

**NEW YORK STATE
DEPARTMENT OF HEALTH**

OFFICE OF MANAGED CARE

**CHAPTER II ADMINISTRATIVE RULES
AND REGULATIONS
SUBCHAPTER R**

PART 98

MANAGED CARE ORGANIZATIONS

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(Statutory authority: Public Health Law, section 4403(2), 4403-f (7), 4414)

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**NEW YORK CODES, RULES AND REGULATIONS TITLE 10
CHAPTER II ADMINISTRATIVE RULES AND REGULATIONS
SUBCHAPTER R**

PART 98

MANAGED CARE ORGANIZATIONS

SUBPART 98-1

MANAGED CARE ORGANIZATIONS

(Statutory authority: Public Health Law, Sections 4403 (2), 4403-f(7), 4414)

Section 98-1.1 Applicability. This Part shall be applicable to all persons who propose to establish and/or operate a health maintenance organization (HMO), special purpose health maintenance organization, also known as a prepaid health services plan (PHSP), comprehensive HIV special needs plan (HIV SNP) or, as specified, a primary care partial capitation provider (PCPCP) or managed long term care plan (MLTCP) or who currently operate an HMO, PHSP, HIV SNP or, as specified, a PCPCP or MLTCP certified under article 44 of the Public Health Law within the State of New York, which may hereinafter be referred to individually or collectively as managed care organizations (MCOs).

98-1.2 Definitions. The following words or terms when used in this Part shall have the following meanings:

- (a) *Admitted assets* means assets recognized and accepted by the State Insurance Department under article 13 of the Insurance Law in determining the solvency of insurers. Admitted assets shall be the sole basis for determining compliance with any applicable financial requirement or quantitative limitation imposed upon an MCO, as further specified in Insurance Department Regulation 172 (11 NYCRR 83).
- (b) *Article 44 service area* means the geographic area, defined by counties or other geographic subdivisions, identified in the application for a certificate of authority to operate an MCO for which there is identified a provider network capable of providing comprehensive health services of sufficient availability and accessibility to the projected enrolled population within the meaning of article 44 of the Public Health Law and this Subpart, as approved by the commissioner. Enrollment within the article 44 service area must be offered to any eligible persons who work or reside within the service area, except that for MLTCPs and, for programs authorized by Title XIX, enrollment may be offered only to eligible persons who reside within the service area.

- (c) *Capitation* means a payment made on a per enrollee basis;
 - (d) *Care management* within an MLTCP means a process which assists enrollees with establishing a written care plan and accessing necessary covered services. It also provides referral to and coordination of other medical, social, educational, psychosocial, financial and other services in support of the care plan irrespective of whether such services are covered by the plan.
 - (e) *Commissioner* means the Commissioner of Health of the State of New York.
 - (f) *Community rating* means a rating methodology in which the premium for all persons covered by a policy or contract form is the same based on the experience of the entire pool of risks covered by that policy or contract form without regard to age, sex, health status or occupation. Refunds, rebates, credits or dividends based on such factors are also prohibited.
 - (g) *Comprehensive health services* means:
 - (1) for HMOs and PHSPs, all those health services which an enrolled population might require in order to be maintained in good health, and shall include, but shall not be limited to, physician and other provider services (including consultant and referral services), inpatient and outpatient hospital services, diagnostic laboratory and therapeutic and diagnostic radiologic services, and emergency and preventive health services, including providing HIV counseling and recommending voluntary HIV testing to pregnant women, which counseling and testing shall be conducted pursuant to Public Health Law article 27-F, referring HIV positive persons for necessary, clinically appropriate services, and services required to be covered under article 43 of the Insurance Law;
 - (2) for MLTCPs, health and long term care services, including but not limited to, primary care, acute care, home and community based and institution based long term care and ancillary services that are necessary to meet the needs of persons whom the plan is authorized to serve. However, consistent with the provisions of section 4403-f of the Public Health Law, while an MLTCP may provide less than comprehensive services, it remains subject to the provisions of this Subpart;
 - (3) for PCPCPs, comprehensive primary and preventive care and case management of inpatient, emergency room and specialty services; and
 - (4) for HIV SNPs, all those health and supportive services provided as necessary to meet the specialized needs of the persons whom the plan is authorized to serve by providers with appropriate training and
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experience in the care, treatment and prevention of HIV/AIDS, as determined by the commissioner. These comprehensive services include, but are not limited to, those described in (1) above, those set forth in subdivision (8) of section 4403-c of the Public Health Law and the following: primary care services by a qualified HIV specialist; HIV primary and secondary prevention and risk reduction services; treatment adherence services; HIV SNP case management; and access and referral to community health and social service providers that support members' ability to sustain wellness and adhere to treatment regimes. Such term may also be further defined by agreement with enrolled populations to provide for additional benefits necessary, desirable or appropriate to meet their health care needs.

- (h) *Comprehensive health services plan or plan* means a plan through which each member of an enrolled population is entitled to receive comprehensive health services in consideration for a basic advance or periodic charge.
- (i) *Comprehensive HIV special needs plan or HIV SNP* means an MCO certified pursuant to section 4403-c of article 44 of the Public Health Law which provides or arranges for the provision of comprehensive health and supportive services and specialized HIV care to HIV positive persons and their related children up to the age of 19, as defined in the HIV SNP contract with a local social services district (LDSS) or the commissioner, who are eligible to receive benefits under title XIX or other public programs.
- (j) *Control*, which shall be synonymous with the terms *controlling, controlled by* and *under common control with*, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities or voting rights, by contract (except a commercial contract for goods or nonmanagement services) or otherwise; but no person shall be deemed to control another person solely by reason of his or her being an officer or director of such other person. Control shall be presumed to exist if any person directly or indirectly owns, controls or holds the power to vote 10 percent or more of the voting securities or voting rights of any other person, or is a corporate member of a not-for-profit corporation.
- (k) *Controlled MCO* means any proposed or certified MCO that is controlled directly or indirectly by a holding company.
- (l) *Controlled person* means any person, other than a controlled MCO, that is controlled directly or indirectly by a holding company.
- (m) *Department* means the Department of Health of the State of New York.

- (n) *Enrolled population* means a group of persons which receives comprehensive health services from an MCO in consideration for a basic advance or periodic charge. An enrolled population is composed of enrollees who are entitled by contract to receive comprehensive health services from the MCO. Except for HMOs, MCOs may only enroll certain populations as authorized in the Public Health Law.
- (o) *Enrollee* means an individual who has entered into a contractual relationship with the MCO, or an individual on whose behalf a contractual arrangement has been entered into with the MCO, under which the MCO assumes the responsibility for the provision to the individual of comprehensive health services.
- (p) *Enrollment* means the act of an individual signing a contract, or having someone sign it on his or her behalf, which obligates the MCO to provide comprehensive health services, and which obligates the individual enrolling, or someone on his or her behalf, to pay a periodic premium or fee for all covered services. A signature may be made electronically to the extent permitted by applicable law and regulation.
- (q) *Governing authority of the MCO* means the policymaking body that is responsible for the operation of an MCO, including:
- (1) the policymaking body of a public MCO;
 - (2) the board of directors or trustees of a corporation;
 - (3) partners of a partnership operating an MCO;
 - (4) the owners of a proprietary business operating an MCO; and
 - (5) the members, or managers who are also members of a limited liability company. Managers who are not members of a limited liability company participate in the management of an MCO pursuant to the provisions of Section 98-1.11 of this Subpart governing management contracts, and in no way comprise the governing authority.
- (r) *Health Maintenance Organization* or *HMO* means any person, natural or corporate, or any groups of such persons who enter into an arrangement, agreement or plan, or any combination of arrangements or plans, which proposes to provide or offer, or which does provide or offer, a comprehensive health services plan to individuals and groups.
- (s) *HIV SNP case management* means a process which includes clinical coordination and medical/clinical case management in consultation with the PCP, service utilization monitoring, assessment and service plan development that address identified patient needs, case manager involvement in quality assurance and quality improvement and non-intensive HIV psychosocial case management as defined by the department.

- (t) *HIV specialist primary care provider* or *HIV specialist PCP* means a primary care provider who meets the qualifications for HIV Specialist as defined by the Medical Care Criteria Committee of the Department's AIDS Institute.
- (u) *Holding company* means any person who directly or indirectly controls any proposed or certified MCO.
- (v) *Holding company system* means a holding company together with a controlled MCO and/or controlled persons.
- (w) *Independent practice association* or *IPA* means a corporation, limited liability company, or professional services limited liability company, other than a corporation or limited liability company established pursuant to articles 28, 36, 40, 44 or 47 of the Public Health Law, which contracts directly with providers of medical or medically related services or another IPA in order that it may then contract with one or more MCOs and/or workers' compensation preferred provider organizations to make the services of such providers available to the enrollees of an MCO and/or to injured workers participating in a workers' compensation preferred provider arrangement. An IPA may also be considered a provider within the meaning of section 4403(1)(c) of the Public Health Law, but only for the purpose of and to the extent it shares risk with an MCO and/or the IPA's contracting providers, and shall be considered a provider for the purposes of paragraphs (1) and (2) of subdivision (a) of Section 98-1.21 of this Subpart.
- (x) *Managed care organization* or *MCO* means an HMO, PHSP, HIV SNP and, where specified in this Subpart, PCPCP and MLTCP. An HIV SNP may be an entity that is independently incorporated and certified to operate an HIV SNP or an incorporated and certified MCO that is issued a separate certificate of authority to operate the HIV SNP.
- (y) *Managed long term care plan* or *MLTCP* means an entity that has received a certificate of authority pursuant to section 4403-f of the Public Health Law to provide or arrange for health and long term care services on a capitated basis for a population which the plan is authorized to enroll.
- (z) *Management contractor* means any person, other than staff employed by the MCO, entering into an agreement with the governing authority of an MCO for the purpose of managing the day-to-day operations of the MCO.
- (aa) *Material change to a contract* between an MCO and a provider or an IPA, other than a management contract, means:

- (a) any change to a required contract provision or appendix as per contract guidelines issued by the commissioner;
 - (b) any change to or addition of a risk sharing arrangement, other than the routine trending of fees or other reimbursement amounts;
 - (c) any proposed addition of an exclusivity, most favored nation or non-compete clause;
 - (d) any proposed subcontracting of the existing contractual obligations of an IPA;
 - (e) any proposed subcontracting of the statutory or regulatory responsibilities of an MCO, and;
 - (f) any proposed revocation of an approved delegation as set forth in (d) and (e) above.
- (bb) *Medical director*, other than the medical director of a utilization review agent as defined in Section 4900 of the Public Health Law who shall be licensed by at least one of the United States, means a New York State-licensed physician whose responsibilities include, but are not limited to, the supervision of the quality assurance and improvement and utilization review programs and advising the governing authority on the adoption and enforcement of policies concerning medical services.
- (cc) *Net premium income* means the gross amount of revenue derived from premiums less any returned premium.
- (dd) *Person* means an individual, partnership, corporation, any other legal entity, including a joint venture, or any combination of the foregoing acting in concert.
- (ee) *Premium* means the amount of money the MCO charges each enrollee or payer for the specified benefit package.
- (ff) *Prepaid health services plan* or *PHSP* means a provider, including a not-for-profit corporation established to operate a hospital pursuant to article 28 of the Public Health Law, a government agency or an entity or group of entities, other than a shared health facility, seeking to provide comprehensive health care services which has received a special purpose certificate of authority pursuant to section 4403-a of the Public Health Law to deliver comprehensive health care services on a prepaid contractual basis either directly, or through an arrangement, agreement or plan or combination thereof to an enrolled population which is substantially composed of persons eligible to receive benefits under title XIX or other public programs.
- (gg) *Primary care partial capitation provider* or *PCPCP* means a qualified individual medical services provider or a county or entity comprised of

medical services providers offering comprehensive primary and preventive care and case management of inpatient, emergency room and specialty services to persons eligible to receive benefits under title XIX and to enroll in managed care plans.

- (hh) *Primary care practitioner* or *PCP* means a physician or other licensed provider who supervises, coordinates and provides initial and basic care to enrollees and maintains continuity of care for enrollees.
- (ii) *Referral* means the internal mechanism utilized by the MCO to allow members to access needed services.
- (jj) *Reinsurance* means a transaction whereby the reinsurer, for a consideration, agrees to indemnify the MCO, or other provider, against all or part of the loss which the latter may sustain under the subscriber contracts which it has issued.
- (kk) *Risk-sharing* means the contractual assumption of liability by the health care provider or IPA by means of a capitation arrangement or other mechanism whereby the provider or IPA assumes financial risk from the MCO for the delivery of specified health care services to enrollees of the MCO.
- (ll) *Superintendent* means the Superintendent of Insurance of the State of New York.
- (mm) *Title XIX*, as referenced in this Subpart, means any federally authorized Medicaid program under such title of the Social Security Act and any programs authorized by state law that cover the Medicaid population, specifically, Titles 11 and 11-D of Article 5 of the Social Services Law.
- (nn) *Title XXI*, as referenced in this Subpart, means any federally authorized Child Health Insurance Program under such title of the Social Security Act and any programs authorized by state law that cover the state's Child Health Plus population, specifically, Title I-A of Article 25 of the Public Health Law.
- (oo) *Transitional period* shall for the purposes of subparagraph (i) of paragraph (e)(1) of subdivision (6) of section 4403 of the Public Health Law mean a period commencing on the date a provider's contractual obligation to provide services to an MCO's enrollees terminates and ending no more than 90 days thereafter.

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98-1.4 Certificate of incorporation or articles of organization.

- (a) No person shall file a certificate of incorporation or articles of organization, or amendment thereto, containing powers related to the operation of an MCO or an IPA with the Secretary of State, without first having submitted the proposed certificate, articles or amendment to the commissioner for his or her review and approval and received all approvals required by law.
- (b) The proposed purpose and powers of an MCO shall include the following:
 - (1) to perform studies, feasibility surveys and planning with respect to the development and formation of an MCO; and in conjunction, to accumulate, compile and analyze statistics and such other data that will promote the health, safety and welfare of the general public; and
 - (2) upon obtaining a certificate of authority from the commissioner, to own, operate and manage a health maintenance organization or, as appropriate, a PHSP, or comprehensive HIV special needs plan, or managed long term care plan or primary care partial capitation provider, including providing or arranging for the provision of comprehensive health services, to an enrolled population, and to have and exercise all powers necessary and convenient to effect any or all of the foregoing purposes for which the entity is formed, together with all the powers now or hereafter granted to it by the State of New York.

98-1.5 Application for a certificate of authority.

