A CMD intervention enrollee that has previously opted-out of the CMD, who at a later time elects to become a CMD intervention enrollee and receive active CM services and interventions.

RECIPIENT - An individual eligible for medical assistance in accordance with the New York State Medicaid Program and who has been certified as eligible by the appropriate agency and has received services.

REGULATION - Any federal, state or local regulation, rule or ordinance.

RFP - Request for Proposal, a term used by the State to solicit proposals for services such as consulting. Typically used when the requesting agency requires vendor assistance in identifying an acceptable manner of solving a problem.

RURAL AREA - A New York State (NYS) counties having a population of 200,000 persons or less as per the 2000 NYS Census Report.

SERVICE AREA - A designated area in New York State where a CMO has proposed to conduct a CMD for eligible enrollees.

SPECIALIST - A provider whose practice is limited to a particular branch of medicine or surgery, including one who, by virtue of advanced training, is certified by a specialty board as being a qualified expert in that area of medicine.

STANDARDS - Professionally developed expressions of the range of acceptable variation from a norm or criterion.

STATE – NEW YORK STATE

SUBCONTRACT - Any separate agreement or contract between the contractor and an individual or entity (subcontractor) to perform all or a portion of the duties and obligations that the contractor is obligated to perform pursuant to this contract.

URBAN AREA - A New York State (NYS) counties having a population of greater than 200,000 people, as of the 2000 NYS Census Report.

VENDOR - An organization, agency or other entity that provides specialized or unique services to the State of New York.

APPENDIX P

Price Provisions

(To be based upon the approved bidder's proposal and resulting contract.)

APPENDIX X

Modification Agreement Form

ATTACHMENT 1

New York State 2004 Legislation

Authorizing Disease Management Demonstration Programs

1 be, may, consistent with this paragraph, rescind its designation as an
2 approved managed long term care demonstration and its authorization to
3 operate, and, consistent with this paragraph, designate an alternate
4 applicant as an approved managed long term care demonstration.

5 s 20. Intentionally omitted.

6 s 21. The public health law is amended by adding a new section 2111 to
7 read as follows:

8 **s 2111. Disease management demonstration programs.** 1. The department
9 may establish up to six disease management demonstration programs
10 through a request for proposals process to enhance the quality and
11 cost-effectiveness of care rendered to medicaid-eligible persons with
12 chronic health problems whose care and treatment, because of one or more
13 hospitalizations or other health care requirements, results in high
14 medicaid expenditures. In order to be eligible to sponsor and to under-
15 take a disease management demonstration program, the proposed sponsor
16 may be a not-for-profit, for-profit or local government organization
17 that has demonstrated expertise in the management or coordination of
18 care to persons with chronic diseases or that has the experience of
19 providing cost-effective community-based care to such patients, or in
20 the case of a local government organization, has expressed a strong
21 willingness to sponsor such a program. The department may also approve
22 disease management demonstration programs which include, but are not
23 limited to, the promotion of adherence to evidence-based guidelines,
24 improvement of provider and patient communication and provide informa-
25 tion on provider and beneficiary utilization of services. The department
26 shall grant no fewer than six demonstration programs, no more than one-
27 third of such programs shall be selected to provide these services in
28 any single social services district; provided further, where the depart-
29 ment grants less than six demonstration programs, no more than one such
30 program shall be selected to provide these services in any single social
31 services district. The department shall approve disease management
32 demonstration programs which are geographically diverse and represen-
33 tative of both urban and rural social services districts. The program
34 sponsor must establish, to the satisfaction of the department, its
35 capacity to enroll and serve sufficient numbers of enrollees to demon-
36 strate the cost-effectiveness of the demonstration program.

37 2. The department shall establish the criteria by which individuals
38 will be identified as eligible for enrollment in the demonstration
39 programs. Persons eligible for enrollment in the disease management
40 demonstration program shall be limited to individuals who: receive
41 medical assistance pursuant to title eleven of article five of the
42 social services law and may be eligible for benefits pursuant to title
43 18 of the social security act (medicare); are not enrolled in a medicaid
44 managed care plan, including individuals who are not required or not
45 eligible to participate in medicaid managed care programs pursuant to
46 section three hundred sixty-four-j of the social services law; are diag-
47 nosed with chronic health problems as may be specified by the entity
48 undertaking the demonstration program, including, but not limited to one
49 or more of the following: congestive heart failure, chronic obstructive
50 pulmonary disease, asthma, diabetes or other chronic health conditions
51 as may be specified by the department; or have experienced or are likely
52 to experience one or more hospitalizations or are otherwise expected to
53 incur excessive costs and high utilization of health care services.

54 3. Enrollment in a demonstration program shall be voluntary. A partic-
55 ipating individual may discontinue his or her enrollment at any time

1 without cause. The commissioner shall review and approve all enrollment
2 and marketing materials for a demonstration program.

3 4. The demonstration program shall offer evidence-based services and
4 interventions designed to ensure that the enrollees receive high quality
5 ty, preventative and cost-effective care, aimed at reducing the necessi-
6 ty for hospitalization or emergency room care or at reducing lengths of
7 stay when hospitalization is necessary. The demonstration program may
8 include screening of eligible enrollees, developing an individualized
9 care management plan for each enrollee and implementing that plan.
10 disease management demonstration programs that utilize information tech-
11 nology systems that allow for continuous application of evidence-based
12 guidelines to medical assistance claims data and other available data to
13 identify specific instances in which clinical interventions are justi-
14 fied and communicate indicated interventions to physicians, health care
15 providers and/or patients, and monitor physician and health care provid-
16 er response to such interventions, shall have the enrollees, or groups
17 of enrollees, approved by the department for participation. The services
18 provided by the demonstration program as part of the care management
19 plan may include, but are not limited to, case management, social work,
20 individualized health counselors, multi-behavioral goals plans, claims
21 data management, health and self-care education, drug therapy management
22 and oversight, personal emergency response systems and other monitoring
23 technologies, telehealth services and similar services designed to
24 improve the quality and cost-effectiveness of health care services.

25 5. The department shall be responsible for monitoring the quality,
26 appropriateness and cost-effectiveness of a demonstration program. The
27 department shall utilize, to the extent possible, all potential sources
28 of funding for demonstration programs, including, but not limited to,
29 private payments, donations, and any funding or shared savings that may
30 be available through federal waivers or otherwise under titles 18 and 19
31 of the federal social security act. Services provided as part of a
32 demonstration program and related administrative expenses not otherwise
33 eligible for coverage under these or other funding sources shall be
34 eligible for reimbursement under the medical assistance program for the
35 purposes of this section only if federal financial participation is
36 available.

37 6. Payments shall be made by the department to the entity responsible
38 for the operation of the demonstration program on a fixed amount per
39 member per month of enrollment and shall reimburse the program sponsor
40 for the services rendered pursuant to subdivision four of this section.
41 the amount paid shall be an amount reasonably necessary to meet the
42 costs of providing such services, provided that the total amount paid
43 for medical assistance to enrollees in any such disease management
44 demonstration program, including any demonstration program expenditures,
45 shall not exceed ninety-five percent of the medical assistance expendi-
46 ture related to such enrollee that would reasonably have been antic-
47 ipated if the enrollee had not been enrolled in such demonstration
48 program. The department may make payments to demonstration programs that
49 provide administrative services only, provided that expenditures made
50 for enrollees, or a group of enrollees, participating in the demon-
51 stration program shall provide sufficient savings as determined by the
52 department, had the enrollees, or groups of enrollees, not been enrolled
53 in such demonstration. The department shall provide an interim report to
54 the governor, and the legislature on or before december thirty-first,
55 two thousand six and a final report on or before december thirty-first,
56 two thousand seven on the results of demonstration programs. Both

1 reports shall include findings as to the demonstration programs`
 2 contribution to improving quality of care and their cost-effectiveness.
 3 in the final report, the department shall offer recommendations as to
 4 whether demonstration programs should be extended, modified, eliminated
 5 or made permanent.

6 S 22. Section 3621 of the public health law is renumbered 3622 and a
 7 new section 3621 is added to read as follows:

..... **Portion omitted**

42 s 23. Subdivision 1 of section 2807-v of the public health law is
 43 amended by adding a new paragraph (vv) to read as follows:

44 (vv) funds shall be reserved and accumulated from year to year by the
 45 commissioner and shall be available, including income from invested
 46 funds, for the purpose of supporting disease management and telemedicine
 47 demonstration programs authorized pursuant to sections twenty-one
 48 hundred eleven and thirty-six hundred twenty-one of this chapter,
 49 respectively, for the following periods in the following amounts:

50 (i) five million dollars for the period january first, two thousand
 51 four through december thirty-first, two thousand four, of which three
 52 million dollars shall be available for disease management demonstration
 53 programs and two million dollars shall be available for telemedicine
 54 demonstration programs;

55 (ii) two million five hundred thousand dollars for the period january
 56 first, two thousand five through june thirtieth, two thousand five, of

1 which one million five hundred thousand dollars shall be available for
 2 disease management demonstration programs and one million dollars shall
 3 be available for telemedicine demonstration programs;

ATTACHMENT 2

**Estimated Number of CMD Prospective Enrollees
(By Region and County for Nine Chronic Disease States)**

Narrative and Charts

**ESTIMATED NUMBER OF CMD PROSPECTIVE ENROLLEES
(BY REGION AND COUNTY FOR NINE CHRONIC DISEASE STATES)**

A. INTRODUCTION:

The attached charts provide data on the estimated number of prospective CMD enrollees for nine chronic disease states. The data indicates the number of Medicaid recipients who meet the general criteria for inclusion/exclusion included in PART I, C and have at least six (6) months of recent and continuous Medicaid eligibility and have indications of the following disease states as described below.

1. The first chart entitled “Medicaid Enrollee Population Eligible for Enrollment in CMDs Excluding Dual Eligibles” provides CMD prospective enrollee data that excludes Medicaid eligibles that are in the following categories:
 - Institutional patients: OMH inpatient or OMRDD inpatient/developmental centers, Long Term Care institutions (nursing homes and residential treatment facilities), or hospice.
 - Enrollees of managed care plans, managed long term care plans, or in Family Health Plus (FHPlus).
 - Enrollees in Medicare and Medicaid (dual eligibles).

2. The second chart entitled, “Medicaid Enrollee Population Eligible for Enrollment in CMDs Including Dual Eligibles”, provides CMD prospective enrollee data that only excludes Medicaid eligibles in the following categories:
 - Residents of OMH or OMRDD licensed facilities, or hospice.
 - Enrollees of managed care plans, managed long term care plans, or in Family Health Plus (FHPlus).

Please note: CMDs that plan to enroll dual eligibles will not be able to do so until after July 1, 2006.

Selection of these prospective enrollees was made via a targeted selection of claims transactions from the NYS DOH Office of Medicaid Management’s (OMM) Audit, Fiscal, and Program Planning DataMart.

Of Note: The bidder is not limited to proposing a CMD for one of the disease states provided in this attachment nor does their proposal have to be disease specific. The bidder will be responsible for providing DOH the criteria for claims selection and data analysis to target the population for the proposed CMD. All criteria for identification and population selection for the CMD will be subject to DOH approval.

The following information provides an overview of how this data analysis for the following disease states was completed, and the criteria utilized by DOH to identify the prospective enrollees for these specific disease states.