- (a) No person shall establish or operate an MCO or otherwise hold itself out as an MCO in this State unless it has complied with article 44 of the Public Health Law and this Subpart. However, an applicant may file a certificate of incorporation, articles of organization or amendment thereto, in accordance with section 98-1.4 of this Subpart, without violating this subdivision. Except for operating or approved MLTC demonstrations, no person shall initiate enrollment of individuals or deliver prepaid comprehensive health services until it has received a certificate of authority from the commissioner. A foreign corporation or limited liability company shall not be a proper applicant for a certificate of authority. A corporation licensed under the provisions of article 43 of the Insurance Law, which is also certified pursuant to article 44 of the Public Health Law as an HMO to offer a comprehensive health benefit package, shall designate its health maintenance organization as a separate line of business. In the case of such a separate line of business, separate accounting records shall be maintained and separate HMO reporting forms shall be filed with the superintendent and commissioner.

- (b) In order to obtain a certificate of authority to operate an MCO, a person shall file an application on forms prescribed by the commissioner. The application shall be signed by the chief executive officer duly authorized by the board of a corporate applicant, a general partner or owner of a proprietary applicant, or the president, the chairman of the board or chief executive officer of a public applicant, or an authorized representative of the applicant. An original and seven copies of the application shall be filed and shall set forth or be accompanied by the following, except that in the case of a PCPCP, the application shall include the information as specified herein and the information prescribed by section 4403-e of the Public Health Law:
- (1) copies of the basic organizational documents of the applicant, e.g., the certificate of incorporation, bylaws, articles of organization, partnership agreement, trust agreement, operating agreement or other applicable documents and agreements, and all amendments thereto;
 - (2)
 - (i) a list of the names, addresses and official positions of the members of the board of directors, members or managers of a limited liability company, officers, controlling persons, owners or partners and medical director of the proposed MCO, and if the applicant will be a controlled MCO, the same information for the holding company;
 - (ii) the applicant shall provide written acknowledgement that, once certified, the MCO will provide written notice to DOH immediately upon (A) the departure, resignation or termination of any officer, member of the board, member or manager of a limited liability company or the medical director, together with the identity of the individual; and (B) the hiring of an individual to replace an individual concerning whom notice is required under (A), together with the identity of the individual hired.
 - (3) copies of the same financial and personal disclosure information required by the department for the members of the board, officers, controlling persons, owners, partners and medical director of the proposed MCO as set forth in subparagraphs (ii) and (iii) herein.
 - (i) The applicant shall be responsible for obtaining from the appropriate licensing authorities the information necessary for the determination by the commissioner of character, competence and performance when information adequate to make such determination is not available to the commissioner in the records of the department.
 - (ii) Disclosure information shall include, but not be limited to: a list of health care entities owned or operated by the applicant, its
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holding company or other persons in the holding company system or with which an officer, member of the board, member or manager of a limited liability company, controlling person, owner, partner or medical director has been affiliated; the address of each such entity; the dates of ownership or operation of each such entity; and documentation from the appropriate licensing and regulatory authorities indicating that those health care entities are in substantial compliance with applicable laws and regulations.

- (iii) In the event that any such health care entity specified in subparagraph (ii) of this paragraph, while under the control or operation of the applicant, its holding company or other persons in the holding company system, or with which an officer, member of the board, member or manager of a limited liability company, controlling person, owner, partner or medical director has been affiliated, has been subjected to financial penalties or suspension or revocation of its operating certificate or license because of failure to comply with provisions governing the conduct and operation of the facility, then information must be provided that describes the nature of the violation, the agency or body enforcing the violation (including its name and address), the steps taken by the facility to remedy the violation, and an indication of whether the suspension, revocation or accreditation has since been restored;
- (4) except for PCPCPs, statements of the current financial condition of the applicant and any holding company, including
- (i) a balance sheet and a detailed financial plan covering not less than three years' projected operation of the MCO demonstrating the basis upon which the plan will become self-supporting and repay indebtedness and specifying the methods and arrangements for assurance and protection of the MCO's solvency, including complying with required reserves and deposits,
 - (ii) any insurance policies and
 - (iii) a plan for enrollee protection and payment of incurred costs of services in the event of insolvency. For purposes of demonstrating compliance with required reserves and deposits prior to commencing operations, the MCO must determine such reserve and deposit based on subdivisions (e) and (f) of Section 98-1.11 of this Subpart using projected net premium income and estimated expenditures for the first calendar year as indicated in the detailed financial plan described in (i) above;

- (5) if the applicant intends to contract with a management contractor to manage the proposed MCO, information specified in subdivisions (i) through (r) of section 98-1.11 of this Subpart shall be required as part of the application;
- (6) a copy of any proposed contract or form of contract, and all attachments thereto, to be made between or among hospitals and any other type of providers of covered services and the proposed MCO.
 - (i) Such contract should specify any risk-sharing arrangements between the proposed MCO and the provider.
 - (ii) Such contract shall include express provisions indicating that the provider shall hold MCO enrollees harmless from liability, and shall not bill enrollees under any circumstances for the costs of covered services rendered by the contracting provider, except that nothing herein shall prevent collection of applicable co-payments or co-insurance or permitted deductibles.
 - (iii) Such contract shall include provisions allowing access by the MCO and participating IPAs, as necessary, to the medical records of all health care providers serving the MCO's enrollees provided the consent of the enrollee is first obtained either at the time of initial enrollment or initial visit with a participating provider.
 - (iv) Such contract shall include provisions which require prior approval by the commissioner of any material changes in contracts between the MCO and health services providers. Proposed material changes shall be submitted to the commissioner in advance of their implementation in accordance with guidelines issued by the commissioner as per subparagraph (v) of this subdivision.
 - (v) The commissioner may issue guidelines, in consultation with regulated parties, with respect to the process for contract review and required contract provisions, and to effectuate the provisions of this Subpart.
 - (vi) Prior to approval of the certificate of authority, a photocopy of each of the executed contracts with hospitals, a photocopy of one executed contract with each type of provider for approval as to form and content, and a sworn list in affidavit form of all providers with whom contracts have been executed must be submitted by the proposed MCO.
 - (vii) An MCO shall not enter into a contract with a not-for-profit or business corporation, limited liability company or professional services limited liability company or professional services limited liability company which proposes to provide the services of an IPA unless:

- (a) the certificate of incorporation or articles of organization of the IPA, which shall include "Independent Practice Association" or "IPA" within the IPA name, contains powers and purposes permitting the arranging by contract for the delivery or provision of health services by individuals, entities and facilities licensed or certified to practice medicine and other health professions, and, as appropriate, ancillary medical services and equipment, by which arrangements such health care providers and suppliers will provide their services in accordance with and for such compensation as may be established by a contract between the IPA and one or more MCOs which have been granted a certificate of authority pursuant to the provisions of article 44 of the Public Health Law of the State of New York, as amended;
- (b) the IPA certificate of incorporation or articles of organization contain(s) the following provision: notwithstanding any other provision herein to the contrary, nothing contained herein shall authorize the corporation, limited liability company or professional services limited liability company to establish, operate, construct, lease or maintain a hospital or to provide hospital services or health-related services or to operate a certified home health agency, a hospice, or an MCO, or to provide a comprehensive health services plan as defined and covered by articles 28, 36, 40, and 44, respectively, of the Public Health Law, or to solicit, collect or otherwise raise or obtain any funds, contributions or grants from any source for the establishment or operation of any hospital or to establish, operate, construct, lease or maintain an adult care facility as provided by article 7 of the Social Services Law, or to solicit, collect or otherwise raise or obtain any funds, contributions or grants from any source for any such purposes; and
- (c) any general powers and purposes contained in the certificate of incorporation or articles of organization, as authorized by section 202 of either the Business Corporation Law, or the Not for-Profit Corporation Law or the Limited Liability Company Law, are by express provision in the certificate of incorporation or articles of organization to be exercised only as powers and purposes incidental to accomplishing the primary IPA powers and purposes of the corporation or limited liability company; and

- (d) the IPA's certificate of incorporation or articles of organization has been reviewed by the Education and Insurance Departments and the commissioner, have been filed with the Secretary of State and, when presented for filing, had annexed thereto the waiver, approval or consent of the Education and Insurance Departments and the commissioner.
- (e) An IPA may, as incidental to its primary IPA powers and purposes:
 - (1) share risk for the provision of medical services with authorized MCOs and subcontract or otherwise compensate providers and IPAs with which it has contracted, provided, however, that with respect to each proposed risk sharing contract, the IPA has demonstrated to the commissioner and/or, when applicable, the superintendent, that it is financially responsible and capable of assuming such risk and has satisfactory insurance, stop-loss, reserves or other arrangements so that it may be expected to satisfy its obligations to MCOs, providers and enrollees;
 - (2) enter into management contracts with MCOs to perform management functions permitted to be delegated by this Subpart or guidelines issued by the commissioner from time to time, subject to the prior written approval of any such contract by the commissioner pursuant to section 98-1.11 of this Subpart, provided, however, that the standards applied by the IPA in performing such delegated functions shall be approved in writing by the delegating MCO as being substantially similar to those applied by the MCO directly and/or pursuant to delegation to the MCO's enrollee population as a whole. IPAs performing management functions pursuant to management contracts with MCOs, as authorized by this paragraph, shall comply with all statutory and regulatory requirements, including registration as a utilization review agent, and timeframes applicable to the responsibilities delegated and activities being managed;
 - (3) contract with other individuals and entities to obtain technical and administrative services, provided, however, that an IPA may not through contract or any other arrangement, delegate to any person

authority to exercise the governing authority and responsibilities of the IPA, nor may it delegate, through assignment or otherwise, any IPA authority or responsibility acquired pursuant to a management agreement with an MCO in accordance with this Subpart to any person unless the parties have received the prior approvals of the commissioner and the delegating MCO as required by statute or this Subpart;

- (4) contract with other IPAs in order that providers under contract with such other IPA may be made available to the MCOs and/or workers' compensation preferred provider organizations for which the contracting IPA arranges for the delivery of services; and
 - (5) have access to enrollee medical records to the extent necessary to perform management functions pursuant to a management contract with an MCO in accordance with this Subpart and pursuant to article 44 of the Public Health Law and guidelines issued by the commissioner, subject to applicable state and federal requirements concerning the confidentiality of records, including those involving HIV and alcohol and substance abuse services.
- (7) a copy of any proposed contract to be made with a licensed insurer or accredited reinsurer for the purpose of insuring or reinsuring for individual catastrophic costs or out-of-area emergency care, if applicable. Prior to approval of the certificate of authority, photocopies of the executed contracts must be submitted to the commissioner and superintendent;
 - (8) draft copies of individual enrollee contracts and group contracts that are to be entered into with employers, unions, trustees or other organizations, if applicable. Prior to approval of the certificate of authority, the final contracts must be submitted to the commissioner and superintendent;
 - (9) identification of the type of MCO that is proposed and a description of the service delivery system of the proposed MCO including the location of primary care providers and, if applicable, providers of other services such as ambulatory, ancillary and hospital services;
 - (10) a description of the staff for the proposed MCO, including the functional titles of staff. The number and type of staff that will be hired should relate to projections of utilization. Except for PCPCPs, the applicant should discuss the basis on which providers and services have been developed to meet the needs of the projected enrolled

- population initially and up to the break-even point of operation. The PCPCP applicant should discuss the basis on which providers have been developed to meet the needs of the projected enrolled population;
- (11) a description of the population to be enrolled, including projections of enrollment on a monthly basis until the break-even point, or for PCPCPs, a description of the population to be enrolled, including projections of enrollment on a monthly basis for the first three years of operation;
 - (12) a description of the proposed service area, including a description of access to services as it relates to existing transportation modes;
 - (13) a description of the benefit package, including a description of copayments, if applicable;
 - (14) a description of the marketing plan, including all draft marketing materials;
 - (15) a detailed description of the enrollee grievance and appeal system and complaint procedures to be utilized;
 - (16) a description of the quality assurance program and the quality assessment and performance improvement plan to be implemented;
 - (17) a description of the data management information system;
 - (18) the applicant's proposed rates of payment for enrollees, including the basis and manner of calculating those rates. Except for the MCO in-network component of a large group point-of-service (POS) product of MCOs, which may be experience rated consistent with the formula used in rating the out-of-network component of the POS product and in accordance with section 43089b) of the Insurance Law, such proposed rates shall be consistent with the principles of community rating. For PCPCPs, such information shall be provided upon request by the commissioner;
 - (19) for HMO applicants, demonstration of a willingness to provide community services that include at least the following: a willingness to enter into a contract with the local social services district to enroll and serve individuals eligible for benefits under title XIX, including the steps and a time frame for entering into such contract; a willingness to provide coverage to Medicare beneficiaries; and demonstration that the HMO offers open enrollment pursuant to Articles 32 and 43 of the Insurance Law, including steps and a time frame for offering such coverage. For the purpose of this section, open enrollment shall mean offering enrollment throughout the year to individuals and groups consisting of two or more eligible members who elect to enroll, subject to such reasonable limitations as an affiliation or waiting period not to exceed two months from the date of the enrollee's application until the commencement of coverage, provided that coverage may not be excluded based upon a preexisting condition for groups of more than fifty; and

- (20) such other and additional information as the commissioner may require to make the determinations required in sections 4403, 4403-a, 4403-c, 4403-e, 4403-f and 4408-a of the Public Health Law. Additional information must be provided within 30 days of the date of a request. The applicant may request from the commissioner an extension beyond the 30-day period, the granting of which may be made by the commissioner upon a finding that an extension is justified by the public interest. Failure to provide such additional information within the time prescribed or as extended by the commissioner shall constitute a withdrawal of the application.
- (c) An application under this section may be amended while the matter is pending before the commissioner. Any amendment to an application must be accompanied by a written explanation of the reason for the amendment.
- (d) Except for PHSPs, HIV SNPs and PCPCPs, upon receipt of the application for a certificate of authority, the commissioner shall transmit copies of such application and accompanying documents to the superintendent for review and comment.
- (e) (1) An MCO or IPA proposing to change its corporate, company or other name, or to use a new assumed name or change an approved assumed name shall submit an executed copy of the required documentation to the commissioner for review and prior written approval. The submission shall include a certification by an MCO or IPA officer, owner or counsel that use of the proposed name or assumed name in New York is not prohibited by law, that it is not already in use and that it is not otherwise unavailable for use.
- (2) The commissioner shall, when reviewing a proposed name, consider whether it is reasonably likely that its use could confuse or mislead the public, MCO enrollees or providers to their detriment and, if he/she determines that it could so confuse or mislead, shall withhold approval.
- (3) An MCO or IPA which proposes to use an approved assumed name in an additional jurisdiction(s), or to discontinue the use of an approved assumed name completely or in a particular jurisdiction(s), shall provide the commissioner with 30 days prior notice of such proposed change(s) together with an executed copy (ies) of the required documentation.
- (4) The commissioner may consult with the superintendent concerning any proposed name or assumed name and make available copies of any documentation submitted pursuant to this subdivision.
- (5) Use of a name or assumed name which has not received the commissioner's prior approval pursuant to this subdivision shall render

the MCO or IPA subject to action or civil penalty pursuant to section 12 of the Public Health Law.

- (f) Nothing contained in article 44 of the Public Health Law or this Subpart shall be construed to diminish the applicability of the requirements or provisions of any other laws pursuant to which an entity is organized.

98-1.6 Issuance of the certificate of authority. Prior to issuance of a certificate of authority to an MCO, the commissioner, and, in the case of an HMO or MLTCP, the superintendent where applicable, must be satisfied that the following conditions have been met:

- (a) The applicant has demonstrated its capability to organize, market, manage, promote and operate the proposed MCO in order to provide comprehensive health services to a proposed enrolled population that is identified in the application, the manner in which the applicant will comply with the requirements of subdivision (g) of section 98-1.11 of this subpart, that the governing authority shall assemble to conduct the business of the MCO at least four times annually, once in each quarter, and that the governing authority shall for each such assembly provide prior notice to and shall include in each such assembly each enrollee or consumer representative and/or enrollee advisory council member elected or appointed to represent the MCO's enrollees.
- (b) Except for PCPCPs, the applicant has demonstrated, to the satisfaction of the commissioner and, except for entities certified pursuant to sections 4403-a and 4403-c of the Public Health Law, the superintendent, that it is capable of assuming full financial risk for covered services. The applicant may make risk sharing arrangements for the provision of comprehensive health services to the population to be enrolled within the area to be served by the plan as prescribed by regulations and guidelines of the commissioner. When such an arrangement includes risk sharing as defined in this Subpart, such an arrangement shall be approved by the superintendent pursuant to the requirements of 11 NYCRR Part 101 (Regulation 164), where applicable, or the commissioner pursuant to regulations and guidelines. In making a determination of financial soundness, the commissioner and the superintendent shall consider financial information, contracts and agreements required as part of the application for a certificate of authority, and any other materials that the commissioner or the superintendent shall deem necessary to make that determination.
- (c) The applicant has demonstrated, to the satisfaction of the commissioner, that it will retain full responsibility for the operation of the MCO and the protection of its enrollees in compliance with article 44 of the Public Health

Law and this Subpart, including protection for enrollees from billing by providers for services covered under the enrollee contract during the operation of the MCO or in the event of insolvency.

- (d) Except for PCPCPs, the applicant has demonstrated, to the satisfaction of the commissioner, that the medical director and the members of the board and officers, controlling persons of a corporation or holding company or the owners, or all the partners of a partnership, or the members and managers of a limited liability company are of such character, experience, competence and standing in the community as to give reasonable assurance of their ability to conduct the affairs of the proposed MCO in the best interest of the MCO and in the public interest, and to provide proper care for the enrollees. In the case of an applicant that is controlled, the commissioner must be satisfied that the holding company has conducted itself in a manner that is consistent with the public interest. In determining the character and competence of applicants and holding companies, the commissioner shall consider criminal convictions, bankruptcy proceedings, and the quality of health-related services provided by any facility or organization owned or operated by the applicant or its holding company or other persons in the holding company system or with which an officer, member of the board, controlling person, member or manager of a limited liability company, owner, partner or medical director has been affiliated. PCPCPs must provide the information prescribed in section 4403-e(2)(b) of the Public Health Law.
- (e) Except for PCPCPs, the applicant demonstrates that there are adequate finances and sources of future revenue to properly establish and operate the proposed MCO. In the case of a PCPCP, the applicant demonstrates financial responsibility pursuant to section 4403-e(3)(e) of the Public Health Law.
- (f) The applicant demonstrates that the arrangements for health care services assure the availability and accessibility of those services to the proposed enrolled population, and are conducive to the appropriate and efficient use of ambulatory care and hospital services, and that utilization review procedures, if applicable, have been developed consistent with article 49 of the Public Health Law and/or, in the case of an entity participating in federally sponsored programs, consistent with federal law and regulation.
- (g) The applicant demonstrates that an effective program has been developed to monitor and assess the quality of care provided by the MCO, together with a performance improvement program, approved prior to issuance of its certificate of authority, consistent with section 98-1.12 of this Subpart, pursuant to which, actual and potential problems will be identified and corrections accomplished promptly. In the case of an entity participating in

federally sponsored programs, quality of care monitoring and quality improvement programs shall be consistent with federal law and regulation.

- (h) The applicant demonstrates that an acceptable mechanism has been developed, consistent with sections 4403(1)(g) and 4408-a of the Public Health Law and/or, in the case of an entity participating in federally sponsored programs, consistent with federal law and regulation, to receive and resolve complaints and grievances initiated by enrollees of the MCO.
- (i) The applicant demonstrates that acceptable contracts between the potential enrollee or anyone on behalf of the enrollee and the MCO have been developed. Such contracts shall be approved by the superintendent pursuant to section 4406 of the Public Health Law. In the case of contracts for services provided pursuant to title XIX, such contracts shall require prior approval by the commissioner and, as required by federal law or regulation, the federal agency with oversight responsibility for programs authorized by such title.
- (j) The applicant demonstrates that the proposed premium rates have been submitted to and approved by the superintendent or, in the case of services provided pursuant to title XIX, the commissioner.
- (k) Except for PCPCPs, the applicant demonstrates that it has established a system which appropriately accounts for costs and a uniform system of reports and audits meeting the requirements of the commissioner and/or the superintendent, as appropriate.
- (l) Demonstration by the HMO applicant of a willingness to provide community services that include at least the following: a willingness to enter into a contract with the local social services district to enroll individuals eligible for benefits under title XIX, including the steps and a time frame for entering into such contract; a willingness to provide coverage to Medicare beneficiaries; and demonstration that the HMO offers open enrollment pursuant to Articles 32 and 43 of the Insurance Law, including steps and a time frame for offering such coverage. For the purpose of this section, open enrollment shall mean offering enrollment throughout the year to individuals and groups consisting of two or more eligible members who elect to enroll, subject to such reasonable limitations as an affiliation or waiting period not to exceed two months from the date of the enrollee's application until the commencement of coverage, provided that coverage may not be excluded based upon a preexisting condition for groups of more than fifty.
- (m) Requirements and conditions for issuance of a certificate of authority for an MLTCP shall be as set forth in section 4403-f of the Public Health Law and subdivisions (a) through (k) of this section.

98-1.7 Limitations of a certificate of authority.

- (a) A certificate of authority pursuant to this Subpart shall be limited to the proposed article 44 service area described in the application upon which the certificate is issued.
- (b) A certified operating MCO which seeks to extend its approved article 44 service area, and has defined a new potential enrolled population therein, shall submit an application, and shall not extend the service area until an amended certificate of authority is issued. An application for extension of the service area shall include:
 - (1) identification of the new service area for which approval is sought, and the projected enrollment on a monthly basis for three years;
 - (2) copies of all proposed contracts with providers of services for the proposed new service area; these contracts shall include the provisions in section 98-1.5(b)(6)(i-v);
 - (3) a list of providers and facilities with whom contracts have been or will be executed, including the location and specialty area of each provider; and
 - (4) except for PCPCPs, such other information, including financial projections, as the commissioner, in consultation with the superintendent, as appropriate, shall deem necessary to determine the ability of the applicant to make services available and accessible to the identified potential enrollment population, and to otherwise approve the service area expansion application.

98-1.8 Continuance of a certificate of authority.

- (a) Continuance of a certificate of authority shall be contingent upon satisfactory performance by the MCO of delivery, continuity, accessibility and quality of the services to which an enrolled member is entitled, compliance of the MCO with the provisions of article 44 of the Public Health Law and this Subpart, the continuing fiscal solvency of the MCO, except for PCPCPs, and compliance with all conditions set forth on the certificate of authority. The commissioner may impose conditions and limitations on a certificate of authority. Failure to comply with such conditions and limitations shall be deemed unsatisfactory performance.
- (b) All new contracts or forms of contracts and material amendments to existing contracts, including all attachments thereto, between the MCO and health services providers, whenever proposed, shall include the provisions in section 98-1.5(b)(6)(i-v) and shall require prior approval and be submitted to the commissioner in advance of their proposed implementation in

accordance with guidelines issued by the commissioner as per section 98-1.5(b)(6)(v).

- (c) Any amendments to any risk-sharing arrangements contained in any contracts between the MCO and providers, with the exception of routine trending of fees or other reimbursement amounts, shall not be entered into without prior approval of the commissioner and, as appropriate, the superintendent.
- (d) Any contemplated amendment to or revision of an approved contract with, or on behalf of, the enrollees of an MCO shall be submitted to the superintendent and approved by the superintendent prior to the execution of an amended or revised contract with, or, as applicable, on behalf of the enrollees of an MCO, except in the case of contracts entered into between an MCO and a social services district or the state on behalf of the enrollees of an MCO for services provided pursuant to title XIX, which shall require prior approval by the commissioner and, as required by federal law, the federal agency with oversight responsibility for such programs.
- (e) Any revisions in rates of payment for enrollees of programs authorized by title XIX must receive the prior approval of the commissioner.

98-1.9 Acquisition or retention of control of MCOs.

- (a) No person shall acquire control of any New York State-certified MCO, whether by purchase of its securities or otherwise, unless it receives the commissioner's prior approval, which shall not be issued until the commissioner has consulted with the superintendent, as appropriate.
- (b) The commissioner may disapprove such acquisition if he or she determines, upon notice and an opportunity to be heard, that such disapproval is reasonably necessary to protect the interests of the people of this State. The following factors shall be considered in making such determination:
 - (1) the financial condition of the acquiring person and the MCO;
 - (2) the character, competence and standing in the community of the acquiring person and, if the acquiring person is a holding company, the performance of the holding company, its owners, directors, members and managers of a limited liability company and any health care facilities operated by that holding company or its controlled persons; and
 - (3) the continuing assurance that the MCO's operations will be in compliance with article 44 of the Public Health Law and this Subpart.

- (c) The commissioner may require the submission of such information as he or she deems necessary to make the determination required in subdivisions (a) and (b) of this section and may require, as a condition of approval of such acquisition or retention of control, that all or any portion of such information be disclosed to the MCO enrollees.
- (d) The commissioner may determine, upon notice and opportunity to be heard, that a person exercises, directly or indirectly, either alone or pursuant to an agreement with one or more other persons, such a controlling influence over the management or policies of a licensed MCO as to make it necessary or appropriate, in the public interest or for the protection of the MCO's enrollees, that the person be deemed to control the MCO. In the event of such a determination, control shall not be exercised pending issuance of an approval pursuant to the provisions of this section.
- (e) The commissioner may determine, upon the filing of a request for a ruling, that any person does not or will not, upon the taking of some proposed action, control another person. Such determination shall be made within 30 days, or such further period as the commissioner may prescribe. The filing of the request in good faith by any person shall relieve the requesting person from any obligation or liability imposed by this section, with respect to the subject of the request, until the commissioner has acted upon the request. The commissioner may prospectively revoke or modify his or her determination, after notice and opportunity to be heard, whenever in his or her judgment revocation or modification is consistent with article 44 of the Public Health Law and this Subpart. When the commissioner finds that control would exist upon implementation of the proposal, or does exist, or upon the revocation of an earlier determination that no control was present, no such control shall be exercised, or existing control shall be relinquished or modified as directed by the commissioner pending issuance of approval pursuant to the provisions of this section.

98-1.10 Transactions within a holding company system affecting controlled MCOs.

- (a) Transactions within a holding company system to which a controlled MCO is a party shall be subject to the following guidelines:
 - (1) the terms of the financial transaction shall be fair and equitable to the MCO at the time of the transaction;
 - (2) charges or fees for services performed shall be reasonable; and
 - (3) expenses incurred and payments received shall be allocated to the MCO on an equitable basis in conformity with customary accounting practices consistently applied.

- (b) The books, accounts and records of each party to all such transactions shall be so maintained as to clearly and accurately disclose the nature and details of the transactions, including such accounting information as is necessary to support the reasonableness of the charges or fees to the respective parties.
- (c) The commissioner's and, except in the case of PHSP, HIV SNP or PCPCP, the superintendent's prior approval shall be required for the following transactions between a controlled MCO and any person in its holding company system: sales, purchases, exchanges, loans, extensions of credit or investments the aggregate of which involves five percent or more of the MCO's admitted assets at last year-end. Thirty days prior notice to the commissioner and, except in the case of a PHSP, HIV SNP or PCPCP, the superintendent, is required before entering into the following transactions between a controlled MCO and any person in its holding company system: a reinsurance agreement or an agreement for rendering services on a regular or systematic basis, other than medical or management services that require prior approval under this Subpart. Such transactions may become effective unless the commissioner or the superintendent has disapproved the transaction within such period.
- (d) The commissioner, in reviewing transactions pursuant to subdivision (c) of this section, shall consider whether they comply with the standards set forth in subdivision (a) of this section, and whether they may adversely affect the interests of enrollees.
- (e) Nothing herein shall prevent a corporation licensed under article 43 of the Insurance Law from exercising its rights and undertaking transactions authorized by such law, provided that no such transaction shall affect or involve the corporation's Public Health Law article 44 business or line of business or resources thereof, without compliance with the provisions of this section.

98-1.11 Operational and financial requirements for MCOs.

- (a) The functions, activities and services undertaken and performed pursuant to the MCO's article 44 certificate of authority shall be clearly distinguished from any other function, activity or service through the maintenance of separate records, reports and accounts for each such MCO function, activity or service. The records, reports and accounts of each MCO shall be maintained separately from those of other persons or MCOs in a holding company system. All records pertaining to the article 44 certified MCO shall be maintained in New York State.
- (b) No funds the aggregate of which involves five percent or more of the MCO's admitted assets at last year-end shall be transferred or loaned from

the MCO article 44 business to any other business, function or contractor of the MCO, or to any subsidiary or member of the MCO's holding company system over the course of a single calendar year, without the prior approval of the commissioner and except in the case of a PHSP, HIV SNP or PCPCP, the superintendent. Repayment of any such approved loans, to the extent required, shall be made in accordance with schedules approved by the superintendent and commissioner.