B. GUIDING PRINCIPLES IN POPULATION SELECTION

1. Maximize Populations / Minimize False Positives

The population will be maximized by a search of original claims and a search of primary and secondary codes. False positive identifications will be minimized via the search for two (2) or more claims limited to healthcare settings where the principal provider is a doctor or nurse practitioner, such as: physician office, clinic location, inpatient, or ambulatory environment.

2. Standard National Medical Coding

The identification of the population will involve a scan of claims in search of generally accepted, national/international standard coding: International Classification of Diseases, 9th Edition (ICD-9) primary and secondary diagnosis codes and Healthcare Common Procedure Coding System (HCPCS) primary and secondary procedure codes.

3. All Inclusive Populations

DOH will ensure that the prospective CM population will include Medicaid recipients from the broadest range of the clinical spectrum. The inclusive nature of the prospective CM population will allow DOH to generalize the analytical results of CM to the full Medicaid population.

C. TECHNICAL SPECIFICATIONS: FOR DEMONSTRATED DISEASE STATES

Prospective CMD enrollees were selected for each of the following chronic disease condition as specified below:

(Disease conditions listed in alphabetical order)

Asthma

Codes:

ICD-9 diagnosis code: 493, excluding 493.2 (chronic obstructive asthma)

Category of Service Criteria:

Physician, Clinic, Inpatient, Child/Teen Health Program, Referred Ambulatory, Nurse Practitioner

Claims Criteria:

Two (2) or more original service claims exhibiting any combination of ICD-9 primary or secondary diagnosis code for asthma.

Chronic Kidney Disease

Codes:

ICD-9 diagnosis codes: 585, 589, 402.00, 402.10, 402.90, 403, 404.00, 404.02, 404.10, 404.12, 404.90, 404.92, 581, 582, 583

HCPCS procedure codes: 36819, 36820, 36821, 36825, 36830, 49421

HCPCS procedure codes: Q9920-Q9940

Category of Service Criteria:

Physician, Clinic, Inpatient, Child/Teen Health Program, Referred Ambulatory, Nurse Practitioner

Claims Criteria:

Two (2) or more original service claims exhibiting any combination of ICD-9 primary or secondary diagnosis codes or HCPCS primary or secondary procedure codes for chronic kidney disease.

Chronic Obstructive Pulmonary Disease

Codes:

ICD-9 diagnosis codes: 491, 492, 493.2, 496, 518.83, 518.84

Category of Service Criteria:

Physician, Clinic, Inpatient, Child/Teen Health Program, Referred Ambulatory, Nurse Practitioner

Claims Criteria:

Two (2) or more original service claims exhibiting any combination of ICD-9 primary or secondary diagnosis codes for COPD conditions.

Congestive Heart Failure

Codes:

ICD-9 diagnosis codes: 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 425.4, 425.5, 428

Category of Service Criteria:

Physician, Clinic, Inpatient, Child/Teen Health Program, Referred Ambulatory, Nurse Practitioner

Claims Criteria:

Two (2) or more original service claims exhibiting any combination of ICD-9 primary or secondary diagnosis codes for congestive heart failure.

Coronary Artery Disease

Codes:

ICD-9 diagnosis codes: 410-414, 433-435, 429.2, 437, 440

HCPCS procedure codes: 33510-33523, 33533-33536, 92980-92984, 33530, 33542, 33572, 92995, 92996, 92975, 92977, 93540

Category of Service Criteria:

Physician, Clinic, Inpatient, Child/Teen Health Program, Referred Ambulatory, Nurse Practitioner

Claims Criteria:

Two (2) or more original service claims exhibiting any combination of ICD-9 primary or secondary diagnosis codes or HCPCS primary or secondary procedure codes for coronary artery disease.

Diabetes

Codes:

ICD-9 diagnosis codes: 250, 357.2, 362.01, 362.02, 366.41

Category of Service Criteria:

Physician, Clinic, Inpatient, Child/Teen Health Program, Referred Ambulatory, Nurse Practitioner

Claims Criteria:

Two (2) or more original service claims exhibiting any combination of ICD-9 primary or secondary diagnosis codes for diabetic conditions.

End-stage Renal Disease

Codes:

HCPCS procedure codes: 90918-90999

Category of Service Criteria:

Physician, Clinic, Inpatient, Child/Teen Health Program, Referred Ambulatory, Nurse Practitioner

Claims Criteria:

Two (2) or more original service claims exhibiting any combination of HCPCS (CPT-4) primary or secondary procedure codes for end-stage renal disease.

Mental Health

The following specifications, for the identification of the severely and persistently mentally ill (SPMI), have been developed as a result of a memorandum of understanding (MOU) between the OMM and the Office of Mental Health (OMH). Therefore, the algorithm designed to identify this population is different than the algorithm used for identification of Medicaid recipients with other disease conditions.

The mental health category will comprise two (2) distinct populations of mental health disease conditions. Individuals will be assigned to the mental health – children or to the mental health – adult populations by age (see age criteria below).

Initial claim screen:

Any claim with a rate code for an OMH licensed service/facility: 4000-4010, 4050-4056, 4060-4067, 4070-4077, 4091-4099, 4150-4180, 4250-4271, 4301-4397, 4500-4507, 4601-4606, 4650-4670, 5203-5207, 5231-5242, 5250-5259, 1212, 2261, 2340, 2852, 2858, 2962, 2963, 5200

Utilization Threshold Screen:

Three (3) or more Medicaid days in OMH licensed inpatient facilities (rate codes: 4001-4004, 1212, 2852, 2858).

Ten (10) or more outpatient visits in OMH licensed clinics (rate codes: 4007-4010, 4301-4306, 4093-4099).

One (1) or more service claims in OMH licensed specialty services (rate codes: 5250-5259, 4508-4529, 4307- 4368, 4060- 4067, 4601- 4606, 4650- 4659, 4369- 4397, 2261, 2340, 2852, 2858, 5200, 5203, 5205, 5206 or provider ID = 02276286).

Diagnosis Screen:

At least one (1) claim exhibiting the ICD-9 primary diagnosis code in the following ranges: 295-297.99, 300.3-300.49, 300.6-300.79, 301.0-301.09, 307.1-307.19, 300.01, 300.02, 300.11, 300.12, 300.13, 300.14, 300.21, 300.22, 300.81, 301.13, 301.20, 301.22, 301.81, 301.83, 307.51, 309.81

Age Criteria:

The age criteria will result in two (2) distinct disease group populations.

Children: 0-17, Adults: 18 plus

Sickle Cell Anemia**Codes:**

ICD-9 diagnosis code: 282.6

Category of Service Criteria:

Physician, Clinic, Inpatient, Child/Teen Health Program, Referred Ambulatory, Nurse Practitioner

Claims Criteria:

Two (2) or more original service claims exhibiting any combination of ICD-9 primary or secondary diagnosis codes for sickle cell anemia.

MEDICAID ENROLLEE POPULATION ELIGIBLE FOR ENROLLMENT IN CMDs EXCLUDING MEDICARE DUAL ELIGIBLES
 MEDICAID ENROLLMENT OF 6 MONTHS OR MORE IN CY 2003

NYS DOH / OFFICE OF MEDICAID MANAGEMENT

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|------------------|-----------------|--------------------------|--------------------|-------------------------|--------------------|--------------------------|---------------|-------------------------|---------------------------------------|---------------|------------------------|---------------------------------|--------------------------------|
| REGION | COUNTY NAME | TOTAL MEDICAID ENROLLEES | TOTAL CM PROSPECTS | END STAGE RENAL DISEASE | SICKLE CELL ANEMIA | CONGESTIVE HEART FAILURE | DIABETES | CORONARY ARTERY DISEASE | CHRONIC OBSTRUCTIVE PULMONARY DISEASE | ASTHMA | CHRONIC KIDNEY DISEASE | MENTAL HEALTH / CHILDREN (< 18) | MENTAL HEALTH / ADULTS (>= 18) |
| TOTALS | | 980,482 | 159,618 | 1,816 | 1,824 | 8,499 | 39,257 | 22,265 | 8,708 | 48,237 | 9,719 | 6,205 | 55,903 |
| N Y CITY | | 580,836 | 112,175 | 1,449 | 1,481 | 6,184 | 28,858 | 16,157 | 4,958 | 34,235 | 7,919 | 3,685 | 39,900 |
| | BRONX | 142,007 | 28,910 | 369 | 451 | 1,533 | 7,410 | 3,503 | 1,052 | 11,441 | 1,760 | 898 | 8,679 |
| | KINGS | 181,387 | 35,915 | 518 | 513 | 2,129 | 9,610 | 5,971 | 1,709 | 10,157 | 3,010 | 867 | 13,000 |
| | NEW YORK | 118,879 | 24,049 | 226 | 274 | 1,336 | 6,053 | 2,996 | 977 | 7,223 | 1,500 | 967 | 9,127 |
| | NYC UNKOWN (13) | 21,997 | 2,859 | 22 | 33 | 139 | 472 | 300 | 127 | 752 | 135 | 171 | 1,290 |
| | QUEENS | 102,503 | 18,085 | 289 | 184 | 949 | 4,814 | 3,052 | 921 | 4,040 | 1,380 | 721 | 6,825 |
| | RICHMOND | 14,063 | 2,357 | 25 | 26 | 98 | 499 | 335 | 172 | 622 | 134 | 61 | 979 |
| METRO | | 128,578 | 15,966 | 168 | 152 | 828 | 3,337 | 2,147 | 979 | 3,910 | 715 | 901 | 6,336 |
| | DUTCHESS | 11,781 | 1,470 | 8 | 12 | 34 | 267 | 119 | 112 | 452 | 43 | 117 | 587 |
| | NASSAU | 22,391 | 2,939 | 49 | 30 | 183 | 659 | 491 | 144 | 514 | 170 | 92 | 1,302 |
| | ORANGE | 24,947 | 2,024 | 10 | 9 | 92 | 386 | 234 | 117 | 774 | 66 | 107 | 630 |
| | PUTNAM | 1,888 | 234 | 0 | 1 | 11 | 35 | 13 | 19 | 71 | 7 | 19 | 99 |
| | ROCKLAND | 4,667 | 701 | 12 | 7 | 38 | 202 | 78 | 49 | 115 | 52 | 27 | 303 |
| | SUFFOLK | 22,438 | 3,209 | 49 | 42 | 191 | 695 | 579 | 199 | 585 | 171 | 172 | 1,314 |
| | SULLIVAN | 5,178 | 685 | 4 | 0 | 39 | 149 | 69 | 90 | 241 | 22 | 51 | 159 |
| | ULSTER | 10,857 | 1,467 | 2 | 7 | 66 | 265 | 144 | 93 | 518 | 42 | 150 | 436 |
| | WESTCHESTER | 24,431 | 3,237 | 34 | 44 | 174 | 679 | 420 | 156 | 640 | 142 | 166 | 1,506 |
| NORTHEAST | | 173,935 | 20,473 | 81 | 59 | 865 | 4,426 | 2,440 | 1,912 | 7,458 | 644 | 1,074 | 5,693 |
| | ALBANY | 6,700 | 1,056 | 9 | 15 | 71 | 211 | 143 | 75 | 290 | 51 | 61 | 392 |
| | BROOME | 11,103 | 1,394 | 2 | 5 | 50 | 326 | 138 | 139 | 529 | 24 | 82 | 385 |
| | CAYUGA | 7,495 | 798 | 1 | 0 | 35 | 147 | 89 | 62 | 297 | 30 | 45 | 244 |
| | CHENANGO | 6,610 | 684 | 2 | 0 | 25 | 146 | 77 | 57 | 318 | 27 | 31 | 124 |
| | CLINTON | 8,779 | 1,129 | 4 | 0 | 29 | 259 | 121 | 102 | 474 | 18 | 56 | 281 |
| | COLUMBIA | 1,557 | 197 | 3 | 1 | 10 | 45 | 28 | 21 | 48 | 7 | 18 | 70 |
| | CORTLAND | 5,036 | 509 | 0 | 1 | 14 | 82 | 34 | 36 | 256 | 10 | 31 | 108 |
| | DELAWARE | 4,095 | 446 | 1 | 0 | 16 | 81 | 62 | 63 | 186 | 10 | 27 | 86 |
| | ESSEX | 3,219 | 326 | 2 | 0 | 20 | 75 | 39 | 28 | 134 | 5 | 14 | 71 |
| | FRANKLIN | 5,193 | 600 | 6 | 0 | 17 | 155 | 68 | 61 | 235 | 14 | 22 | 126 |
| | FULTON | 6,273 | 921 | 0 | 1 | 21 | 142 | 102 | 89 | 462 | 10 | 55 | 222 |
| | GREENE | 993 | 125 | 1 | 0 | 9 | 29 | 21 | 16 | 26 | 4 | 9 | 42 |
| | HAMILTON | 295 | 29 | 0 | 0 | 1 | 7 | 7 | 3 | 10 | 2 | 1 | 6 |
| | HERKIMER | 3,308 | 317 | 0 | 0 | 13 | 71 | 54 | 20 | 132 | 11 | 8 | 67 |
| | JEFFERSON | 12,026 | 1,350 | 2 | 0 | 69 | 266 | 141 | 150 | 569 | 23 | 59 | 362 |
| | LEWIS | 3,181 | 302 | 0 | 0 | 12 | 60 | 27 | 24 | 100 | 8 | 20 | 102 |
| | MADISON | 5,840 | 537 | 0 | 0 | 12 | 87 | 43 | 36 | 283 | 17 | 22 | 108 |
| | MONTGOMERY | 4,967 | 518 | 0 | 0 | 22 | 117 | 58 | 46 | 231 | 13 | 36 | 114 |
| | ONEIDA | 7,164 | 997 | 7 | 2 | 54 | 273 | 147 | 106 | 251 | 54 | 43 | 320 |
| | ONONDAGA | 14,143 | 1,937 | 16 | 26 | 100 | 489 | 244 | 150 | 503 | 107 | 72 | 699 |
| | OSWEGO | 3,354 | 384 | 3 | 0 | 18 | 112 | 54 | 54 | 70 | 21 | 12 | 135 |
| | OTSEGO | 5,179 | 634 | 0 | 0 | 22 | 107 | 64 | 49 | 331 | 13 | 37 | 112 |
| | RENSSELAER | 2,767 | 493 | 5 | 4 | 21 | 122 | 63 | 56 | 113 | 25 | 26 | 203 |
| | SAINT LAWRENCE | 13,353 | 1,332 | 4 | 0 | 41 | 295 | 166 | 176 | 539 | 53 | 56 | 223 |

MEDICAID ENROLLEE POPULATION ELIGIBLE FOR ENROLLMENT IN CMDs EXCLUDING MEDICARE DUAL ELIGIBLES
 MEDICAID ENROLLMENT OF 6 MONTHS OR MORE IN CY 2003

NYS DOH / OFFICE OF MEDICAID MANAGEMENT

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|--------|-------------|--------------------------|--------------------|-------------------------|--------------------|--------------------------|----------|-------------------------|---------------------------------------|--------|------------------------|---------------------------------|--------------------------------|
| REGION | COUNTY NAME | TOTAL MEDICAID ENROLLEES | TOTAL CM PROSPECTS | END STAGE RENAL DISEASE | SICKLE CELL ANEMIA | CONGESTIVE HEART FAILURE | DIABETES | CORONARY ARTERY DISEASE | CHRONIC OBSTRUCTIVE PULMONARY DISEASE | ASTHMA | CHRONIC KIDNEY DISEASE | MENTAL HEALTH / CHILDREN (< 18) | MENTAL HEALTH / ADULTS (>= 18) |
| | SARATOGA | 3,984 | 500 | 0 | 1 | 22 | 114 | 78 | 60 | 116 | 17 | 26 | 179 |
| | SCHENECTADY | 7,009 | 841 | 5 | 3 | 44 | 192 | 112 | 77 | 234 | 18 | 45 | 292 |
| | SCHOHARIE | 2,887 | 317 | 0 | 0 | 9 | 74 | 26 | 30 | 144 | 11 | 22 | 61 |
| | TIOGA | 4,498 | 429 | 1 | 0 | 15 | 73 | 51 | 39 | 169 | 4 | 27 | 133 |
| | TOMPKINS | 6,569 | 641 | 2 | 0 | 26 | 100 | 58 | 27 | 206 | 12 | 64 | 224 |
| | WARREN | 2,604 | 335 | 1 | 0 | 22 | 85 | 64 | 28 | 76 | 7 | 22 | 98 |
| | WASHINGTON | 3,754 | 395 | 4 | 0 | 25 | 84 | 61 | 32 | 126 | 18 | 25 | 104 |
| WEST | | 97,133 | 11,004 | 118 | 132 | 622 | 2,636 | 1,521 | 859 | 2,634 | 441 | 545 | 3,974 |
| | ALLEGANY | 4,050 | 373 | 2 | 0 | 19 | 65 | 59 | 60 | 106 | 11 | 11 | 114 |
| | CATTARAUGUS | 2,498 | 272 | 4 | 0 | 16 | 69 | 34 | 44 | 67 | 11 | 17 | 85 |
| | CHAUTAUQUA | 5,046 | 537 | 2 | 0 | 22 | 100 | 59 | 54 | 120 | 26 | 36 | 230 |
| | CHEMUNG | 6,453 | 609 | 1 | 1 | 26 | 114 | 72 | 58 | 226 | 10 | 29 | 195 |
| | ERIE | 22,574 | 2,925 | 33 | 58 | 197 | 775 | 450 | 230 | 592 | 128 | 151 | 1,001 |
| | GENESEE | 2,278 | 234 | 2 | 2 | 10 | 46 | 27 | 20 | 83 | 7 | 6 | 82 |
| | LIVINGSTON | 1,311 | 177 | 4 | 0 | 12 | 52 | 23 | 10 | 38 | 15 | 10 | 66 |
| | MONROE | 28,160 | 3,274 | 63 | 61 | 211 | 901 | 475 | 170 | 654 | 150 | 113 | 1,268 |
| | NIAGARA | 3,450 | 567 | 2 | 5 | 21 | 106 | 74 | 35 | 80 | 8 | 52 | 303 |
| | ONTARIO | 1,866 | 188 | 2 | 0 | 9 | 32 | 31 | 13 | 32 | 6 | 17 | 94 |
| | ORLEANS | 2,019 | 163 | 0 | 0 | 4 | 39 | 23 | 15 | 60 | 7 | 12 | 34 |
| | SCHUYLER | 1,907 | 180 | 0 | 0 | 10 | 32 | 21 | 25 | 57 | 4 | 10 | 58 |
| | SENECA | 1,134 | 134 | 1 | 0 | 9 | 20 | 18 | 11 | 35 | 5 | 10 | 47 |
| | STEBEN | 8,932 | 841 | 1 | 2 | 33 | 162 | 89 | 72 | 365 | 33 | 34 | 187 |
| | WAYNE | 1,860 | 236 | 1 | 3 | 13 | 60 | 34 | 12 | 32 | 12 | 21 | 102 |
| | WYOMING | 2,731 | 210 | 0 | 0 | 6 | 44 | 22 | 21 | 64 | 4 | 8 | 78 |
| | YATES | 864 | 84 | 0 | 0 | 4 | 19 | 10 | 9 | 23 | 4 | 8 | 30 |

NOTES:

Column 3 -- Unique Medicaid population count of enrollees eligible for 6 months or more in CY 2003, excluding all managed care enrollees, institutional patients, and Medicare enrollees.

Column 4 -- Unique Medicaid population count of enrollees with at least one of the 8 disease groups listed (to the right), excluding all managed care enrollees, institutional patients, and Medicare enrollees.

Columns 5-14 -- These column counts are not mutually exclusive (ex: a Medicaid enrollee with ESRD may also have CHF etc...).

(13) The disease screening algorithm uses zip code ranges to obtain counts in NYC boroughs (see columns 4-12). Since some zip code entries may be invalid, the category "NYC unknown" consists of a count of Medicaid enrollees with a county code of '66' (NYC) but with an invalid zip code (unable to be placed in a borough).

(14) Exclusions are defined as follows: managed care: HMO, managed LT care, and Family Health Plus enrollment; institutional patients: OMH inpatient, OMRDD inpatient/developmental centers, LTC institutions (nursing homes and residential treatment centers); and hospice patients.

DATA SOURCE: DOH/OMM AFPP DataMart (claims/enrollment updated through August 2004 for disease specific counts in columns 4-12, and Sept.2004 for total Medicaid enrollee counts in column 3).

MEDICAID ENROLLEE POPULATION ELIGIBLE FOR ENROLLMENT IN CMDs INCLUDING MEDICARE DUAL ELIGIBLES*
 MEDICAID ENROLLMENT OF 6 MONTHS OR MORE IN CY 2003