- (c) No HMO which is organized as a stock corporation shall declare or distribute any dividend on its capital stock, except out of earned surplus, unless upon prior application therefore, the commissioner, with the advice of the superintendent, approves such distribution. No such company shall declare or distribute any dividend to shareholders which, together with all such dividends declared or distributed by it during the prior twelve month period, exceeds the lesser of ten percent of its capital and surplus ("net worth"), as shown by its last statement on file with the commissioner, or 100 percent of adjusted net investment income for such period unless, upon prior application therefore, the commissioner, with the advice of the superintendent, approves a greater dividend payment based upon his/her finding that the insurer will retain sufficient surplus to support its obligations and writings. For the purposes of this section, "adjusted net investment income" means net investment income for the twelve months immediately preceding the declaration or distribution of the current dividend increased by the excess, if any, of net investment income over dividends declared or distributed during the period commencing 36 months prior to the declaration or distribution of the current dividend and ending twelve months prior thereto; "surplus" means the amount of the HMO's admitted assets in excess of its capital and its liabilities; and "surplus" and "net worth" shall include any voluntary reserves, or any part thereof, which are not required by law; "earned surplus" means the portion of the surplus that represents the net earnings, gains or profits, after deduction of all losses, that have not been distributed to the shareholders as dividends, or transferred to stated capital or capital surplus or applied to other purposes permitted by law, but does not include unrealized appreciation of assets.
- (d) Nothing herein shall prevent a corporation licensed under article 43 of the Insurance Law from exercising its rights and undertaking transactions authorized by such law, provided that no such transaction shall affect or involve the corporation's Public Health Law article 44 business or line of business or resources thereof, without compliance with the provisions of this section.
- (e) (1) Except for a PCPCP, a certified operating MCO, or an MCO that is initially commencing operations, shall maintain a reserve, to be designated as the contingent reserve, which must be equal to five

percent of its annual net premium income. The contingent reserve for an HMO, PHSP or HIV SNP shall be equal to and shall not exceed:

- (i) 5 percent of net premium income for the first calendar year subsequent to the effective date of this Subpart;
- (ii) 6.5 percent of net premium income for the second calendar year subsequent;
- (iii) 7.5 percent of net premium income for the third calendar year subsequent;
- (iv) 8.5 percent of net premium income for the fourth calendar year subsequent;
- (v) 9.5 percent of net premium income for the fifth calendar year subsequent;
- (vi) 10.5 percent of net premium income for the sixth calendar year subsequent;
- (vii) 11.5 percent of net premium income for the seventh calendar year subsequent;
- (viii) 12.5 percent of net premium income for calendar years thereafter.

Upon an HMO, PHSP or HIV SNP reaching its maximum contingent reserve of 12.5 percent of its net premium income for a calendar year, it must continue to maintain its contingent reserve at this level thereafter. Such contingent reserve requirement shall be deemed to have been met if the net worth of the HMO, PHSP or HIV SNP, based upon admitted assets, equals or exceeds the applicable contingent reserve requirement for such calendar year.

- (2) except for PCPCPs, any applicant for certification as an MCO must establish a contingent reserve in an amount equal to 5 percent of projected net premium income for its initial calendar year of operations prior to commencing operations. For each subsequent year of operations, except for an MLTCP, it must increase its contingent reserve according to the schedule set forth above.
- (3) except for PCPCPs, if such MCO reinsures part of its risk under any or all of its contracts by means of a reinsurance contract approved by the superintendent, with the advice of the commissioner, as an appropriate substitute for a portion (up to fifty percent) of the required contingent reserve increase, then the required increase to the contingent reserve at the end of any calendar year may be reduced up to the amount of the premium paid by such MCO for such reinsurance during such calendar year.
- (4) such contingent reserve may be additionally offset by up to 50 percent of the required level at the end of each calendar year by means of a

reinsurance agreement approved by the superintendent with the advice of the commissioner.

- (5) except for PCPCPs, such contingent reserve may, after application therefor by the MCO and approval thereof by the superintendent and/or commissioner, as appropriate, be reduced below the amount required to be maintained by this subdivision, provided that no such reduction, except in the event of an epidemic or other catastrophe resulting in extraordinary hospital or medical utilization, shall, in the case of such MCO having a net premium income for the preceding calendar year of
 - (i) less than \$10 million, or
 - (ii) \$10 million or more, reduce the contingent reserve below an amount equal to 75 percent and 50 percent, respectively, of the amount required to be maintained by paragraph (i) of this subdivision. Any reduction so authorized by the superintendent and/or commissioner, as appropriate, shall be restored within a period of not more than three years in accordance with a plan, submitted by the MCO and approved by the superintendent and/or commissioner, as appropriate, which shall provide that such restoration shall be in addition to, and not in lieu of, the increase in the contingent reserve herein required, which increase must be made in every year except the year in which a reduction in the contingent reserve is approved by the superintendent and/or commissioner, as appropriate.
 - (6) In the case of MLTCPs, the superintendent, in consultation with the commissioner, may exclude from the contingent reserve calculation premium income derived from chronically ill individuals who are covered by the title XIX program and are confined to a nursing facility.
 - (f) (1) Except for PCPCPs, each MCO shall establish a deposit in the form of an escrow account for the protection of enrollees (including enrollee health care service claim obligations), in the form of a trust account with a custodian, without preference or priority to any beneficiary entitled to share therein, that shall be either a member of the Federal Reserve System located in New York State or a New York State chartered bank or trust company. The superintendent, with the advice of the commissioner, shall approve the form of the deed of trust and all amendments thereto. The assets deposited in the escrow account shall be valued according to their current fair market value, and shall consist only of cash, certificates of deposit, and investments of the types specified in paragraphs (1) and (2) of Section 1404(a) of the New York
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Insurance Law. The amount deposited in the escrow account shall be adjusted annually by the last day of March of each calendar year and shall be equal to the greater of the following:

- (i) 5 percent of the estimated expenditures for health care services for the calendar year conforming to the year of filing; or
 - (ii) \$100,000.
 - (2) As of the thirtieth day of April of each year, the custodian shall furnish a statement to the commissioner and superintendent, identifying the assets that are held in trust as of the thirty-first day of March of such year, including the estimated fair market value of such assets. To the extent that the deposit required as described above for any calendar year is less than the deposit held in the deed of trust, the State Insurance Department shall approve withdrawal of any excess funds in the escrow account.
 - (3) In the case of an MLTCP, such escrow account may, at the discretion of the superintendent in consultation with the commissioner, be reduced below the amount required to be maintained by this subdivision based on the financial condition of the MLTCP and the provision of less than comprehensive services as defined in this Subpart. In no event will a reduction of greater than 50 percent of the amount required by this subdivision be granted.
 - (4) A reduction granted to an MLTCP pursuant to paragraph (3) of this subdivision will remain in effect as long as the underlying requirements, agreements and safeguards submitted to the superintendent in support of such reduction remain in effect. Proposed changes to any of these items must be submitted to the superintendent by the MLTCP at least 30 days prior to their effective date for a new determination pursuant to paragraph (3) of this subdivision.
- (g) Except in the case of an HMO operated by a corporation licensed under article 43 of the Insurance Law which also operates a Public Health Law article 44 line of business, no less than one third of the members of the governing authority of an MCO shall be composed of residents of New York State.
- (1) Within one year of the MCO becoming operational, no less than 20 percent of the members of the governing authority shall be enrollees of such MCO, except that:
 - (i) in the case of a PHSP or MLTCP, enrollee or consumer representatives may be substituted for enrollees;

- (ii) in the case of a PCPCP, such requirements shall apply only if the PCPCP has a separate body, for example a local social services district, that functions as a governing authority;
 - (iii) an HMO, PHSP, PCPCP or MLTCP may, as an alternative to or in addition to subparagraphs (i) and (ii) above, establish an enrollee advisory council which is representative of the HMO's, PHSP's, PCPCP's or MLTCP's enrollment and which has direct input to the governing authority;
 - (iv) in the case of an MCO that operates an HIV SNP as one of its lines of business or as its sole line of business, the governing authority must include at least one person with HIV infection to serve as a consumer representative.
 - (2) Employees of the MCO, providers of health services or persons having a business relationship with the MCO may not serve as enrollee or consumer representatives.
 - (h) The governing authority of the MCO shall be responsible for establishment and oversight of the MCO's policies, management and overall operation, regardless of the existence of any management contract.
 - (i) The governing authority shall not delegate the following elements of management authority to another person:
 - (1) direct independent authority to hire or terminate the chief executive officer;
 - (2) adoption of budgets and independent control of the books and records;
 - (3) authority over the disposition of assets and the authority to incur on behalf of the MCO liabilities not normally associated with the day to day operation of the MCO;
 - (4) independent adoption and/or enforcement of policies affecting the operation of the MCO and the delivery of health care services;
 - (5) oversight by the MCO of any management functions delegated to a management contractor pursuant to the provisions of this section or section 98-1.18; and
 - (6) pursuant to paragraph (1) of subdivision (b) of section 98-1.21 of this Subpart, primary responsibility for the development and implementation of the MCO's fraud and abuse prevention plan.
 - (j) The elements of management authority described in paragraphs (1) through (8) of this subdivision may be delegated to another person only pursuant to a management contract approved by the commissioner. An MCO shall not enter into any agreement delegating management authority except pursuant to a management contract which complies with the requirements of subdivisions (h) through (s) of this section and section 98-1.18 of this
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Subpart. No management contract shall be approved if the governing authority of the MCO does not retain sufficient authority and control to discharge its responsibility as the governing authority of the MCO, including the authority to discharge the management contractor.

- (1) maintenance of the books and records;
- (2) disposition of assets and the incurring of liabilities normally associated with the day to day operations of the MCO;
- (3) implementation of policies affecting the delivery of health care services;
- (4) claims payment;
- (5) implementation of the MCO's budgets and provision for annual audits;
- (6) quality assurance and improvement, except that when a provider risk sharing arrangement is entered into between the MCO and a management contractor or an entity related to the management contractor, the MCO may delegate either utilization review activity or quality assurance and/or quality improvement functions, but not both, to that management contractor or to an entity related to that management contractor. Assisting in the implementation of the MCO's quality assurance activities and functions is not considered a delegation. If the contractor has decision making authority and responsibility for the implemented functions, it is considered a delegation of quality assurance. For the purposes of this subdivision, an entity related to the management contractor is defined as an entity which is under common ownership and/or control with or has control of or is controlled by the management contractor. An MCO shall not contract with a management contractor to conduct quality assurance and/or quality improvement functions on the MCO's behalf unless the management contractor utilizes the MCO's quality assurance and quality improvement standards or unless the MCO approves the management contractor's quality assurance and quality improvement standards. The MCO shall not approve of the management contractor's standards for quality assurance and quality improvement unless the standards are substantially equivalent to those of the MCO and to those of other management contractors which have contracted with the MCO to conduct quality assurance and improvement, and such standards have been approved by the commissioner;
- (7) any utilization review activity, except that when a provider risk sharing arrangement is entered into between the MCO and a management contractor or an entity related to the management contractor, the MCO may delegate either utilization review activity or quality assurance and/or quality improvement functions, but not both, to that management contractor, or to an entity related to that management contractor as defined in paragraph (6) above. An MCO shall not contract with a management contractor to conduct utilization

review activity on its behalf unless the management contractor is utilizing the MCO's clinical review standards for utilization review or unless the MCO has approved of the management contractor's clinical review standards. The MCO shall not approve of the management contractor's clinical review standards unless they are substantially equivalent to those of the MCO and to those of other management contractors performing similar functions for the same or similar services. All utilization review processes must comply with article 49 of the Public Health Law and must be approved by the commissioner. Utilization review may only be delegated to a registered utilization review agent, as defined in article 49 of the Public Health Law; and

- (8) pursuant to paragraph (1) of subdivision (b) of section 98-1.21 of this Subpart, all or part of the functions of the special investigations unit, which include investigation of cases of suspected fraudulent and abusive activity and fraud and abuse prevention and reduction activities under the MCO's fraud and abuse prevention plan.

- (k) A proposed management contract must be submitted to the department for its prior approval at least 90 days prior to the management contract's proposed effective date. Management contracts shall be effective only with the prior written consent of the commissioner, and shall include the following:
 - (1) a clear description of the proposed role of the MCO's governing authority and the elements of authority proposed to be delegated to the management contractor during the term of the proposed management contract. The description shall clearly reflect retention by the governing authority of the MCO of ongoing responsibility for statutory and regulatory compliance;
 - (2) a provision that clearly recognizes that the responsibilities of the governing authority of the MCO are in no way lessened by entering into a management contract, and that any powers not specifically delegated to the management contractor through the provisions of the contract remain with the governing authority of the MCO;
 - (3) a clear acknowledgment of the authority of the commissioner to terminate the contract pursuant to subdivision (o) of this section;
 - (4) a provision listing procedures and requirements which shall be established by the MCO for ongoing monitoring by the MCO of the implementation of the contract and the MCO's fiscal stability, level of services provided and quality of care rendered during the term of the contract, including requirements for periodic reporting by the manager;
 - (5) a provision that annual reports on the financial operations and any other operational data requested by the governing authority of the

MCO, the commissioner or superintendent, will be provided by the management contractor;

- (6) a provision stating that the management contract approved by the department shall be the sole agreement between the management contractor and the governing authority of the MCO for the purpose of management of the MCO and payment to the management contractor for management services, and that any amendments or revisions to the management contract shall be effective only with the prior written consent of the commissioner;
 - (7) specification of payment terms that are reasonable and do not jeopardize the financial security of the MCO;
 - (8) a provision whereby the parties agree that any changes to the contract required by the commissioner will be made by the parties immediately upon receipt of written notice from the commissioner; and
 - (9) a provision whereby the parties agree to terminate the management contract within 60 days, in accordance with subdivision (o) below, upon receipt of written notice from the commissioner.
- (l) In addition to a proposed written contract complying with the provisions of subdivisions (h) through (s) of this section and section 98-1.18 of this Subpart, the governing authority of the MCO seeking to enter into a management contract shall submit to the department the following:
- (1) documentation indicating that the proposed management contractor holds all necessary approvals to do business in New York State including, as appropriate, an application for authority to do business in New York State filed with the Secretary of State;
 - (2) proposed terms of the management contract, including but not limited to the term and purposes of the agreement, identification of the contractor's responsibilities, and descriptions of all staffing to be provided, major equipment, computer and information systems, required reports, performance criteria, a termination provision, projected costs and any management or other fee to be charged by the management contractor;
 - (3) evidence of the management contractor's financial stability;
 - (4) information necessary to determine the character and competence of the proposed management contractor, its controlling persons, officers and directors, owners, members or managers of a limited liability company and any medical director proposed by the management contractor for the general or medical management of the MCO and/or for utilization review activities, including evidence that all MCOs and health care facilities managed or operated by the management contractor, in or out of New York State, have provided a substantially consistent high level of care during the term of their management contract or operating certificate. The department may conduct a

limited review of character and competence where the agreement delegates management activities involving only a single medical service such as dental, vision or chiropractic services, or delegates limited management responsibility such as utilization review. For the purposes of this paragraph, a limited review shall consist of a review of the proposed management contractor's past performance as a management contractor or in any other capacity performing any of the functions set forth in subdivision (j) of this section, as well as the character and competence of the officers and directors, members or managers of a limited liability company and partners of the contractor, and, if the proposed delegated management activity is either medical management or utilization review, the medical director of the proposed management contractor; and

(5) except for PCPCPs, evidence that it is financially feasible for the MCO to enter into the proposed management contract for the term of the contract, recognizing that the costs of the contract are subject to the approval of the commissioner and superintendent. To demonstrate evidence of financial feasibility, such MCO shall submit projected operating and capital budgets for the required periods. Such budgets shall be consistent with any previously submitted, certified financial statements and be subject to future audits. However, no review of financial feasibility shall be required where:

- (i) the agreement delegates management activities for limited services such as dental, vision, behavioral health and chiropractic services, and the management fee is equal to no more than 25% of the MCO's total administrative costs; or
- (ii) the agreement delegates a limited scope of management activities, such as utilization review, for some, most or all medical services and the management fee is equal to no more than 25% of the MCO's total administrative cost.