NYS DOH / OFFICE OF MEDICAID MANAGEMENT

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|----------------------|-----------------|--------------------------|--------------------|-------------------------|--------------------|--------------------------|----------------|-------------------------|---------------------------------------|---------------|------------------------|---------------------------------|--------------------------------|
| REGION | COUNTY NAME | TOTAL MEDICAID ENROLLEES | TOTAL CM PROSPECTS | END STAGE RENAL DISEASE | SICKLE CELL ANEMIA | CONGESTIVE HEART FAILURE | DIABETES | CORONARY ARTERY DISEASE | CHRONIC OBSTRUCTIVE PULMONARY DISEASE | ASTHMA | CHRONIC KIDNEY DISEASE | MENTAL HEALTH / CHILDREN (< 18) | MENTAL HEALTH / ADULTS (>= 18) |
| TOTALS | | 1,531,736 | 473,838 | 10,723 | 2,330 | 49,295 | 115,333 | 111,641 | 35,783 | 65,466 | 46,988 | 41,200 | 175,028 |
| NEW YORK CITY | | 907,846 | 301,956 | 7,415 | 1,843 | 33,355 | 79,283 | 77,562 | 18,735 | 46,073 | 35,834 | 24,611 | 102,906 |
| | BRONX | 201,921 | 67,142 | 1,596 | 550 | 6,385 | 17,914 | 12,959 | 3,348 | 14,607 | 6,161 | 7,277 | 22,377 |
| | KINGS | 290,158 | 101,460 | 2,610 | 625 | 12,919 | 27,563 | 32,483 | 6,915 | 14,091 | 14,353 | 6,639 | 31,217 |
| | NEW YORK | 186,453 | 62,584 | 1,373 | 359 | 5,659 | 16,312 | 12,582 | 3,263 | 9,858 | 6,956 | 5,517 | 23,921 |
| | NYC UNKOWN (13) | 32,279 | 8,334 | 125 | 37 | 917 | 1,407 | 1,581 | 568 | 914 | 570 | 1,034 | 3,578 |
| | QUEENS | 172,180 | 54,655 | 1,517 | 236 | 6,858 | 14,537 | 16,052 | 4,035 | 5,745 | 7,026 | 3,510 | 18,392 |
| | RICHMOND | 24,855 | 7,781 | 194 | 36 | 617 | 1,550 | 1,905 | 606 | 858 | 768 | 634 | 3,421 |
| METRO | | 215,585 | 60,725 | 1,337 | 216 | 6,624 | 12,837 | 14,433 | 5,689 | 5,884 | 5,103 | 4,197 | 25,475 |
| | DUTCHESS | 16,750 | 4,767 | 47 | 16 | 321 | 887 | 756 | 526 | 541 | 221 | 631 | 2,240 |
| | NASSAU | 44,131 | 13,070 | 308 | 45 | 1,483 | 2,533 | 3,392 | 1,133 | 963 | 1,243 | 519 | 5,894 |
| | ORANGE | 31,183 | 6,066 | 96 | 14 | 567 | 1,314 | 1,220 | 667 | 982 | 407 | 630 | 2,232 |
| | PUTNAM | 3,003 | 887 | 8 | 1 | 74 | 133 | 129 | 72 | 97 | 41 | 69 | 479 |
| | ROCKLAND | 9,817 | 3,120 | 61 | 10 | 380 | 859 | 648 | 276 | 219 | 421 | 117 | 1,295 |
| | SUFFOLK | 45,399 | 13,668 | 379 | 48 | 1,615 | 2,982 | 4,100 | 1,317 | 1,069 | 1,297 | 793 | 5,128 |
| | SULLIVAN | 7,540 | 2,153 | 41 | 3 | 190 | 419 | 328 | 275 | 311 | 146 | 213 | 868 |
| | ULSTER | 15,260 | 3,984 | 47 | 9 | 333 | 816 | 669 | 433 | 628 | 210 | 459 | 1,599 |
| | WESTCHESTER | 42,502 | 13,010 | 350 | 70 | 1,661 | 2,894 | 3,191 | 990 | 1,074 | 1,117 | 766 | 5,740 |
| NORTHEAST | | 248,430 | 64,808 | 991 | 81 | 5,167 | 13,715 | 11,382 | 7,296 | 9,421 | 3,319 | 7,432 | 25,477 |
| | ALBANY | 12,941 | 4,100 | 109 | 21 | 477 | 942 | 892 | 406 | 482 | 314 | 258 | 1,692 |
| | BROOME | 15,920 | 4,174 | 64 | 5 | 251 | 891 | 624 | 472 | 667 | 151 | 500 | 1,693 |
| | CAYUGA | 9,484 | 2,335 | 19 | 0 | 219 | 377 | 355 | 205 | 338 | 140 | 386 | 932 |
| | CHENANGO | 8,049 | 1,690 | 11 | 0 | 111 | 335 | 237 | 153 | 345 | 61 | 265 | 574 |
| | CLINTON | 11,145 | 2,939 | 38 | 0 | 178 | 670 | 470 | 339 | 572 | 106 | 378 | 1,074 |
| | COLUMBIA | 3,161 | 1,068 | 19 | 2 | 112 | 207 | 210 | 151 | 67 | 46 | 64 | 513 |
| | CORTLAND | 6,322 | 1,595 | 10 | 1 | 97 | 276 | 185 | 149 | 283 | 74 | 298 | 585 |
| | DELAWARE | 5,334 | 1,332 | 15 | 0 | 95 | 214 | 214 | 177 | 214 | 43 | 255 | 466 |
| | ESSEX | 4,383 | 906 | 11 | 0 | 87 | 223 | 170 | 110 | 158 | 43 | 97 | 272 |
| | FRANKLIN | 6,811 | 1,786 | 30 | 0 | 93 | 377 | 261 | 202 | 277 | 63 | 279 | 665 |
| | FULTON | 8,133 | 2,429 | 19 | 1 | 148 | 394 | 346 | 289 | 518 | 60 | 398 | 963 |
| | GREENE | 2,097 | 650 | 19 | 0 | 90 | 153 | 163 | 108 | 39 | 34 | 35 | 241 |
| | HAMILTON | 423 | 96 | 0 | 0 | 10 | 28 | 26 | 10 | 16 | 4 | 6 | 26 |
| | HERKIMER | 5,206 | 1,242 | 23 | 0 | 126 | 328 | 351 | 150 | 187 | 86 | 80 | 355 |
| | JEFFERSON | 14,784 | 3,286 | 35 | 0 | 298 | 710 | 515 | 446 | 653 | 119 | 401 | 1,059 |
| | LEWIS | 3,914 | 982 | 10 | 0 | 62 | 176 | 118 | 84 | 116 | 33 | 213 | 399 |
| | MADISON | 7,325 | 1,509 | 12 | 0 | 96 | 277 | 217 | 177 | 332 | 78 | 182 | 547 |
| | MONTGOMERY | 6,556 | 1,659 | 22 | 0 | 134 | 360 | 344 | 180 | 275 | 87 | 220 | 604 |
| | ONEIDA | 13,751 | 4,063 | 73 | 4 | 377 | 980 | 880 | 501 | 459 | 331 | 294 | 1,635 |
| | ONONDAGA | 23,257 | 6,516 | 205 | 36 | 522 | 1,524 | 1,233 | 603 | 711 | 535 | 502 | 2,874 |
| | OSWEGO | 5,886 | 1,621 | 29 | 0 | 123 | 370 | 334 | 227 | 110 | 78 | 105 | 706 |
| | OTSEGO | 6,639 | 1,638 | 13 | 0 | 120 | 279 | 234 | 150 | 375 | 52 | 233 | 606 |
| | RENSSELAER | 6,265 | 2,364 | 41 | 4 | 236 | 568 | 482 | 343 | 225 | 170 | 154 | 1,087 |
| | SAINT LAWRENCE | 16,549 | 3,129 | 40 | 0 | 229 | 764 | 531 | 504 | 608 | 151 | 377 | 738 |

MEDICAID ENROLLEE POPULATION ELIGIBLE FOR ENROLLMENT IN CMDs INCLUDING MEDICARE DUAL ELIGIBLES*
MEDICAID ENROLLMENT OF 6 MONTHS OR MORE IN CY 2003

NYS DOH / OFFICE OF MEDICAID MANAGEMENT

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|-------------|-------------|--------------------------|--------------------|-------------------------|--------------------|--------------------------|--------------|-------------------------|---------------------------------------|--------------|------------------------|---------------------------------|--------------------------------|
| REGION | COUNTY NAME | TOTAL MEDICAID ENROLLEES | TOTAL CM PROSPECTS | END STAGE RENAL DISEASE | SICKLE CELL ANEMIA | CONGESTIVE HEART FAILURE | DIABETES | CORONARY ARTERY DISEASE | CHRONIC OBSTRUCTIVE PULMONARY DISEASE | ASTHMA | CHRONIC KIDNEY DISEASE | MENTAL HEALTH / CHILDREN (< 18) | MENTAL HEALTH / ADULTS (>= 18) |
| | SARATOGA | 7,110 | 2,111 | 18 | 1 | 188 | 504 | 466 | 273 | 188 | 89 | 122 | 940 |
| | SCHENECTADY | 10,342 | 2,936 | 49 | 5 | 228 | 581 | 548 | 297 | 314 | 129 | 295 | 1,392 |
| | SCHOHARIE | 3,654 | 889 | 6 | 0 | 62 | 207 | 134 | 116 | 163 | 36 | 138 | 293 |
| | TIOGA | 1,188 | 1,188 | 11 | 0 | 74 | 204 | 134 | 113 | 203 | 33 | 216 | 468 |
| | TOMPKINS | 8,038 | 1,967 | 12 | 1 | 89 | 272 | 189 | 108 | 247 | 46 | 371 | 978 |
| | WARREN | 4,226 | 1,272 | 13 | 0 | 116 | 270 | 272 | 130 | 117 | 56 | 133 | 547 |
| | WASHINGTON | 5,248 | 1,336 | 15 | 0 | 119 | 254 | 247 | 123 | 162 | 71 | 177 | 553 |
| WEST | | 159,875 | 46,349 | 980 | 190 | 4,149 | 9,498 | 8,264 | 4,063 | 4,088 | 2,732 | 4,960 | 21,170 |
| | ALLEGANY | 5,308 | 1,165 | 21 | 0 | 108 | 192 | 224 | 176 | 132 | 56 | 157 | 434 |
| | CATTARAUGUS | 4,748 | 1,584 | 25 | 0 | 153 | 355 | 356 | 252 | 122 | 88 | 118 | 649 |
| | CHAUTAUQUA | 8,868 | 2,646 | 50 | 1 | 247 | 518 | 441 | 291 | 224 | 193 | 264 | 1,187 |
| | CHEMUNG | 9,001 | 2,339 | 21 | 1 | 160 | 422 | 335 | 305 | 301 | 58 | 275 | 1,154 |
| | ERIE | 44,405 | 12,873 | 332 | 78 | 1,475 | 3,069 | 2,747 | 1,190 | 1,131 | 887 | 1,213 | 4,944 |
| | GENESEE | 3,508 | 928 | 19 | 2 | 74 | 140 | 131 | 66 | 103 | 49 | 143 | 424 |
| | LIVINGSTON | 2,306 | 817 | 12 | 0 | 90 | 181 | 139 | 47 | 64 | 86 | 78 | 388 |
| | MONROE | 42,905 | 12,602 | 344 | 91 | 876 | 2,387 | 1,780 | 621 | 955 | 666 | 1,267 | 7,047 |
| | NIAGARA | 8,132 | 3,084 | 59 | 9 | 321 | 620 | 728 | 333 | 198 | 208 | 185 | 1,488 |
| | ONTARIO | 3,711 | 1,219 | 20 | 1 | 105 | 251 | 234 | 118 | 65 | 76 | 99 | 632 |
| | ORLEANS | 2,941 | 770 | 17 | 1 | 52 | 168 | 145 | 57 | 85 | 41 | 110 | 322 |
| | SCHUYLER | 2,388 | 614 | 2 | 0 | 39 | 89 | 68 | 59 | 67 | 12 | 145 | 245 |
| | SENECA | 1,800 | 580 | 5 | 0 | 46 | 101 | 117 | 57 | 50 | 43 | 80 | 270 |
| | STEUBEN | 11,407 | 2,609 | 31 | 2 | 224 | 508 | 379 | 275 | 434 | 147 | 464 | 813 |
| | WAYNE | 3,534 | 1,201 | 16 | 4 | 77 | 254 | 240 | 88 | 49 | 74 | 115 | 601 |
| | WYOMING | 3,482 | 837 | 3 | 0 | 64 | 145 | 117 | 75 | 77 | 24 | 184 | 358 |
| | YATES | 1,431 | 481 | 3 | 0 | 38 | 98 | 83 | 53 | 31 | 24 | 63 | 214 |

NOTES:

Column 3 -- Unique Medicaid population count of enrollees eligible for 6 months or more in CY 2003, excluding all managed care enrollees, Institutional patients and hospice patients

Column 4 -- Unique Medicaid population count of enrollees with at least one of the 8 disease groups listed (to the right), excluding all managed care enrollees and institutional patients

Columns 5-14 -- These column counts are not mutually exclusive (ex: a Medicaid enrollee with ESRD may also have CHF etc...)