(m) The term of a management contract shall be limited to five years and may be renewed only when authorized by the commissioner, provided compliance with this section and the following provisions can be demonstrated:

- (1) that the goals and objectives of the contract have been met within specified time frames;
- (2) that the quality of care provided by the MCO during the term of the contract has been maintained or has improved; and
- (3) that any reporting requirements contained in the management contract have been met.

Any application for renewal shall be submitted at least 90 days prior to the expiration of the existing contract.

- (n) Any termination or non-renewal of a management contract shall require the prior written approval of the commissioner following 90 days prior written notice. The governing authority of the MCO shall, within the terms of the contract, retain the authority to discharge the management contractor for cause or based on mutual agreement between the MCO and the management contractor. The governing authority of the MCO shall provide a plan for the management of the MCO subsequent to the discharge, to be submitted with 90 days prior notification to the department of the MCO's decision to discharge the management contractor. The department shall be given at least 90 days prior written notice by the MCO of all terminations whether initiated by the MCO or the manager. Termination may be upon less than 90 days notice provided it is demonstrated to the satisfaction of the commissioner prior to termination that circumstances exist which justify more immediate termination.
- (o) A management contract shall terminate and be deemed cancelled, without financial penalty to the governing authority of the MCO or the MCO itself, not more than 60 days after notification to the governing authority of the MCO and the management contractor by the department of a determination that the MCO is not providing adequate care or otherwise assuring the health, safety and welfare of the enrollees.
- (p) In the event that the management contractor proposes to subcontract any management functions, the subcontractor must be a signatory to the management contract which must expressly provide for the subcontracting of management functions to the subcontractor. The subcontractor will be subject to the provisions of this Subpart to the same extent as the management contractor, including all termination provisions, provided that the subcontractor may also be terminated by the management contractor upon at least 90 days notice and with the prior written approval of the commissioner.
- (q) Any MCO which commits or engages in any of the following acts shall be subject to action against its certificate of authority and/or civil penalties under the authority of sections 12 and 4404 of the Public Health Law and section 98-1.8 of this Subpart;
 - (1) the governing body of the MCO delegates one or more management functions without having effected such delegation pursuant to a management contract approved by the commissioner;
 - (2) the governing body of the MCO fails to retain ongoing responsibility for statutory and regulatory compliance;

- (3) the governing body of the MCO allows the management contractor to assume responsibilities which cannot be delegated by the governing authority of the MCO;
 - (4) the governing body of the MCO enters into more than one agreement with the management contractor for the purpose of management of the MCO and/or payment to the management contractor for management services;
 - (5) the management contract is amended without the prior written approval of the commissioner;
 - (6) the management contractor is discharged without the prior approval of the commissioner;
 - (7) the MCO fails to comply with a direction from the commissioner to terminate the management contractor;
 - (8) the MCO or the management contractor subcontracts delegated functions without the approval of the commissioner; or
 - (9) the MCO fails to comply or maintain compliance with any other requirements of article 44 of the Public Health Law and this Subpart.
- (r) Where the MCO has delegated claims payment to a management contractor, including an IPA, the management contractor shall compensate contracted providers in a timely manner consistent with the provisions of section 3224-a of the Insurance Law, provided, however, that nothing herein shall limit the liability of an MCO pursuant to such law for any failure to pay providers in accordance with the provisions of such law. The MCO may, in its contract with the management contractor, require the management contractor to indemnify the MCO for all claims and payments made by the MCO as a result of the management contractor's failure to make timely payments to providers in a manner consistent with section 3224-a of the Insurance Law.
- (s) Any management contract approved by the commissioner and entered into by an MCO and a management contractor prior to the effective date of this subdivision shall remain in effect for the term of the contract. In no event shall such a management contract remain in effect for more than five years from its effective date, nor shall such a management contract be renewed without complying with the provisions of this Subpart and without receiving the prior written approval of the commissioner in accordance with this Subpart. No written interim consultative agreement entered into between a proposed management contractor and an MCO prior to the effective date of this subdivision shall remain in effect for more than ninety days following the effective date of this subdivision. An existing contract which, upon the effective date hereof qualifies as a management contract pursuant to the provisions of subdivision (j) of this section, shall be amended to comply with the provisions of this section relating to management contracts and

submitted for approval prior to its renewal pursuant to the terms thereof or within one year of the effective date hereof, whichever first occurs.

- (t) An MCO may employ salaried solicitors and accept business from licensed insurance brokers and agents for business other than title XIX, and title XXI, and Title 11 of Article 5 of the Social Services Law and Title I-A of Article 25 of the Public Health Law, respectively, on a commission basis provided, however, that:
 - (1) HMOs shall comply with section 4312 of the State Insurance Law with respect to accepting business from licensed insurance brokers and agents on a commission basis;
 - (2) no MCO, for its commercial line of business, shall pay a fee or commission to a broker or agent who has not agreed to provide information concerning its arrangements with participating employers to the MCO upon request;
 - (3) any broker or agent selling MCO coverage shall be licensed by the Insurance Department as an insurance broker or agent;
 - (4) no MCO shall accept more than 10 percent of an individual or group premium, which shall be refundable in the event enrollment is denied by such MCO, from a broker or agent unless upon such acceptance an individual, or group subject to any waiting period permitted in this Subpart concerning the commencement of coverage, is enrolled and entitled to receive comprehensive health services pursuant to a contract approved by the Superintendent of Insurance; and
 - (5) any fees or commission rates payable by an MCO to a broker or agent, which shall be at the same rate for all brokers and agents utilized by such MCO, shall be reviewed by the Superintendent of Insurance as part of the MCO's rate filing process and pursuant to any other applicable provisions of the Insurance Law and regulations.

98-1.12 Quality management program.

- (a) An MCO shall develop and implement a quality management program, that is supervised by the medical director and that includes organizational arrangements and ongoing procedures for the identification, evaluation, resolution and follow-up of potential and actual problems in health care administration and delivery to enrollees. MCOs shall include in such quality management programs standards for management of access to, continuity and quality of care and, except for PCPCPs, utilization and cost of services.
- (b) MCOs shall also develop a quality assessment and performance improvement program that includes performance and outcome-based quality standards for enrollee health status, satisfaction, and for MLTCPs, functional status also. The program shall achieve required minimum levels

of performance on standardized quality measures established by the commissioner. In the case of an HIV SNP, the quality indicator measures must include HIV-specific quality measures.

- (c) A health information system shall be maintained that collects, analyzes, integrates, and reports data necessary to develop and implement the quality assurance and performance improvement programs.
 - (d) The quality assessment and performance improvement programs shall be approved by the commissioner prior to issuance of a certificate of authority and monitored periodically thereafter by the commissioner.
 - (e) The quality assessment organizational arrangements and ongoing procedures must be fully described in written form, provided to all members of the governing authority, providers and staff, and made available to enrollees in the MCO.
 - (f) The organizational arrangements for the quality assessment program must be clearly defined and transmitted to all individuals involved in the quality assessment program, and should include, but not be limited to, the following:
 - (1) an internal quality assurance committee or comparable designated committee responsible for quality assurance activities;
 - (i) accountability of the committee to the governing authority of the MCO, including periodic written and oral reports to the governing authority;
 - (ii) participation from an appropriate base of providers and support staff;
 - (iii) regularly scheduled meetings at appropriate periodic intervals, no fewer than four per year; and
 - (iv) minutes or records of the meetings, describing in detail the actions of the committee, including the medical charts reviewed, problems discussed, recommendations made, and any other pertinent discussions and activities; and
 - (2) a peer review committee responsible for monitoring provider performance.
 - (g) The quality assurance procedures shall include defined methods for the identification and selection of clinical and administrative problems. Input for problem identification should come from multiple sources, including but not limited to medical chart reviews, member complaints, epidemiological data, utilization data, patient surveys, utilization review, and other data
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which identify patterns of care, and shall cover all MCO services. Methods shall be established by which potential problems are selected and scheduled for further study.

- (h) An MCO shall document the manner by which it examines actual and potential problems in health care administration and delivery to enrollees. While a variety of methods may be utilized, the following components should be present:
 - (1) the existence of procedures for the analysis;
 - (2) the acquisition of sufficient data to perform a meaningful analysis; for example, a statistically valid sample size for medical chart review; and
 - (3) involvement of appropriate clinical personnel, including physicians and other providers for peer review.

 - (i) The quality assurance activities shall include the development of timely and appropriate recommendations. For problems in health care administration and delivery to enrollees that are identified, the MCO must demonstrate an operational mechanism for responding to those problems. Such a mechanism should include:
 - (1) development of appropriate recommendations for corrective action or, when no action is indicated, an appropriate response;
 - (2) assignment of responsibility at the appropriate level or with the appropriate person for the implementation of the recommendation; and
 - (3) implementation of action which is appropriate to the subject or problem in health care administration and delivery to enrollees.

 - (j) There shall be evidence of adequate follow-up on recommendations. The MCO must be able to demonstrate that recommendations of the committee responsible for quality assurance activities are reviewed in a timely manner, in order to:
 - (1) assure the implementation of action relative to the recommendations;
 - (2) assess the results of such action; and
 - (3) provide for revision of recommendations or actions and continued monitoring when necessary.

 - (k) Physicians and other health professionals providing covered services to enrollees shall be licensed, certified and currently registered, in accordance with New York State law. MCOs must develop and utilize credentialing and recredentialing processes, consistent with generally accepted standards, that are performed under the direction of the medical director.
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- (l) Whenever a health care professional is unable to provide health care services due to a final disciplinary action by a state licensing board or other governmental agency that impairs the health care professional's ability to practice, the MCO must take immediate action, upon receipt of notice, to remove the professional from the network.
- (m) Laboratory, pathology and radiology services shall be under the direction of a qualified medical professional.
- (n) The MCO shall require and assure that the medical records of enrollees be retained for six years after the date of service rendered to enrollees, and in the case of a minor, for three years after majority or six years after the date of the service, whichever is later.
- (o) The MCO or, if specifically provided for in the contract, the contracted provider must provide to each health care provider or to each IPA with which the MCO contracts a provider manual which, unless otherwise provided for in the contract, shall contain a description of the policies and operating procedures established by the MCO for the provision of covered services to enrollees of the MCO, and include provider rights. The provider manual shall be furnished to the provider prior to the effective date of the provider's participation in the network and subsequent to the satisfactory completion of the MCO's credentialing process, and shall be amended as the MCO's operational policies change. Revisions to the provider manual may be provided through provider bulletins or other communication to providers; however, revisions must be incorporated in the appropriate section of the manual.

98-1.13 Assurance of access to care.

- (a) All covered services must be directly provided or arranged for within the approved provider network pursuant to written contracts developed and maintained in a form and manner prescribed by the commissioner, except that when services are unavailable within the provider network, such services must be arranged for outside of the approved provider network. An MCO shall establish a process for the resolution of requests for medically necessary services to be provided by out-of-network providers when such services are not available in network. Such process shall require the approval of the commissioner prior to implementation and shall thereupon be included in the member handbook. Emergency services do not require prior authorization; no MCO or utilization review agent may require enrollees to obtain prior authorization for the provision of such services.
- (b) The limitation in subdivision (a) of this Subpart, and other limitations imposed on accessing the entire approved network, must be clearly

transmitted to eligible persons and enrollees via marketing materials, member handbooks and subscriber contracts.

- (c)
 - (i) Prior approval of the Commissioner is required for assignment of an IPA or institutional network provider contract, or of a medical group provider contract that serves five percent or more of the enrolled population in a county.
 - (ii) A minimum of 45 days prior written notice to the commissioner is required for termination or non-renewal of an IPA or institutional network provider contract, or of a medical group provider contract that serves five percent or more of the enrolled population in a county or when the termination or non-renewal of the medical group provider will leave fewer than two participating providers of that type within the county. The notice shall include an impact analysis of the termination or non-renewal with regard to enrollee access to care.
 - (iii) All provider contracts assigned by an MCO or an IPA prior to, and which remain in effect following, the effective date hereof shall be amended within one year of such effective date or upon renewal, whichever first occurs, to achieve compliance with the provisions of this subpart and guidelines for provider and IPA contracts established by the commissioner.

- (d) An MCO which provides primary care services shall make available to each enrollee a primary care practitioner to supervise and coordinate the health care of the enrollee. In the case of an HIV SNP, the primary care practitioners for enrollees with HIV infection must meet HIV specialist requirements as defined by the commissioner; the qualifications of HIV specialist primary care practitioners shall be reassessed annually to assure the requirements for HIV specialist status are met. The HIV SNP member-to-primary care practitioner ratios shall be developed to reflect HIV SNP patient caseload characteristics as prescribed by the commissioner. When required by federal and/or state law or regulation, an enrollee of an MCO who is dissatisfied with the assigned or selected primary care practitioner shall be allowed to select another. However, the MCO may impose a reasonable waiting period to accomplish this transfer. Waiting times for enrollees eligible for benefits under title XIX shall be consistent with section 364-j of the Social Services Law.