(13) The disease screening algorithm uses zip code ranges to obtain counts in NYC boroughs (see columns 4-12). Since some zip code entries may be invalid, the category "NYC unknown" consists of a count of Medicaid enrollee with a county code of '66' (NYC) but with an invalid zip code (unable to be placed in a borough).

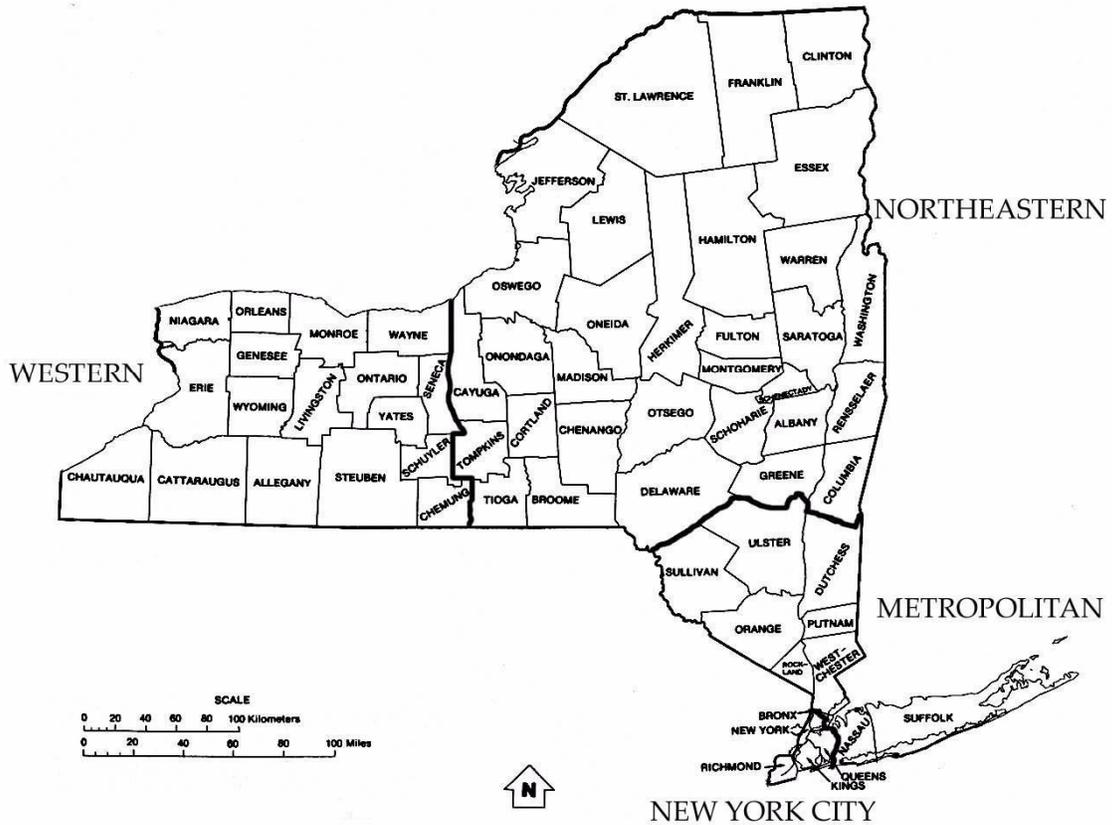
(14) Exclusions are defined as follows: managed care: HMO, managed LT care, and Family Health Plus enrollment; institutional patients: OMH inpatient, OMRDD inpatient/developmental centers and hospice patients.

* **CMDs that plan to enroll dual eligibles will not be able to do so until after July 1, 2006**

DATA SOURCE: DOH/OMM AFPP DataMart (claims/enrollment updated through August 2004 for disease specific counts in columns 4-12, and Sept.2004 for total Medicaid enrollee counts in column 3 (revised 3/1/2005).

ATTACHMENT 3

NYS DOH Region Map



ATTACHMENT 4

Process and Data Flow for Selection of Intervention Enrollees

Narrative and Flow Chart

PROCESS AND DATA FLOW FOR SELECTION OF INTERVENTION ENROLLEES

STAGE 1. POPULATION DEFINITIONS ESTABLISHED:

- A.** Contractor submits to the DOH for approval the following:
 - 1. The selection criteria for the prospective intervention enrollees.
 - 2. The disease severity indicators to be applied
 - 3. The specific definition of “intervention enrollee” who is actively managed by the contractor. This definition will be used as the basis of payment.
- B.** DOH reviews and approves the selection criteria, and applies the criteria to Medicaid data.

STAGE 2. CONTRACTOR ASSIGNS DISEASE SEVERITY INDICATOR (DSI)

- A.** DOH sends the contractor the Medicaid health care information for the prospective enrollment group.
- B.** Contractor applies the approved criteria, assigns a DSI to each recipient record in the prospective CM enrollee population and returns the list to DOH.

STAGE 3. DOH ESTABLISHES EVALUATION MODEL

- A.** DOH conducts weighted, stratified random selection process to establish a control group from the prospective CM enrollee population.
- B.** DOH returns to Contractor the remainder of the prospective CM enrollee population for enrollment into CM intervention program.
- C.** To meet Medicaid confidentiality regulations, Contractor returns to DOH all Medicaid health care information for control group population.

STAGE 4. CONTRACTOR BEGINS / MANAGES CM INTERVENTION PROGRAM

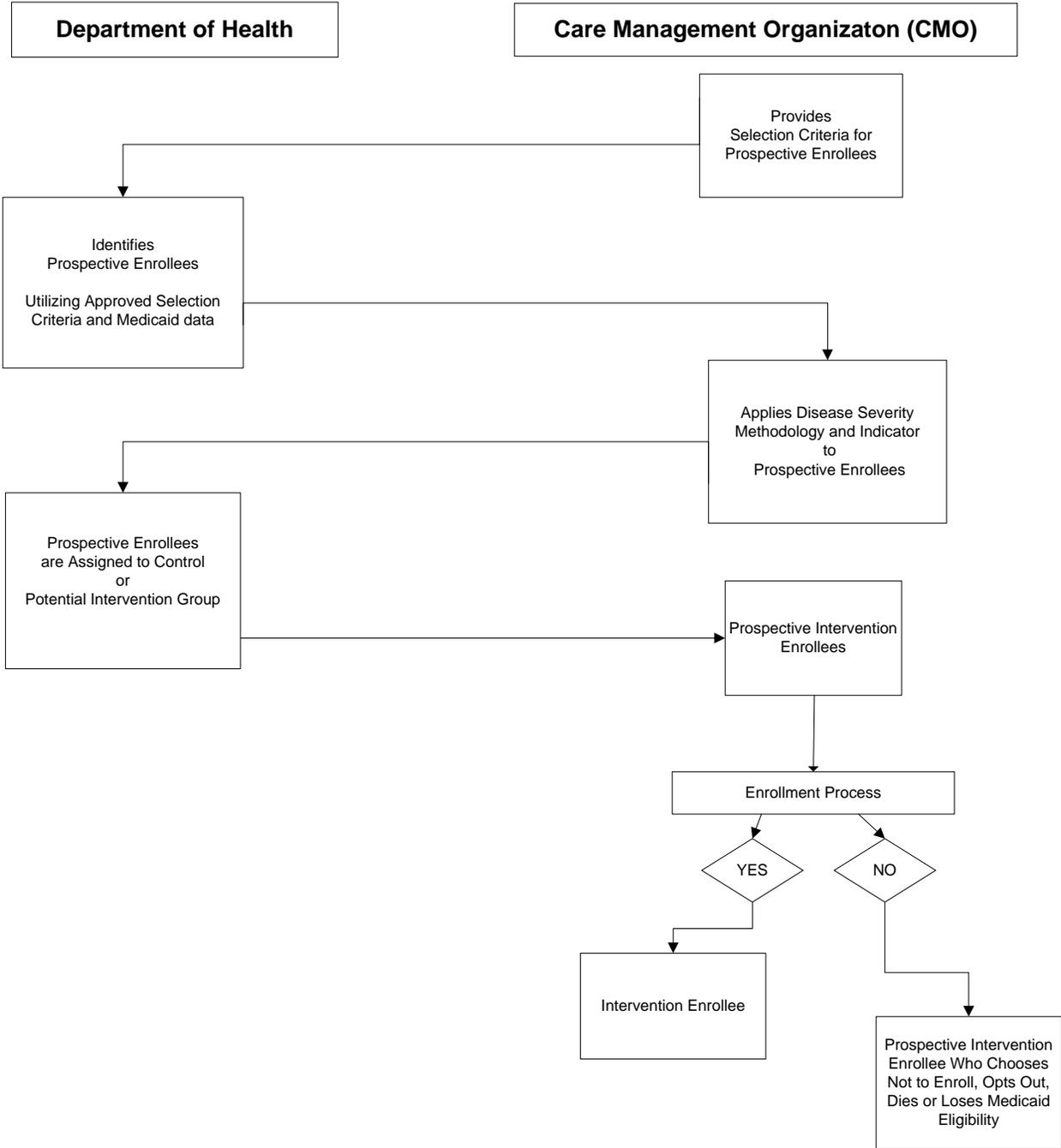
- A.** Contractor initiates enrollment activities, maintaining records of enrollment status of all prospective enrollees. Contractor meets all reporting requirements to DOH as specified in the RFP.
- B.** DOH will calculate payments based on monthly rosters of intervention enrollees submitted by Contractor, who are simultaneously enrolled in Medicaid and meet the approved criteria.

- C.** DOH observes CM intervention program, prepares periodic Medicaid health care information refreshes for active CM intervention enrollees, maintains a replacement pool of prospects, and tracks and resolves Medicaid eligibility of active CM intervention enrollees to ensure appropriate payment.
- D.** Based on a predetermined schedule, Contractor requests the replacement for the CM intervention enrollee population (if necessary).

STAGE 5. DOH CONDUCTS EVALUATION

- A.** Contractor concludes CM intervention program and prepares final reports (and any additional ad-hoc requests) for DOH.
- B.** DOH conducts final reconciliation for final payments to Contractor.
- C.** DOH begins CM evaluation, as specified in the RFP, documents conclusions in a report, and sends copies of the report to the Governor and NYS Legislature.

Overview of Intervention Enrollee Selection and Assignment Process



ATTACHMENT 5

Medicaid Disease and Care Management Demonstration Evaluation

MEDICAID DISEASE AND CARE MANAGEMENT DEMONSTRATION EVALUATION

1. Four Key Areas of Evaluation

DOH will perform the evaluation of each CMD with metrics in the following four areas:

- a. Cost of the program relative to change in cost of CM enrollees;
- b. Changes in health care utilization patterns of CM enrollees;
- c. Health-related outcomes relating to behavior modification, capacity for self-management, and improved relationships with providers (especially Primary Care Providers) of CM enrollees receiving direct communication and/or interventions;
- d. Delivery of intervention services provided by the contractor to CM enrollees and/or providers.

2. Statistical and Methodological Controls

DOH will institute the appropriate statistical and methodological controls in the evaluation design.

3. Comparison Analysis Utilizing an Intervention and Control Group

DOH will structure each CMD as a pre-post evaluation with a control group. DOH will select metrics to analyze cost and health care utilization and will assess health-related outcomes against evidenced-based clinical guidelines.

The following comparisons will be made between the intervention and control groups for each demonstration:

- a. Pre- to post-intervention group
- b. Pre- to post-control group
- c. Post-intervention group to post-control group

4. Disease Severity

Each comparison between intervention and control group in each CMD will be made according to disease severity. The composition of severity between intervention and control groups will mirror the composition of severity in the full Medicaid population. Therefore, analytical results may be generalized to the Medicaid population.

5. Process Analysis of Intervention Services

DOH will conduct a process analysis to assess the number, type, timing, and outcomes of intervention services provided by the contractor to CM enrollees. The Quarterly Report on CMD Intervention Progress will be the chief source for the process analysis.

6. Final Report and Recommendations

DOH will take the final step of reporting analytical results and recommendations for a possible statewide CM effort in a written report to the Governor and the New York State Legislature. DOH will reserve the right to perform all evaluations and to prepare written reports via state resources or through a third party evaluation contractor.

ATTACHMENT 6

Clinical Performance Measures

CLINICAL PERFORMANCE MEASURES

The contractor will structure and conduct care management interventions and services utilizing evidence-based clinical performance measures. The bidder's proposal must include the clinical performance measures that the demonstration activities and interventions will be based on. Throughout the course of the demonstration the contractor will be responsible to meet and improve health outcomes based on the selected clinical performance measures.

During contract negotiations, the contractor will provide expert clinical review of the clinical performance measures and collaborate with the Department to accept, modify, expand and/or change the defined measures. The CMD contract will only include clinical performance measures which are approved by the DOH. The contractor will be required to report on clinical performance measure outcomes annually and at the conclusion of the program, as described in PART II B.2.c.9.c).i.

The following Clinical Performance Measures are included for your review and reference.

CLINICAL PERFORMANCE MEASURES

| Variable to be Measured | Level to be Achieved |
|--|---|
| <i>Congestive Heart Failure (CHF)</i> | |
| ACE inhibitors/angiotensin receptor blocker (ARB) or hybralabine/isosorbide | Either >65% or increase of 10% from previous year. |
| Self Weight Monitoring | Either >65% or increase of 10% from previous year. |
| Salt Intake | >50% of participants have evidenced of dietary education to reduce sodium intake. |
| Flu Shot | Either >65% or increase of 10% vaccination rate from previous year. |
| ER Usage (all except trauma) | 25% or more reduction of ER visits from previous year. |
| Hospital Admissions | 10% reduction or more of hospital admissions from previous year. |
| <i>Coronary Artery Disease (CAD)</i> | |
| Beta-Blocker Usage post-MI | Either >65% or increase of 10% from previous year. |
| Statin Therapy Usage | Either >65% or increase of 10% from previous year. |
| 1. LDL-Cholesterol Testing Rate | 1. Annual increase of 5% or more from the baseline LDL testing rate. |
| 2. LDL – Cholesterol Levels | 2. Either average <100 or 10 mg/dl improvement from previous year. |
| Antiplatelet Therapy | Either >50% or increase of 5% from previous year. |
| Flu Shot | Either >65% or increase of 10% vaccination |

| <u>Variable to be Measured</u> | <u>Level to be Achieved</u> |
|---|--|
| | rate from previous year. |
| Admission for Myocardial Infarction | Decrease of 4 % or more for myocardial infarction from the previous year. |
| ER Usage (all except trauma) | 25% reduction or more of ER visits from previous year. |
| Hospital Admissions | 10% reduction or more of hospital admissions from previous year. |
| Diabetes | |
| 1. Rate of HbA1c – Testing | 1. Either >65% or increase of 10% from previous year. |
| 2. HbA1c level | 2. Annual improvements from the previous year or average of 8 or less. |
| Retinal Exams | Either >50% or increases of 10% from previous year. |
| ACE inhibitors/angiotensin receptor blocker (ARB) | Either >65 % or increase of 10% from previous year of diabetic members with microalbuminuria or clinical albuminuria (per American Diabetes Association (ADA) guidelines taking ACE inhibitors or ARB. |
| Microalbumin | Either >65% or increase of 10 % of members with diabetes who had one screening test in measurement year or receiving treatment for existing nephropathy. |
| Fasting Lipid panel | Either >65% or increase of 10% from previous year. |
| Flu Shot | Either >65% or increase of 10% vaccination rate from previous year. |
| ER Usage (all except trauma) | 25% reduction or more of ER visits from previous year. |
| Hospital Admissions | 10% reduction or more of hospital admissions from previous year. |
| Asthma | |
| <i>Explicit Assessment of Asthma for Level of Severity Using National Asthma Education Preventive Program (NAEPP) Guidelines</i> | 90% or more of all CMD asthma enrollees have received an explicit assessment of their asthma. |
| Presence/Knowledge of Asthma Action Plan of Care | Either >65% or increase of 10% from previous year. |
| LTC agents prescribed for persistent asthma | Either >85% or increase of 10% from previous year. |
| ER Usage (all except trauma) | 25% reduction or more of ER visits from previous year. |
| Hospital Admissions | 10% reduction or more of hospital admissions from previous year. |
| FLU Vaccine | Either >65% or increase of 10% from previous year. |
| Smoking Cessation Rate | Either >65% or increase of 10% from previous year. |

| Variable to be Measured | Level to be Achieved |
|---|---|
| <i>Chronic Obstructive Pulmonary Disease (COPD)</i> | |
| Classification of COPD by Severity in accordance with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines | 90% or more of all CMD COPD enrollees have received a classification of their disease. |
| Flu Vaccine | Either >80% or an increase of 10% from previous year. |
| Patients with history of hospitalization filling scripts for bronchodilator meds in accordance with GOLD guidelines | Increases 10% a year to standard of >80% from the baseline except for people with this history who are not indicated, do not count (vendor responsibility to point them out). |
| Oxygen Therapy | Either >65% or an increase of 10% from previous year of CMD COPD enrollees who meet the GOLD guideline requirements for long-term oxygen therapy. |
| Smoking Cessation Rate | Either >65% or an increase of 10% from the previous year. |
| ER Usage (all except trauma) | 20% reduction or more of ER visits from previous year. |
| Hospital Admissions | 10% reduction or more of hospital admissions from previous year. |
| <i>Sickle Cell Disease (SCD)</i> | |
| Hospital Admissions | 50% reduction or more of hospital admissions from previous year for SCD enrollees identified as recidivists. |
| ER Usage (all except trauma) | 50% reduction or more of ER visits from previous year for SCD enrollees identified as recidivists. |
| Care Management Plan | 50% or more increase in the number of SCD enrollees identified as recidivists with a negotiated care management plan. |
| Use of Hydroxyurea | 5% or more increase in the number of SCD enrollees identified as recidivists who are using Hydroxyurea to control sickle cell pain crises. |
| Pain Management Regimen | 10% or more increase in the number of SCD enrollees identified as recidivists compliant with a negotiated pain management regimen. |
| Compliance with scheduled visits to sickle cell clinics and/or doctor's office | 25% or more increase in the rate of compliance of SCD enrollees identified as recidivists with scheduled routine clinic and/or doctor's office visits. |
| Compliance with immunization schedule | 5% or more increase in the rate of compliance |

| Variable to be Measured | Level to be Achieved |
|--|--|
| including annual flu shots | of SCD enrollees identified as recidivists with immunization schedule including annual flu shots. |
| End Stage Renal Disease (ESRD) | |
| Target lab values: <ul style="list-style-type: none"> • Albumin- 3.5 or greater (measure nutrition) • URR 65% or greater (measure adequacy of dialysis) • Hematocrit- 30 or greater (measure anemia) • Hemoglobin => 10g/dl (measure anemia) • Calcium X Phosphate- 70 or less (measure bone disease) | 65% or more of CMD ESRD enrollees will achieve these targeted lab values during the measurement year. |
| ER Usage (all except trauma) | 25% or more reduction of ER visits from previous year. |
| Hospital Admissions | 10% reduction or more of hospital admissions from previous year. |
| Chronic Kidney Disease (CKD) | |
| Blood Pressure <130/80 mm Hg | 50% or more of CMD CKD enrollees will have their blood pressure monitored and maintain an optimal goal of <130/80 mm Hg., unless there is a documented contraindication in the medical record. |
| Classification of Chronic Kidney Disease as per the National Kidney Foundation Disease Outcome Quality Initiative (NKF/DOQI) | 65% or more CMD CKD enrollees have received a classification of their CKD (Stages 1-5); with documentation of the glomerular filtration rate [GFR] in the medical record. |
| Presence of a CKD clinical action plan | 65% or more CMD CKD enrollees will have a CKD action plan. |
| Annual influenza vaccine | Either >65% or increase of 10% from previous year. |
| Annual pneumococcal vaccine | Either >65% or increase of 10% from previous year. |
| ER Usage (all except trauma) | 25% or more reduction of ER visits from previous year. |
| Hospital Admissions | 10% reduction or more of hospital admissions from previous year. |

ATTACHMENT 7

Medicaid Disease and Care Management Demonstration (CMD) Program Payment Methodology

**MEDICAID DISEASE AND CARE MANAGEMENT
DEMONSTRATION (CMD) PROGRAM
PAYMENT METHODOLOGY**

DOH will reimburse the contractor for intervention enrollees who are being managed under the CMD. Reimbursement will occur on a monthly basis and will consist of a PMPM fee paid for each month per intervention enrollee.

A. DOH calculates PMPM fee using the following formula:

$(\text{Total Price of CMD} - \text{Implementation Price}) / (\text{Total Approved Number of Intervention Enrollees per month} \times \text{Twenty (20) Months})$

B. Contractor must include in their financial proposal the following financial information used to calculate the PMPM fee:

- 1.** Total Price of CMD Intervention Program
All projected prices of the CMD program for the twenty months of operation, excluding projected implementation prices.
- 2.** Total Number of Intervention Enrollees
The average unduplicated number of intervention enrollees that the contractor's intervention process can sustain per month over the twenty month operational phase of the demonstration.

C. Contractor must submit a definition for an "intervention enrollee" actively managed by the Contractor, which will be used to calculate monthly payments.

- 1.** The definition of "intervention enrollee" will be subject to DOH review and approval.
- 2.** DOH will calculate payments based on the monthly rosters of intervention enrollees submitted by Contractor.
- 3.** DOH will trigger a fee payment for each intervention enrollee upon affirmation of Medicaid eligibility.
- 4.** DOH will conduct several payment reconciliations to account for retroactive adjustments in Medicaid eligibility.
- 5.** DOH may appoint a fiscal agent to remit monthly payments to contractor.