- (e) The HIV SNP shall ensure all enrollees access to a full continuum of HIV-specific care, treatment and prevention through:
 - (1) access to the services of facility and community based case managers with expertise in prevention and care needs of persons with HIV infection;

- (2) access to designated AIDS center hospitals or other hospitals with proven experience in HIV care and treatment and to community based HIV prevention and health care providers, including community health centers and, where geographically accessible, co-located substance abuse and HIV primary care programs;
 - (3) access to health and social services providers that support members' ability to sustain wellness and to adhere to treatment regimens;
 - (4) development and implementation of written agreements with community based social services providers to facilitate enrollee access to the full continuum of services needed by HIV-infected individuals, including access to care for vulnerable populations, such as those who are homeless, substance users or others; and
 - (5) mechanisms for monitoring referrals to care, treatment and supportive services and for documenting the outcome of the referral process for enrollees referred to organizations with which the HIV SNP is affiliated through a linkage agreement or memorandum of understanding.
- (f) The MLTCP shall assure that all covered services are available and accessible by:
- (1) establishing standards for timeliness of access to care and member services and frequent and consistent monitoring of the extent to which it meets such standards;
 - (2) implementing a process for selection and retention of network providers; and
 - (3) making care management and health care services available 24 hours a day, seven days a week.
- (g) The MLTCP shall promote continuity of care and integration of services through:
- (1) designation of a health care professional(s) responsible for care management. Services provided or arranged to address the care needs of such enrollee shall be in accordance with a current plan of care developed in consultation with the enrollee;
 - (2) coordination of covered health and long term care services with non-covered services and other community resources; and
 - (3) systematic and timely communication of clinical information among providers and maintenance of a care management record. Such records, which shall be retained for six years after the date of service rendered to enrollees, shall include but shall not be limited to:
 - (i) assessments and reassessments;

- (ii) a plan of care which identifies health care goals of enrollees and covered services to be provided;
 - (iii) medical orders, as applicable;
 - (iv) documentation of non-covered services arranged and coordinated by the plan;
 - (v) advance directives;
 - (vi) signed enrollment agreement and disenrollment agreement; and
 - (vii) contacts with enrollees and their representatives, providers of covered and non-covered services, physicians, local social service districts and other agencies or facilities with whom the plan coordinates services.
- (h) The MCO, or the primary care practitioner on behalf of the MCO, shall be responsible for the management of care for enrollees, including the identification and selection of an appropriate provider of care in each individual instance where services are determined to be necessary for the enrollee. An MCO shall provide, or make arrangements for the provision of the full range of comprehensive health services as defined in subdivision (g) of section 98-1.2 and as covered in the approved benefit package to enrollees. MCOs shall provide such comprehensive health services without exclusion of any appropriately registered, certified or licensed type of provider as a class from participation in such MCO.
- (i) When an enrollee is referred by an MCO or by an MCO primary care practitioner or MCO provider authorized by the MCO to make such referrals to a participating or nonparticipating specialist for services included in the enrollee contract with such MCO, the enrollee shall incur no financial liability other than required co-payments.
- (j) An MCO shall have a written procedure describing coverage for emergency health services received by an enrollee outside of the MCO's service area. The MCO coverage for emergency health services shall be consistent with article 49 of the Public Health Law and, in the case of an entity providing services to Medicare beneficiaries, consistent with federal law and regulation, and clearly described in both the enrollee contract and the enrollee handbook.
- (k) Medical offices and premises not subject to the jurisdiction of article 28 of the Public Health Law, in which primary ambulatory care services are provided to MCO enrollees, shall conform to professional and generally accepted standards of medical practice.
- (l) The MCO shall establish procedures to obtain consent from each enrollee for release of such enrollee's medical records to ensure that it has access to the medical records of enrollees upon request for review by the MCO and

the department for the purposes authorized by law. This shall be assured through an explicit provision in the contracts between the MCO and providers, the MCO and an IPA and providers.

- (m) MCOs shall require that network providers comply with all HIV confidentiality requirements pursuant to title 27-F and Section 2784 of the Public Health Law, through express provision in contracts with providers and express reference in provider manuals. An HIV SNP shall establish procedures for assuring the confidentiality of medical information of all enrolled HIV-infected individuals, including mechanisms to address breaches of confidentiality and a training program for all HIV SNP employees regarding confidentiality and disclosure of HIV-related information.
- (n) Utilization review program standards for retrospective review of a pre-authorized treatment, service, or procedure. An MCO may reverse a pre-authorized treatment, service or procedure on retrospective review pursuant to section 4905(5) of the Public Health Law only when:
 - (1) the relevant medical information presented to the MCO or utilization review agent upon retrospective review is materially different from the information that was presented during the pre-authorization review; and
 - (2) the relevant medical information presented to the MCO or utilization review agent upon retrospective review existed at the time of the pre-authorization but was withheld from or not made available to the MCO or utilization review agent; and
 - (3) the MCO or utilization review agent was not aware of the existence of the information at the time of the pre-authorization review; and
 - (4) had the MCO or utilization review agent been aware of the information, the treatment, service, or procedure being requested would not have been authorized. This determination is to be made using the same specific standards, criteria or procedures as used during the pre-authorization review.
- (o) An MCO shall have written procedures for the implementation of the transitional period provisions set forth in paragraphs (e) and (f) of subdivision (6) of section 4403 and subdivision (4) of section 4408 of the Public Health Law.

98-1.14 Enrollee services and grievance procedures.

- (a) The MCO shall supply enrollee handbooks to each enrollee, and upon request to each prospective enrollee, which explain the operation of the plan. The MCO shall also provide information as required by section 4408 of the

Public Health Law. Except where precluded by applicable law or regulation, changes in operations that affect the enrollee shall be communicated to the enrollee prior to the effective date of the change via the enrollee handbook or by other direct means of communication.

- (1) For MLTCPs, the enrollee handbook and complete provider network directory shall be provided to individuals who have expressed a desire for enrollment. MLTCPs shall also comply with the provisions of paragraph (i) of subdivision 98-1.16 of this Subpart.
 - (2) Information disclosed in the enrollee handbook and changes made thereto shall be approved prior to use of the handbook by:
 - (i) for programs authorized by title XIX, the commissioner and, when such approval is required, the federal agency with oversight responsibility for programs authorized by title XIX;
 - (ii) for programs authorized by title XXI, the commissioner;
 - (iii) for commercial and private pay insurance products, the commissioner; and
 - (iv) for MLTCPs, the superintendent in consultation with the commissioner and director of the State Office for Aging and, as appropriate, the federal agencies with oversight responsibility for programs authorized by title XIX and title XVIII of the Social Security Act.
- (b) The MCO shall establish written policies regarding the rights of enrollees and shall list these rights in the enrollee handbook. Enrollee rights shall include the following:
- (1) to obtain complete current information concerning a diagnosis, treatment and prognosis from a physician or other provider in terms the enrollee can be reasonably expected to understand. When it is not advisable to give such information to the enrollee, the information shall be made available to an appropriate person acting on the enrollee's behalf;
 - (2) to receive information from a physician or other provider necessary to give informed consent prior to the start of any procedure or treatment; and
 - (3) to refuse treatment to the extent permitted by law and to be informed of the medical consequences of that action.
- (c) The MCO shall have written grievance and complaint procedures, including an appeals procedures consistent with section 4408-a of the Public Health Law and/or in the case of an entity participating in federally sponsored programs, consistent with federal law and regulation. Such procedures shall be approved by the commissioner and/or, as appropriate, the federal agency

with oversight responsibility for programs authorized by title XIX and title XVIII of the Social Security Act prior to the start of enrollment.

- (d) The MCO shall document the receipt and disposition of each grievance or complaint, comply with all applicable reporting requirements of section 210 of the Insurance Law, and retain these records for not less than three years.
- (e) Within 15 business days of receipt, the MCO shall provide written acknowledgement to the complainant or grievant of grievances, written complaints, or verbal complaints that are not immediately resolved. Such acknowledgement shall include the name, address and telephone number of the individual or department designated by the MCO to respond. In addition, the MCO shall provide either a written explanation of the determination resulting from the investigation, without releasing protected peer review information, including detailed reasons for the determination for all grievances and for complaints related to quality of care, access to care and billing, including the clinical rationale for the determination when the determination has a clinical basis, or a written statement that insufficient information was presented or available to reach a determination. When the complainant or grievant is dissatisfied with a determination made by the MCO, other than determinations subject to the provisions of article 49 of the Public Health Law, the appeal provisions of article 4408-a of the Public Health Law apply. In the case of an entity participating in a federally sponsored program, the requirements for written acknowledgement of grievances, written or verbal complaints and MCO determinations shall be consistent with federal law and regulations. For purposes of this Subpart, a "complaint" is any issue of dissatisfaction with the MCO's operations other than those grievances identified in article 4408-a of the Public Health Law.
- (f) With respect to its responsibilities to the enrollee, the MCO shall comply with all provisions of section 700.5 (Advance Directives) of this Title. For purposes of this section, the term "facility/agency" as used in section 700.5 shall be deemed to mean "MCO" and the term "patient" shall be deemed to mean "enrollee." The phrase "admission as an inpatient or outpatient" shall be deemed to mean "enrollment in an MCO," and "medical record" shall be deemed to mean "the medical record maintained by the primary care provider in an MCO or care management record in an MLTCP".

98-1.15 Employer requirements.

- (a) All employers subject to the provisions of the Unemployment Insurance Law, except those employers with fewer than 25 employees, shall include in any health benefits plan offered to their employees the option of membership in an HMO which provides or offers a comprehensive health services plan in accordance with the provisions of this Subpart, but only if

such plan serves an area in which 25 of such employer's employees reside and the HMO has been issued a certificate of authority by the commissioner.

- (b) For those employees of an employer represented by a bargaining representative, the offer of the HMO option shall be subject only to the collective bargaining process. For those employees not represented by a bargaining representative, the offer of the health maintenance organization alternative shall be made directly to the employee.
- (c) Employer option.
 - (1) For the purposes of this section, the following definitions shall apply:
 - (i) Staff model/group model category:
 - (a) *Staff model* is an HMO that provides more than one half of its basic health services through physicians and other professionals who work in centralized health centers as salaried employees of the HMO and where health care is delivered at a health center owned or leased by the HMO.
 - (b) *Group model* is an HMO that provides more than one half of its basic health services through physicians and other professionals who are not salaried employees of the organization but instead are members of one or more medical groups which contract with the HMO to deliver health care at a health center.
 - (ii) IPA model/network model category:
 - (a) *Independent practice association (IPA) model* is an HMO organized in such a way that the physicians or other professionals are not salaried employees of the organization and contract individually or as one or more groups with an IPA which in turn contracts with the HMO to make the services of such providers available to the HMO's enrollees.
 - (b) *Network model HMO* is an HMO organized in such a way that physicians or other professionals provide health care in any combination of models as defined in subparagraphs (i) and/or (ii) of this paragraph, but does not qualify as a staff or a group model as set out in subparagraph (i) of this paragraph.

- (iii) *Principal office* is that place of business indicated on the employer's certificate of incorporation or like instrument approved and on file with the Secretary of State.
 - (iv) *Metropolitan region* consists of the counties of Westchester, Rockland, New York, Kings, Queens, Richmond, Bronx, Nassau and Suffolk.
- (2) If there is more than one HMO engaged in the provision of health services in the area in which the employees of the employer reside, then the employer shall be required to offer the option of enrollment in HMOs that are qualified under the provisions of this Part, pursuant to the following:
- (i) if the employer has 25 or more but fewer than 200 employees, the employer shall be required to offer at least one HMO from the staff model/group model category and one HMO from the IPA model/network model category;
 - (ii) if the employer has 200 or more employees and the employer's principal office in this State is located outside the metropolitan region, the employer shall be required to offer at least two HMOs from the staff model/group model category and two HMOs from the IPA model/network model category;
 - (iii) if the employer has 200 or more employees and the employer's principal office in this State is located within the metropolitan region, the employer shall be required to offer at least two HMOs from the staff model/group model category and two HMOs from the IPA model/network model category and one additional HMO of any model;
 - (iv) if within any particular area of the State served by one or more HMOs in which at least 25 of an employer's employees reside there are fewer HMOs by category than the employer is required to offer, then additional HMOs of other categories shall be offered; provided, however, that no employer with fewer than 200 employees shall be required to offer more than a total of two HMOs, and no employer with 200 or more employees shall be required to offer more than a total of four HMOs if the employer's principal office is not located in the metropolitan region, or five such organizations if the employer's principal office is located within the metropolitan region;
 - (v) in the event fewer than the required total minimum number of HMOs are available in an area, the employer shall offer all HMOs then certified to issue subscriber contracts in that area;
 - (vi) nothing in this subdivision shall be deemed to prohibit an employer from choosing to offer more HMOs to its employees than are required under this subdivision; and

- (vii) nothing in this subdivision shall require an employer to offer to its employees an HMO which has not approached the employer seeking to be an offered HMO choice, nor shall it be interpreted as prohibiting an employer from requesting that an HMO consider enrolling its employees.
- (3) In determining employer size for required HMO offerings statewide, the employer shall tabulate the total number of employees at all work sites maintained by the employer within the State of New York. If, for example, an employer has 200 employees at its principal office within the metropolitan region and 25 employees at its nonmetropolitan region office, the employer is required to offer five HMOs in each area, subject to subparagraph (2)(v) of this subdivision. Work sites include, but are not limited to, principal offices, branch offices, district offices or regional offices.
- (4) Any employer who knowingly fails to comply with the provisions of this subdivision shall be subject to a civil penalty of not more than \$1,000 and/or subject to injunctive relief.
- (d) No employer shall be required to pay more for health benefits as a result of the application of this section than would otherwise be required by any prevailing collective bargaining agreement or other legally enforceable contract for the provision of health benefits between an employer and his employees.
- (e) An employer contributing on behalf of employees to the cost of health benefit plan options shall contribute for any HMO option an amount which is not less than 100% of the dollar amount contributed by the employer for any other employee benefit option, or which is based on the same percentage that is applied to any other employer health benefits plan option premium or cost.
- (f) The HMO is responsible for identifying those employers within their service area to which the option of enrollment in the HMO is to be offered, and for notifying in writing those employers to whose employees it intends to offer the HMO option.
- (g) Such notification to an employer by an HMO shall indicate, where appropriate, whether an HMO intends to offer its plan to all employees of an employer who reside within its article 44 service area, or to limit its offer to the employees of a specific organizational subdivision of the employer. When one or more employees of such an employer are not covered by a collective bargaining agreement, and in the cases of public employers, the employer shall have the option of requiring that the HMO option be offered

to all of those employees within the service area who are covered by the employer's existing health benefits contract.