ATTACHMENT 8

Bidder's Response Forms

Technical Forms (TP-1, TP-2, TP-3)

Financial Form

Responsibility Questionnaire

Bidder's Checklist

TP – 1: Summary of Experience and References

Instructions: Corporate & Subcontractors - Complete one (1) copy of this form for each of three (3) previous or current clients.
Local Governments – Complete this form for each relevant experience in providing CMD services.

| | |
|--|---|
| A. Name of Reference Client: _____ | B. Telephone #: ____ - ____ - _____ |
| C. Contact Name: _____ D. Contact Title: _____ | E. e-Mail Address: _____ |
| F. Contact Address: _____ | G. Role – Please check one. Prime Contractor – Corporate _____ Prime Contractor – Government _____ Subcontractor _____ |
| H. Service Dates: ____/____/____ From To | I. Number of Covered Medicaid Lives: _____ |
| <p>1. Describe the previous experience with management and coordination of care to persons with chronic diseases, or providing cost effective care to patients with chronic diseases. Include the program size and type of target population.</p> <p>2. Describe the specific role of the bidder in the design, implementation, operation and maintenance of the program.</p> <p>3. Describe the specific health outcomes and changes in utilization which resulted from operation of the care management program.</p> <p>4. Describe the evaluation of the program and documented cost savings achieved. (Include a copy of all final reports.)</p> <p>5. Describe any experience operating disease and care management services with the Medicaid program.</p> | |

TP- 3: Key Personnel Proposed for CMD

| |
|---|
| <p>Title of Key Personnel Position Proposed:</p> |
| <p>Percentage (%) of Time Dedicated to NYS Medicaid Account: _____</p> |
| <p>Provide a brief description of the position, including duties and responsibilities, as well as reporting relationships:</p> |

| |
|--|
| <p>Name of Candidate Proposed for Position:</p> |
| <p>Relevant Professional Experience and Qualifications:</p> |

Education & Certification:

| From | To | Institution | Degree/Hours |
|------|----|-------------|--------------|
| | | | |

**Provide three (3) references from previous supervisors and employers:
(Include a "Contractor Disclosure of Contacts" form [Attachment 9] for each reference)**

| From | To | Reference | Responsibilities |
|------|----|--|------------------|
| | | (Contact Person Name, Title, Address, E-Mail and Telephone Number) | |
| | | | |
| | | | |
| | | | |

Financial Proposal Form

Bidder Name: _____

Region (choose only one) Western _____ Northeastern _____ Metropolitan _____ NYC _____

Are you proposing a CMD for the entire region? Yes No

If not, list the county name(s):

| | Year 1 (Month Year - Month Year) | Year 2 (Month Year - Month Year) | Total (Month Year - Month Year) |
|-----------------------------------|-------------------------------------|-------------------------------------|------------------------------------|
| Implementation Price ¹ | | | |
| Operation Price ² | | | |
| Total Price | | | |

¹ One time expense, limited to the first four (4) months in Year 1. May not be greater than twenty five percent (25%) of the Total Price in Year 1.

² In Year 1, based on the last eight (8) months on the contract year.

STATE OF NEW YORK
OFFICE OF THE STATE COMPTROLLER - BUREAU OF CONTRACTS
VENDOR RESPONSIBILITY QUESTIONNAIRE

Instructions:

A contracting agency is required to conduct a review of a prospective contractor to provide reasonable assurances that the vendor is responsible. This questionnaire is designed to provide information to assist a contracting agency in assessing a vendor's responsibility prior to entering into a contract with the vendor. Vendor responsibility is determined by a review of each bidder or proposer's authorization to do business in New York, business integrity, financial and organizational capacity, and performance history.

Prospective contractors must answer every question contained in this questionnaire. Each "Yes" response requires additional information. The vendor must attach a written response that adequately details each affirmative response. The completed questionnaire and attached responses will become part of the procurement record.

It is imperative that the person completing the vendor responsibility questionnaire be knowledgeable about the proposing contractor's business and operations as the questionnaire information must be attested to by an owner or officer of the vendor. **Please read the certification requirement at the end of this questionnaire.**

**STATE OF NEW YORK
OFFICE OF THE STATE COMPTROLLER - BUREAU OF CONTRACTS
VENDOR RESPONSIBILITY QUESTIONNAIRE**

FEIN #

| | | | |
|---|-----------------------|---|-----------------------|
| 1. VENDOR IS: <input type="checkbox"/> PRIME CONTRACTOR <input type="checkbox"/> 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: <input type="checkbox"/> Owned <input type="checkbox"/> 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) <input type="checkbox"/> Business Corporation | Date of Incorporation | State of Incorporation* | |
| b) <input type="checkbox"/> Sole Proprietor | Date Established | | |
| c) <input type="checkbox"/> General Partnership | Date Established | | |
| d) <input type="checkbox"/> Not-for-Profit Corporation | Date of Incorporation | State of Incorporation* Charities Registration Number | |
| e) <input type="checkbox"/> Limited Liability Company (LLC) | Date Established | | |
| f) <input type="checkbox"/> Limited Liability Partnership | Date Established | | |
| g) <input type="checkbox"/> 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 |

STATE OF NEW YORK
OFFICE OF THE STATE COMPTROLLER - BUREAU OF CONTRACTS
VENDOR RESPONSIBILITY QUESTIONNAIRE

| | | |
|------------|--|--|
| 21. | <p>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), affiliate¹ or any person involved in the bidding or contracting process:</p> | |
| a) | <ol style="list-style-type: none">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; or9. had a local, state or federal government contract suspended or terminated for cause prior to the completion of the term of the contract? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| b) | <p>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?</p> | <input type="checkbox"/> Yes <input type="checkbox"/> No |

STATE OF NEW YORK
OFFICE OF THE STATE COMPTROLLER - BUREAU OF CONTRACTS
VENDOR RESPONSIBILITY QUESTIONNAIRE

| | |
|---|--|
| <p>c) been issued a citation, notice, violation order, or are pending an administrative hearing or proceeding or determination for violations of:</p> <ol style="list-style-type: none"> 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 laws; 9. state or federal anti-trust laws; or 10. charity or consumer laws? <p><i>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.</i></p> | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <p>22. In the past three (3) years, has the vendor or its affiliates¹ had any claims, judgments, injunctions, liens, fines or penalties secured by any governmental agency?</p> <p><i>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."</i></p> | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <p>23. Has the vendor (for profit and not-for profit corporations) or its affiliates¹, 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?</p> <p><i>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.</i></p> | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <p>24. Is the vendor exempt from income taxes under the Internal Revenue Code?</p> <p><i>Indicate the reason for the exemption and provide a copy of any supporting information.</i></p> | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <p>25. During the past three (3) years, has the vendor failed to:</p> <ol style="list-style-type: none"> a) file returns or pay any applicable federal, state or city taxes? <i>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.</i> b) file returns or pay New York State unemployment insurance? <i>Indicate the years the vendor failed to file/pay the insurance and the current status of the liability.</i> | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No |

STATE OF NEW YORK
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VENDOR RESPONSIBILITY QUESTIONNAIRE

| | | |
|------------|--|--|
| 26. | <p>Have any bankruptcy proceedings been initiated by or against the vendor or its affiliates¹ 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?</p> <p><i>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.</i></p> | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 27. | <p>Is the vendor currently insolvent, or does vendor currently have reason to believe that an involuntary bankruptcy proceeding may be brought against it?</p> <p><i>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.</i></p> | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 28. | <p>Has the vendor been a contractor or subcontractor on any contract with any New York State agency in the past five (5) years?</p> <p><i>List the agency name, address, and contract effective dates. Also provide state contract identification number, if known.</i></p> | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 29. | <p>In the past five (5) years, has the vendor or any affiliates¹:</p> <p>a) defaulted or been terminated on, or had its surety called upon to complete, any contract (public or private) awarded;</p> <p>b) received an overall unsatisfactory performance assessment from any government agency on any contract; or</p> <p>c) had any liens or claims over \$25,000 filed against the firm which remain undischarged or were unsatisfied for more than 90 days ?</p> <p><i>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.</i></p> | <input type="checkbox"/> Yes <input type="checkbox"/> 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 NEW YORK
OFFICE OF THE STATE COMPTROLLER - BUREAU OF CONTRACTS
VENDOR RESPONSIBILITY 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 | Signature of Owner/Officer_____ |
| Address | Printed Name of Signatory |
| City, State, Zip | Title |

Sworn to before me this _____ day of _____, 20____;

Notary Public

Print Name

Signature

Date

**REQUEST FOR PROPOSALS
 MEDICAID DISEASE AND CARE MANAGEMENT DEMONSTRATION PROGRAMS
 BIDDER'S CHECKLIST**

Indicate that the following requirements have been met, and materials included in the response, by checking off each item:

| General Requirements | RFP Page # |
|--|------------------------------------|
| _____ Proposal is being mailed or delivered in two (2) distinct, appropriately labeled and sealed packages, clearly marked as follows: "Medicaid Disease and Care Management Demonstration: Bid Proposal Volume I, Technical Proposal", "Medicaid Disease and Care Management Demonstration: Bid Proposal Volume II, Financial Proposal" | PART III - 4, 7 |
| _____ Volume I does NOT include any proposed price information for this bid. | PART II - 3, 5, 8, PART III - 4 |
| _____ Proposal used required forms in Attachment 8 (Required forms and Bidders Checklist) | PART II - 25 PART III - 4 |
| _____ Proposal is submitted as two (2) originals and ten (10) copies on paper, and one copy on CD ROM in a Microsoft Office or Adobe Acrobat (pdf) format. | PART III - 6 |
| _____ If needed, a letter is included with the Letter of Transmittal (Volume I) identifying trade secrets by page number, line, or other appropriate designation, with explanation why. | PART III - 8 |
| _____ Proposal includes "Contractor Disclosure of Prior Non-Responsibility Determination" Forms for prime contractor and subcontractor(s), as well as "Contractor Disclosure of Contacts" Form for all Contacts, including all Personnel and References. (Attachment 9) | PART II - 2, 5, 6, 7, 20 |

**REQUEST FOR PROPOSALS
 MEDICAID DISEASE AND CARE MANAGEMENT DEMONSTRATION PROGRAMS
 BIDDER'S CHECKLIST**

| Volume I: | RFP Page # |
|--|-------------------|
| _____ Letter of Transmittal | PART II - 3 |
| Qualifications and Experience | |
| _____ Minimum Requirements | PART II - 3, 7 |
| _____ Summary of Corporate Structure and Organization | PART II - 4 |
| _____ Affiliations and Conflicts of Interest | PART II - 4, 8 |
| _____ Corporate Financial Statements | PART II - 4 |
| _____ Corporate Legal Proceedings | PART II - 5 |
| _____ Responsibility Questionnaire-Corporate (Attachment 8) | PART II - 5 |
| _____ Summary of Experience and References (TP-1) | PART II - 5, 7 |
| _____ Experience with State and Federal Legal and Program Requirements | PART II - 6, 8 |
| _____ Subcontractors Information | PART II - 6, 8 |
| Technical Approach Proposed | |
| _____ Management Summary | PART II - 8 |
| _____ Proposed Service Area (Form TP-2) | PART II - 9 |
| _____ Target Population | PART II - 9 |
| _____ Scalability | PART II - 10 |
| _____ Demonstration Operation – includes following: | |
| _____ Intervention Population Selection | PART II - 10 |
| _____ Enrollment of Eligible Recipients and/or Providers | PART II - 11 |
| _____ Enrollee Assessment | PART II - 12 |
| _____ Care Plan Development and Intervention Implementation | PART II - 13 |
| _____ Outreach and Awareness | PART II - 14 |
| _____ Communications | PART II - 14 |
| _____ Quality Assurance | PART II - 15 |

**REQUEST FOR PROPOSALS
 MEDICAID DISEASE AND CARE MANAGEMENT DEMONSTRATION PROGRAMS
 BIDDER'S CHECKLIST**

| | RFP Page # |
|---|-------------------|
| _____ Outcomes Measurement and Clinical Effectiveness | PART II - 15 |
| _____ Reporting Requirements | PART II - 16 |
| _____ Contract Performance Standards | PART II - 18 |
| _____ General Operations – includes following: | |
| _____ Proposed Work plan and Schedule of Deliverables | PART II - 19 |
| _____ Organizational Chart/Reporting Relationships | PART II - 19 |
| _____ Proposed Key Personnel and Staffing (Form TP-3) | PART II - 20 |
| _____ Communication with DOH | PART II - 21 |
| _____ Prime Contractor | PART II - 22 |
| _____ HIPAA Compliance/Confidentiality | PART II - 22 |
| _____ Disaster Recovery | PART II - 22 |
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| _____ Phase Down Plan | PART II - 23 |
| _____ Evaluation of Medicaid Disease and Care Management Demonstration | PART II - 23 |
| Volume II: Financial Proposal | |
| _____ Financial Proposal Form (Attachment 8) | PART II - 24 |

ATTACHMENT 9

Executive Order No. 127 and Applicable Forms

No. 127
EXECUTIVE ORDER

PROVIDING FOR ADDITIONAL STATE PROCUREMENT DISCLOSURE

WHEREAS, the State of New York and its public authorities have an obligation to carry out their responsibilities in the most efficient and effective manner possible;

WHEREAS, over the past eight and one-half years, we have made tremendous progress in streamlining and improving state government;

WHEREAS, the State of New York and its public authorities enter into numerous procurement contracts and real estate transactions which involve substantial sums of public moneys;

WHEREAS, while the State Legislature has enacted strong laws to regulate the procurement process and maintain its integrity (Procurement Stewardship Act, Chapter 83 of the Laws of 1995) and to regulate persons who appear before state government on certain matters (Lobby Law, Chapter 2 of the Laws of 1999), more can be done to maintain continued public confidence in the State's procurement process; and

WHEREAS, increased disclosure regarding persons and organizations contacting state government regarding procurement and real estate transactions would enhance public confidence in the procurement process.

NOW, THEREFORE, I, George E. Pataki, Governor of the State of New York, by virtue of the authority vested in me by the Constitution and Laws of the State of New York, do hereby order as follows:

I. Definitions

1. "Covered agency or authority" shall mean any State department, office or division, or any board, commission or bureau thereof, and any public benefit corporation, public authority or commission at least one of whose members is appointed by the Governor, and shall include the State University of New York and the City University of New York.
2. "Procurement contract" shall mean any contract or agreement, or subsequent amendment thereto, involving an estimated annualized expenditure in excess of fifteen thousand dollars for:
 - (i) the purchase of goods or services;
 - (ii) the purchase, sale, lease, acquisition or granting of other interests in real property; and
 - (iii) public works. The term "procurement contract" shall not include a contract that, by law, must be awarded to the lowest responsible bidder, or a contract that, by law, must be awarded on the basis of lowest price subsequent to a competitive bid process.
3. "Proposal" shall mean any proposal, quotation, bid, offer or response to a covered agency or authority's solicitation of submissions in expectation of an award of a procurement contract.

4. “Attempt to influence the procurement process” shall mean any attempt to influence any determination of a member, officer or employee of a covered agency or authority by a person other than a member, officer or employee of a covered agency or authority with respect to:

(a) the solicitation, evaluation or award of a procurement contract; or

(b) the preparation of specifications or request for submissions of proposals for a procurement contract.

5. “Contractor” shall mean bidder, offeror or proposer for a procurement contract and shall include any subcontractor who may be engaged in the delivery of goods, services or construction pursuant to the procurement contract.

6. “Financial interest in the procurement” shall mean:

(a) owning or exercising direct or indirect control over, or owning a financial interest of more than one percent in, a contractor or other entity that stands to gain or benefit financially from the award of a procurement contract;

(b) receiving, expecting or attempting to receive compensation, fees, remuneration or other financial gain or benefit from a contractor or other individual or entity that stands to benefit financially from a procurement contract;

(c) being compensated by, or being a member of, an entity or organization which is receiving, expecting or attempting to receive compensation, fees, remuneration or other financial gain from a contractor or other individual or entity that stands to benefit financially from a procurement contract;

(d) receiving, expecting or attempting to receive any other financial gain or benefit as a result of the procurement contract;

(e) being a relative of a person with a financial interest in the procurement, as set forth in paragraphs (a) through (d) of this subdivision. For purposes of this paragraph, “relative” shall mean spouse, child, stepchild, stepparent, or any person who is a direct descendant of the grandparents of an individual listed in paragraphs (a) through (d) of this subdivision or of the individual’s spouse.

II. Agency and Authority Responsibilities

1. Every covered agency and authority shall ensure that bid or proposal documents for procurement contracts include the name, address, telephone number, place of principal employment and occupation of every person or organization retained, employed or designated by or on behalf of the contractor to attempt to influence the procurement process and whether such person or organization has a financial interest in the procurement.

2. Every covered agency and authority shall ensure that bid or proposal documents for procurement contracts shall include the name, address, telephone number, place of principal employment and occupation of every person or organization subsequently retained, employed or

designated by or on behalf of the contractor to attempt to influence the procurement process and whether such person or organization has a financial interest in the procurement. Every covered agency and authority shall ensure that contractors shall inform the agency or authority of the identity of any such persons or organizations prior to such person or organization contacting a covered agency or authority.

3. Prior to making an award of a procurement contract, each covered agency or authority shall make a determination of responsibility of the proposed awardee. Every covered agency and authority shall ensure that bid or proposal documents for procurement contracts shall require bidders, offerors or proposers to disclose findings of non-responsibility made within the previous five years by any covered agency or authority where such prior finding of non-responsibility was due to intentional provision of false or incomplete information to a covered agency or authority with respect to this Order. In making a determination of responsibility, covered agencies and authorities shall take into account any such prior finding and shall not award a contract to such bidder, offeror or proposer unless the covered agency or authority finds that the procurement contract would be in the best interests of the State notwithstanding the prior finding of non-responsibility, and such agency or authority shall include in its procurement record a statement describing its basis for such determination.

4. Every covered agency and authority shall ensure that any contacts that reasonably appear to be an attempt to influence the procurement process by persons and organizations other than those identified in bid or proposal documents or supplemental bid or proposal documents shall be recorded by the agency. Upon any such contact, the covered agency or authority shall obtain the same information required in bid or proposal documents pursuant to subdivisions 1 and 2 of this Part and inquire, determine and record whether the person or organization making such contact was retained, employed or designated by or on behalf of the contractor to attempt to influence the procurement process and whether such person or organization has a financial interest in the procurement.

5. Every covered agency and authority shall, for each procurement contract, maintain a written record of all persons and organizations identified in subdivisions 1, 2 and 4 of this Part. Such record shall be open to inspection by the public.

6. The failure of a contractor to timely disclose accurate and complete information or to otherwise cooperate with a covered agency or authority in the implementation of this Order shall be considered by such agency or authority in its determination of the responsibility of such contractor, and no procurement contract shall be awarded to any such contractor unless the procurement record contains a written determination by such agency or authority that the contract award would be in the best interests of the State notwithstanding the failure of the contractor to provide such information or to otherwise cooperate.

7. Every procurement contract made subject to this Order shall contain a certification by the awardee that all information provided to the soliciting agency or authority with respect to this Order is complete, true and accurate and each such procurement contract shall contain a provision authorizing the covered agency or authority to terminate such contract in the event such certification is found to be intentionally false or intentionally incomplete.

III. Remedial Action; Guidance; Applicability

1. Any member, officer or employee of a covered agency or authority who fails to comply with the provisions of this Order shall be subject to appropriate disciplinary action by such agency or authority. In addition, where such conduct violates the Public Officers Law, such matter shall be referred to the State Inspector General and the State Ethics Commission, as may be appropriate.
2. Within 45 days of this Order, the Office of General Services shall issue written guidance to covered agencies and authorities regarding the implementation of this Order. Such guidance shall be deemed to be incorporated in this Order to the extent not inconsistent herewith.
3. The provisions of this Order shall be applicable to procurement contracts with respect to which a solicitation for bids, offers or proposals is made 60 days or more after this Order has taken effect.
4. Nothing in this Order shall be deemed to allow contacts or communications regarding a procurement contract where otherwise prohibited by law, rule, regulation or agency or authority policy.
5. Nothing in this Order shall affect the requirement that members, officers and employees of covered agencies and authorities to report allegations of impropriety involving procurement contracts to appropriate agency personnel, the agency or authority Inspector General, if applicable, and the State Inspector General and the State Ethics Commission, as appropriate.

G I V E N under my hand and the Privy Seal of the State

in the City of Albany this sixteenth day of June in the year two thousand three.

BY THE GOVERNOR /s/ George E. Pataki



Executive Order #127

CONTRACTOR DISCLOSURE OF CONTACTS

This form shall be completed and submitted with your bid/proposal or offer. Failure to complete and submit this form shall result in a determination of non-responsiveness and disqualification of the bid, proposal or offer. If at the time of submission of this form, the specific name of a person authorized to attempt to influence a decision on your behalf is unknown, you agree to provide the specific person's information when it is available. You also agree to update this information during the negotiation or evaluation process of this procurement, and throughout the term of any contract awarded to your company pursuant to this bid/proposal or offer.

Name of Procurement: _____

Name of Contractor: _____

Address: _____

Name of Person Submitting this Form: _____

Title: _____ DATE: _____

Is this an initial filing in accordance with Section II, paragraph 1 of EO 127 or an updated filing in accordance with Section II, paragraph 2 of EO 127?

Initial filing Updated filing

The following person or organization was retained, employed or designated by or on behalf of the Contractor to attempt to influence the procurement process:

Name: _____

Address: _____

Telephone Number: _____

Place of Principal Employment: _____

Occupation: _____

Does the above named person or organization have a financial interest in the procurement?

Yes No

DEFINITIONS:

"Financial Interest in procurement" shall mean:

- (a) owning or exercising direct or indirect control over, or owning a financial interest of more than one percent in, a contractor or other entity that stands to gain or benefit financially from the award of a procurement contract; or
- (b) receiving, expecting or attempting to receive compensation, fees, remuneration or other financial gain or benefit from a contractor or other individual or entity that stands to benefit financially from a procurement contract; or
- (c) being compensated by, or being a member of, an entity or organization which is receiving, expecting or attempting to receive compensation, fees, remuneration or other financial gain from a contractor or other individual or entity that stands to benefit financially from a procurement contract; or
- (d) receiving, expecting or attempting to receive any other financial gain or benefit as a result of the procurement contract; or
- (e) being a relative of a person with a financial interest in the procurement, as set forth in paragraphs (a) through (d) above. For purposes of this paragraph, "relative" shall mean spouse, child, stepchild, stepparent, or any person who is a direct descendant of the grandparents of an individual listed in paragraphs (a) through (d) above or of the individual's spouse.



Executive Order #127

CONTRACTOR DISCLOSURE OF PRIOR NON-RESPONSIBILITY DETERMINATIONS

NAME OF CONTRACTOR: _____

ADDRESS: Street: _____

City: _____ State: _____ Zip: _____

NAME OF PERSON SUBMITTING THIS FORM: _____

TITLE: _____ DATE: _____

Has any covered agency or authority made a finding of non-responsibility regarding the Contractor in the last five years?

YES NO

If Yes, was the basis for the finding of the Contractor's non-responsibility due to the intentional provision of false or incomplete information required by Executive Order Number 127?

YES NO

If Yes, please provide details regarding the finding of non-responsibility below:

COVERED AGENCY OR AUTHORITY: _____

YEAR OF FINDING OF NON-RESPONSIBILITY: _____

BASIS OF FINDING OF NON-RESPONSIBILITY:

Multiple horizontal lines for providing details regarding the finding of non-responsibility.