- (h) An employer, subject to and qualifying under this section, receiving written notification from an HMO of its intent to offer the HMO option, shall, within 30 days, provide written acknowledgement of the HMO notification, and thereafter shall not unreasonably delay the actions necessary to implement the offering of the HMO alternative to employees.
- (i) Material presented to the employer shall include, but not necessarily be limited to, identification of service area, an organizational chart or description of the HMO, identification of the governing authority of the HMO and the holding company of a controlled HMO, identification of the principal providers of medical and hospital services associated with the HMO, present and anticipated enrollment limitations, approved premiums for enrollees and a sample enrollee contract. If the HMO has not received approval for enrollee premiums, the information provided to the employer by the HMO must clearly show that such premiums are not yet approved by the superintendent.
- (j) The HMO shall notify the employer of its intention to market the HMO option at least 90 days prior to the expiration or renewal date of an existing health benefits contract or employer-employee agreement relating to health benefits, and when a collective bargaining agreement includes health benefits, at least 90 days prior to the expiration date of such agreement. For employers with a collective bargaining agreement that is without fixed terms, or is for a fixed term but has provisions for periodically changing the conditions of employment, such agreement shall be treated as renewable on the anniversary date of the agreement or at such other times, not less than annually, as may be provided by such agreement for discussion of changes in its provisions. Existing collective bargaining agreements making no reference to the HMO option or to a particular HMO shall not relieve an employer of the statutory obligation to make the HMO option available to employees in accordance with this section.
- (k) New employees beginning regular employment with an employer subject to this section shall have either seven working days or the customary period allowed by the employer, whichever is longer, to elect the health benefits option under which they desire to be covered.
- (l) Employers subject to this section shall, when responding to notification by an HMO of its intent to offer the HMO option, provide the commencement date and duration of its next annual enrollment period during which employees may elect to change from coverage under one health benefits option offered to another. The HMO(s) shall initially, and on an annual basis

thereafter, have access to employees for marketing purposes during such enrollment period.

- (m) When an annual enrollment period has not been customarily provided, employers subject to this section shall annually provide, after the initial offering of the HMO option which results in the enrollment of employees in an HMO, an enrollment period of reasonable duration to afford employees the opportunity to elect to change their health benefits coverage to or from an HMO option offered, or to or from any other health benefits option which chooses to participate in the annual enrollment period.
- (n) MCOs shall, upon request, disclose to prospective subscribers the information required to be so disclosed by Section 4408 of the Public Health Law. Marketing materials to be distributed to the employees shall be clear, concise, strictly factual and accurate. Such materials shall include identification of the service area, an organizational chart or description, identification of principal providers of medical and hospital services associated with the HMO, present and anticipated enrollment limitations, enrollee premiums, a description of included services, any enrollee costs and required copayments, and any exclusions of coverage.
- (o) The cost of marketing the HMO is the responsibility of the HMO, unless otherwise negotiated.
- (p) The inclusion of any additional marketing material and the method of distribution of all marketing material shall be subject to negotiation between the HMO and the employer.
- (q) Any material distributed by the employer relative to the health maintenance organization plan shall be subject to prior review by the HMO for accuracy.
- (r) Any material to be distributed by an HMO to employees which involves comparison with or discussion of any other health benefit options offered by an employer shall be subject to prior review by the employer for accuracy.
- (s) Employers required to offer the option of membership in an HMO under this section shall provide for the collection of employee premiums through payroll deductions if such payroll deduction is provided for employees choosing other health benefit options.
- (t) An employer shall not discriminate against an employee who chooses the HMO option.
- (u) An employer may utilize or employ a solicitor, broker, agent or other representative to advise and assist in the review, selection, marketing,

offering, processing for enrollment or administration of its employees in a comprehensive health services plan(s); provided, however, that:

- (1) no employer, or the solicitor, agent or employee thereof shall require payment by an HMO, or by an employee through premium payment, of any fee or commission for such services;
- (2) no broker providing such services shall require payment by an employee through premium payment for such services;
- (3) any requirement for payment by an employee for such services shall be clearly identified and itemized in enrollee billings, and described as separate and distinct from the premium rate payable by employees in any materials distributed to employees concerning premium rates and other required enrollee payments; and
- (4) when an employer or its representative prepares for employees a comparison of health benefits options to be offered which includes one or more HMO options, such material shall be comparable in scope and depth for all options and shall include all HMO options to be offered regardless of whether an HMO has negotiated to contribute to the cost of preparing and/or distributing such material.

98-1.16 Disclosure and filing.

- (a) Every MCO, other than a PHSP that only serves enrollees eligible for benefits under title XIX, HIV SNPs and PCPCPs, shall file in duplicate with both the commissioner and the superintendent a financial statement on or before April 1 of each year, in the form and containing such information as the commissioner and the superintendent shall prescribe, showing its condition at last year-end and containing information required by section 4408 of the Public Health Law and the following information:
 - (1) a statement of financial condition, including a balance sheet and summary of receipts and disbursements and an income statement;
 - (2) an analysis of its enrolled population, identifying numbers of enrollees by age groups and sex, and numbers of enrollee contracts by type (family and individual), by contract months, except that for MLTCPs, the analysis may contain other identifying information relevant to the enrolled population; and
 - (3) an analysis of utilization of services, including all services covered by the MCO.
- (b) MCOs that serve enrollees eligible for benefits under title XIX shall file annual financial statements with the commissioner on or before April 1 of each year which shall be in such format and contain such information as prescribed by the commissioner.

- (c) Every MCO shall submit annual financial statements together with an opinion of an independent certified public accountant of the financial statement of such MCO, and an evaluation by such accountant of the accounting procedures and internal control systems of the MCO, by April 1 of each year.
- (d) Every MCO shall make available to the general public and its enrollees those items set forth in paragraph (a)(1) of this section, and a summary of those items set forth in paragraphs (a)(2) and (3) of this section.
- (e) Every controlled MCO shall file with the commissioner such reports or material as the commissioner, with the advice of the superintendent, may direct for the purpose of disclosing information on the operations within the holding company system which materially affect the operations, management or financial condition of the MCO.
- (f) Every MCO, other than a PHSP that only serves enrollees eligible for benefits under title XIX, HIV SNPs and PCPCPs, shall file quarterly statements in duplicate with both the superintendent and commissioner, in the form and containing matters as the commissioner, with the advice of the superintendent, shall prescribe not later than 45 days after the end of each quarter.
- (g) MCOs that serve enrollees eligible for benefits under title XIX shall file quarterly statements with the commissioner, in such format and containing such information as prescribed by the commissioner, not later than 45 days after the end of each quarter.
- (h) In the event an MCO does not provide substantially complete reports or other information required under this Subpart by the due date, or provide requested information within 30 days of any written request for a specific analysis or report by the superintendent or commissioner, the superintendent or commissioner is authorized to levy a civil penalty, after notice and hearing, pursuant to section 12 of the Public Health Law or sections 307 and 308 of the Insurance Law.
- (i) Every MCO shall maintain and update, on a quarterly basis, a listing by specialty of the names, addresses and telephone numbers of all participating providers, including facilities, and in the case of physicians, board certification. Where the MCO contracts with behavioral health facilities rather than directly with behavioral health providers, the provider types available at the facilities must be included in the listing. Members must be notified of updates in writing at least annually in one of the following methods: provide updates in hardcopy; provide a new full listing/directory in hardcopy; provide written notification that a new full listing/directory is

available and will be mailed in hardcopy or electronically upon request. New members, and upon request, current and potential members must receive the most current full listing in hardcopy, or electronically at the request of the member or potential member, along with any updates to such listing.

- (j) No later than 20 business days after the beginning of each calendar year, every MCO shall submit provider network information in an electronic format and including such information as prescribed by the commissioner. Such information shall reflect all signed and implemented contracts in effect as of the first day of such calendar year for all providers and service centers participating in the MCO's network. In addition, a notarized statement attesting to the accuracy of the electronic provider network information submission shall be required. Any modifications or updates to the provider network information must be communicated to the enrolled population, and upon request to potential enrollees, as prescribed in subdivision (i) of this section. Those MCOs that serve enrollees eligible for benefits under title XIX shall submit provider network information in an electronic format and including such information as prescribed by the commissioner no later than 15 business days after the end of each quarter.
- (k) In order to serve enrollees eligible for benefits under title XIX, an MCO must submit a plan for compliance with the federal Americans with Disabilities Act (ADA). Such ADA compliance plan shall be submitted in a form and manner as prescribed by the commissioner.
- (l) An MLTCP shall submit data to the commissioner annually or at such other times as requested and in such manner and form as prescribed by the commissioner regarding enrollee characteristics, utilization of services, enrollments, disenrollments, complaints and grievances and other information deemed necessary to monitor plan operations and care management.

98-1.17 Audits and examinations.

- (a) The commissioner, or his or her representative, and in the case of paragraph (5) of this subdivision, the superintendent, may examine at any time each MCO and all participating entities through which such MCO offers health services, as to the quality of health care services offered, and the adequacy of its provider arrangements. Such examination may include, but shall not necessarily be limited to:
 - (1) all records and reports relative to the number and characteristics (e.g., age and sex) of enrollees;
 - (2) all records and reports relative to utilization of services, by type;

- (3) all records of complaints or grievances submitted by enrollees to the health maintenance organization, and the disposition thereof;
 - (4) evidence of the operation of a mechanism through which the enrolled population provides advice about the policies of an MCO (e.g., enrollee representation on the governing board); and
 - (5) contracts with providers of health services and other vendors.
- (b) The superintendent, the commissioner, or their representatives, may examine the financial affairs of each MCO and all participating entities through which such MCO offers health services at any time. Such examination may include, but shall not be limited to, the following:
- (1) all financial records, including statements of income and expense, budgets and related documents; and
 - (2) all books, records, files and other documents relating to the affairs of such organization, which are relevant to the financial examination.
- (c) Every holding company and every controlled person within a holding company system shall be subject to examination by order of the commissioner, and except for PHSPs, HIV SNPs and PCPCPs, the superintendent, if he or she has reasonable cause to believe that the operations of such person may materially affect the operations, management or financial condition of any controlled MCO within the system operating in New York State, and that he or she is unable to obtain relevant information from such controlled MCO. The grounds relied upon by the commissioner, or where applicable, the superintendent for such examination shall be stated in his or her order. Such examination shall be confined to matters specified in the order.
- (d) All fiscal and statistical records and reports of the MCO shall be subject to audit for a period of six years from the date of their filing with the department. This limitation shall not apply to situations in which fraud may be involved, or where the provider or an agent thereof prevents or obstructs the commissioner or superintendent from performing an audit pursuant to this section. All underlying books, records and documentation which formed the basis for the fiscal and statistical reports, including records of any holding company having a bearing on the operations of the MCO, filed by the MCO with the department, shall be kept and maintained by the MCO and holding company for a period of time not less than six years from the date of filing, or the date upon which the fiscal and statistical records were to be filed, whichever is the later date.

98-1.18 Relationship between an MCO and an IPA.

- (a) An MCO shall be responsible for its agreements with an IPA, for the agreements between the IPA and other IPAs, physicians and other health care providers and suppliers and for the care provided through such arrangements to the same extent as it is responsible for arrangements with all other types of health care providers.
- (b) The requirements of article 44 of the Public Health Law and this Subpart shall apply to an IPA and all physicians, other IPAs, health care providers and suppliers contracting with an IPA to the same extent they apply to all other health care providers participating with an MCO in a comprehensive health services plan.
- (c) Nothing in this Part shall prohibit an IPA from employing providers or other persons to provide review of medical care utilization patterns, quality of care issues, or other program review functions on behalf of its panel of contracted participating providers, even though such providers may also have contracted with the IPA as an independent member or participating provider.
- (d) An MCO contracting with an IPA shall require that the financial records of the IPA shall account in detail for all funds received from the MCO, including, where applicable, fees for services performed by the IPA, and for the disbursement of all such funds.
- (e) An MCO proposing a risk sharing arrangement with an IPA may not enter into any such arrangement without first obtaining approval from the commissioner or superintendent, as appropriate, in accordance with guidelines issued by the commissioner in accordance with section 98-1.5(b)(6)(v) of this Subpart or the superintendent in accordance with Regulation 164. To obtain the commissioner's approval, the MCO shall provide to the satisfaction of the commissioner the following:
 - (1) a current list of the owners, officers, directors, and limited liability company managers and members of the IPA;
 - (2) the complete text of the proposed contract(s), and all attachments thereto, which shall include provisions whereby:
 - (i) the parties expressly agree to amend or terminate the agreement at the direction of the commissioner;
 - (ii) the IPA will submit both quarterly and annual financial statements to the MCO and the MCO will notify the commissioner of any substantial change in the financial condition of the IPA; and

- (iii) the parties agree that all provider contracts shall contain a clause providing that the provider shall not, in the event of default by the IPA, demand payment from the MCO for any covered services rendered to the MCO's enrollees for which payment was made by the MCO to the IPA pursuant to the financial risk sharing agreement;
 - (3) in the event that the MCO contracts with the IPA to delegate management functions, a contract which complies with all the requirements of this Subpart;
 - (4) such information concerning the financial condition of the IPA and any providers participating in a risk sharing arrangement as the commissioner may require to make a determination, including information demonstrating that the IPA and any providers sharing risk with the IPA are financially responsible and capable of assuming such risk and have satisfactory insurance, reserves or other arrangements to support an expectation that they will meet their obligations to MCOs, providers and enrollees; and
 - (5) a demonstration by the MCO and the IPA, to the commissioner's satisfaction, that the elements of a proposed arrangement will not constitute improper incentives to providers, in accordance with physician incentive plan guidelines, and will not result in a deterioration in access to or the quality of care provided to an MCO's enrollees.
- (f) The commissioner may assess fines against an MCO in accordance with section 12 of the Public Health law after a hearing and finding of a violation, by an MCO and/or IPA and/or the physicians and any other health care providers and suppliers contracting with an IPA, of this Subpart and articles 28 and 44 and Title I of article 49 of the Public Health Law.

98-1.19 Marketing by MLTCPs.

- (a) An MLTCP shall prepare a marketing plan. Marketing plans shall not be implemented without the prior written consent of the commissioner.
- (b) *Marketing* means any activity of an MLTCP, a subcontractor of the MLTCP or individuals or entities affiliated with the MLTCP, by which information about the MLTCP is made known to potential enrollees for the purpose of persuading such persons to enroll with the MLTCP. "Marketing activities" are occasions during which marketing information and material regarding managed long term care and a particular MLTCP are presented. Such information may be presented through verbal exchanges and the distribution of written materials and the giving away of nominal gifts (value of \$5.00 or less).

- (c) Each marketing plan for an MLTCP submitted to the department for approval shall include but not be limited to:
 - (1) goals and general marketing strategy;
 - (2) a description of marketing activities and copies of all draft marketing materials;
 - (3) staffing plan including training and compensation methodology and levels;
 - (4) a description of how the MLTCP will meet the informational needs of eligible persons, including those who speak a language other than English as a first language and/or who have a hearing, visual, physical or cognitive impairment, and enable the person to make a voluntary and informed choice;
 - (5) a description of the MLTCP's monitoring activities to ensure compliance with this section; and
 - (6) identification of the primary marketing locations at which marketing will be conducted.

 - (d) *Marketing materials* means materials that are produced in any medium by or on behalf of a MLTCP and can reasonably be interpreted as intended to market to potential enrollees. Marketing materials may not be used by a MLTCP without the prior written consent of the commissioner, the superintendent and the director of the State Office for the Aging. Marketing materials requiring consent include:
 - (1) advertising, public service announcements, printed publications, and other broadcast or electronic messages designed to increase awareness of and interest in, or otherwise persuade an eligible person to enroll in a MLTCP; and
 - (2) any information that references the MLTCP, is intended for general distribution and is produced in a variety of print, broadcast, and direct marketing media, including, but not limited to, scripts, radio, television, billboards, newspapers, leaflets, brochures, videos, telephone books, advertising, letters, posters and the member handbook.

 - (e) A MLTCP is prohibited from engaging in the following practices:
 - (1) making unsolicited calls in person or by telephone or "cold calling" inquiries at the homes of eligible persons;
 - (2) marketing in emergency rooms, patient rooms or other service delivery sites unless requested by the eligible person;
 - (3) requiring providers to distribute plan specific marketing, promotional or informational materials of any kind to eligible enrollees;
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- (4) inappropriate marketing and enrollment encounters such as:
 - (i) making false statements;
 - (ii) deceiving, misleading or threatening an eligible person to influence or induce selection of a particular plan;
 - (iii) discouraging enrollment on the basis of health status or need for health care services;
 - (iv) signing a person's name on the enrollment agreement without consent;
 - (v) enrolling persons who are uninformed about the rules of the plan and/or the voluntary nature of enrollment;
 - (5) seeking to induce selection of a MLTCP by offering gifts which exceed a fair market value of five dollars (\$5.00);
 - (6) distributing new or revised marketing materials that have not been approved by the department;
 - (7) providing misleading or falsified information to the department or the department's designee to substantiate an applicant's eligibility for enrollment; or
 - (8) enrolling persons the plan is not authorized to enroll.
- (f) The MLTCP must process applications for enrollment in the order in which they are received and must not discriminate on the basis of health status.
- (g) Prior to enrollment in a MLTCP each enrollee must sign an enrollment agreement which indicates that the enrollee:
- (1) received a copy of the member handbook which included the rules and responsibilities of plan membership and which expressly delineates covered and non-covered services;
 - (2) agreed to the terms and conditions for plan enrollment stated in the member handbook;
 - (3) understood that enrollment in the MLTCP is voluntary;
 - (4) received a copy of the MLTCP's current provider network listing and agreed to use network providers for covered services; and
 - (5) was advised of the projected date of enrollment.

98-1.20 Waived requirements for MLTCPs. Section 365-i of the Social Services Law, pertaining to prescription drug payments, is deemed waived for MLTCPs by the commissioner.

98-1.21 Fraud and abuse prevention plans and special investigation units.

- (a) Pursuant to Public Health Law section 4414, every MCO that participates in public or government sponsored programs with an enrolled population of

10,000 or more persons in the aggregate in any given year shall develop and file with the commissioner within 180 days of the effective date of these regulations a plan for the detection, investigation and prevention of fraudulent activities in this state and those fraudulent and abusive activities affecting policies or state or local department of social services contracts issued or issued for delivery in this state. The plan must include written policies, procedures and standards of conduct that are distributed to all affected employees and appropriate delegated entities, and that articulate the MCO's commitment to comply with all applicable federal and state standards and identify and address specific areas of risk and vulnerability. The MCO must designate an officer or director who has responsibility and authority for carrying out provisions of the plan, and who reports directly to senior management. Any MCO that has filed and implemented such a plan with the superintendent in compliance with Section 409 of the Insurance Law is exempt from the requirements of this section.

- (1) For the purposes of this section, *fraud* means any type of intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person in a managed care setting, including any act that constitutes fraud under applicable federal or state law, committed by an MCO, contractor, subcontractor, provider, beneficiary or enrollee or other person(s). A "provider" includes any individual or entity that receives funds in exchange for the provision, or arranging for the provision, of health care services to an MCO enrollee.
 - (2) For the purposes of this section, *abuse* means provider practices that are inconsistent with sound fiscal, business or medical practices and result in an unnecessary cost to the state or federal government or MCO, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care in a managed care setting, committed by an MCO, contractor, subcontractor, provider, beneficiary or enrollee. It also includes enrollee practices that result in unnecessary cost to the state or federal government, MCO, contractor, subcontractor or provider. For the purposes of this paragraph, *provider* includes any individual or entity that receives funds in exchange for providing, or arranging for the provision, of a service.
- (b) A fraud and abuse prevention plan shall include the following provisions:
- (1) the establishment of a full time special investigation unit, separate and distinct from any other unit or function of the MCO, which shall be responsible for investigation of cases of suspected fraudulent and abusive activity and for implementation of the MCO's fraud and abuse prevention and reduction activities under the MCO's fraud and abuse

prevention plan, which shall encompass activities of all contracted providers. All documents related to the activities of the special investigations unit shall be maintained for a period of not less than six years. If the MCO enters into a management contract to perform all or part of this function, the management contract shall be submitted to the department for prior approval and included as part of the fraud and abuse prevention plan. The management contract must provide for specified levels of staffing devoted to the investigation of suspected fraudulent and abusive activities. In the event that investigators employed by the management contractor will be working for more than one MCO or on cases in states other than New York, the plan must apportion and specify the percentage of the investigators' efforts which will be devoted to working for the MCO on its New York cases. The agreement shall also require that the management contractor cooperate fully with the department in any examination of the implementation of the fraud and abuse prevention plan and provide any and all assistance requested by the department, any other law enforcement agency or any prosecutorial agency in the investigation and prosecution of fraud and abuse and related crimes;

- (2) a description of the organization of the special investigations unit, including the titles and job descriptions of the various investigators and investigative supervisors, the minimum qualifications for employment in these positions in addition to those required by this regulation, the geographical location and assigned territory of each investigator and investigative supervisor, the support staff and other physical resources, including database access available to the unit and the supervisory and reporting structure within the unit and between the unit and the senior management of the MCO. If investigators employed by the unit will be responsible for investigating cases in more than one state, the plan must apportion that percentage of the investigators' efforts which will be devoted to New York cases;
- (3) the rationale for the level of staffing and resources being provided for the special investigations unit which may include, but is not limited to, objective criteria such as number of enrollees, number of claims received with respect to New York MCOs on an annual basis, volume of suspected fraudulent and abusive New York claims currently being detected, other factors relating to the vulnerability of the MCO to fraud and abuse, and an assessment of optimal caseload which can be handled by an investigator on an annual basis;
- (4) a description of the relationship between the officer or director responsible for carrying out the provisions of the fraud and abuse prevention plan and the special investigations unit; between such persons and the claims, quality, utilization review and underwriting functions of the MCO; and between such persons and the department, other law enforcement agencies and prosecutors;

- (5) procedures for detecting and preventing possible fraud and abuse, as well as procedures for case investigation and detection of patterns of repetitive fraud and abuse involving one or more MCO, including but not limited to the following areas:
 - (i) provision of preventive services;
 - (ii) underutilization;
 - (iii) marketing;
 - (iv) provision of medically necessary services;
 - (v) assignment of a PCP; and
 - (vi) submission of claims for services not provided;
 - (6) criteria for referral of a case to the special investigation unit for evaluation and designation of the individuals authorized to make such a referral; criteria for referral of a case to the department and designation of the individuals authorized to make such referrals; and a policy to avoid duplication of effort due to concurrent referrals by the officer, director or unit to more than one law enforcement agency;
 - (7) provisions for confidential reporting which ensure that the identity of individuals reporting violations of the MCO's standards of conduct, policies and procedures and applicable state and federal standards, is protected. In addition, the MCO must ensure that no individual who reports such violations or suspected fraud and abuse is subjected to retaliation;
 - (8) for MCOs participating in programs authorized by title XIX, provision for the department and/or the New York State Medicaid Fraud Control Unit ("MFCU") to conduct private interviews of MCO personnel, subcontractors and their personnel, witnesses, and enrollees. MCO personnel and subcontractors and their personnel must cooperate fully in making MCO personnel, subcontractors and their personnel available in person for interviews, consultation, grand jury proceedings, pre-trial conference, hearing's own expense. In addition, the MCO must provide to the department, its authorized representatives, and/or the MFCU, originals and/or copies of all records and information requested, in the form requested, and allow access to the MCO's premises. All copies of records must be provided free of charge;
 - (9) provision for in-service training programs for investigative, claims, quality, utilization management and other personnel in identifying and evaluating instances of suspected fraud and abuse, including an introductory training session and periodic refresher sessions. This provision shall include course descriptions, the approximate number of hours to be devoted to these sessions and their frequency. In addition, the training and education required for the officer or director responsible for carrying out the provisions of the fraud and abuse prevention plan must be described;
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- (10) provision for coordination with other units of the MCO to further fraud and abuse investigations, including a periodic review of claims, underwriting, member services, utilization management and complaint procedures and forms for the purpose of enhancing the ability of the MCO to detect fraud and abuse and to increase the likelihood of its successful prosecution, and for initiation of civil actions when appropriate;
 - (11) provision for prompt response to detected offenses, and for development of corrective action initiatives;
 - (12) provision for establishment and consistent application of appropriate disciplinary policies for all employees who fail to comply with the MCO's standards of conduct, policies and procedures and applicable state and federal standards, as well as publication and dissemination of the disciplinary policies and the range of disciplinary actions for improper conduct;
 - (13) development of a fraud and abuse awareness program, appropriate for the size of the MCO, focused on the cost and frequency of fraud and abuse, and methods by which the MCO's enrollees, providers and other contractors can prevent it;
 - (14) development of a fraud and abuse detection procedures manual for use by officers, directors, managers, and claims, underwriting, member services, utilization management, complaint, and investigative personnel; and
 - (15) the timetable for the implementation of the fraud and abuse prevention plan, provided however, that the period preceding implementation shall not exceed six months from the date the plan is submitted.
- (c) Persons employed by special investigations units as investigators or by an independent provider of investigative services under contract with an MCO shall be qualified by education or experience, which shall include an associate's or bachelor's degree in criminal justice or a related field, or five years of insurance claims investigation experience or professional investigation experience with law enforcement agencies, or seven years of professional investigation experience involving economic or insurance related matters. For the purposes of evaluation of medical related claims, MCOs may employ or retain duly licensed or authorized medical professionals. Notwithstanding these minimum requirements, anyone employed as an investigator in a special investigation unit or by a provider of investigative services under contract to an MCO as of the effective date of these regulations may continue in such employment, provided that the insurer identifies such person in writing to the commissioner, giving the date such employment began and a description of the person's qualifications, employment history and current job duties.

- (d) Every MCO required to file a fraud and abuse prevention plan shall file an annual report with the department no later than January 15 of each year on a form approved by the department describing the MCO's experience, performance and cost effectiveness in implementing the plan and its proposals for modifications to the plan, to amend its operations, to improve performance or to remedy observed deficiencies. The MCO must also report at least annually the number of complaints regarding fraud and abuse made to the MCO during the year. In addition, for each confirmed case of fraud and abuse identified through complaints, organizational monitoring, contractors, subcontractors, providers, beneficiaries, enrollees, etc., the following shall be reported to the department on an ongoing basis when the case is confirmed:
- (i) The name of the individual or entity that committed the fraud or abuse;
 - (ii) The source that identified the fraud or abuse;
 - (iii) The type of provider, entity or organization that committed the fraud or abuse;
 - (iv) A description of the fraud or abuse;
 - (v) The approximate range of dollars involved;
 - (vi) The legal and administrative disposition of the case, including actions taken by law enforcement officials to whom the case has been referred; and
 - (vii) Other data/information prescribed by the department.

The reports shall be reviewed and signed by an executive officer of the MCO responsible for the operations of the special investigations unit.

98-1.22 Warning Statements.

- (a) All paper claim forms for health insurance delivered to any person residing or located in this state, in connection with health insurance policies, except health insurance policies for title XVIII of the federal social security act, or state or local department of social services contracts to be issued or issued for delivery in this state shall, as of the date 90 days from the effective date of these regulations, contain the following statement: "Any person who, knowingly and with intent to defraud any MCO or other person, files a statement of claim containing any materially false information, or conceals for the purpose of misleading, information concerning any fact material thereto, is guilty of committing a fraudulent insurance act, which is a crime and shall be subject to a civil penalty not to exceed \$5,000 and the stated value of the claim for each such violation."
- (b) Location of warning statements and type size.

- (1) The warning statements required by subdivisions (a) and (c) of this section shall be placed immediately above the space provided for the signature of the person executing the claim form and shall be printed in type which will produce a warning statement of conspicuous size. On claim forms which require execution by a person other than the claimant, or in addition to the claimant, the warning statements required by subdivisions (a) and (c) of this section shall be placed at the top of the first page of the claim form or on the page containing instructions, either in print, by stamp or by attachments and shall be in type size which will produce a warning statement of conspicuous size.
 - (2) Notwithstanding the provisions of paragraph (1) of this subdivision, MCOs may affix the warning statements required by this Subpart to all claim forms by means of labels and/or stamps or by attachment during the 90 day period following the effective date of these regulations.
- (c) Notwithstanding the provisions of subdivision (a) of this section, MCOs may use substantially similar warning statements, provided such warning statements are submitted to the commissioner for prior approval.

SUBPART 98-2
EXTERNAL APPEALS OF ADVERSE DETERMINATIONS
(Statutory authority: Public Health Law, sections 4910-4916, and
Chapter 586 of the Laws of 1998, section 45)

Section 98-2.1 Preamble. Enrollees, and in the case of a retrospective adverse determination, an enrollee's health care provider shall have the right to request an external appeal of a final adverse determination which is made by a health care plan on the grounds that the health care service is not medically necessary or is experimental or investigational. This Subpart shall be applicable to health care plans as defined in subdivision 4-e of section 4900 of the Public Health Law that offer health care services to an enrolled population that is not exclusively covered by Title XVIII of the Social Security Act and to external appeal agents certified pursuant to Title II of Article 49 of the Public Health Law and Insurance Law and this Subpart and to applicants for certification as external appeal agents.

98-2.2 Definitions. The following words or terms shall have the following meanings when used in this Subpart:

- (a) Attending physician means, for the purpose of requesting an external appeal of an experimental or investigational treatment or service, a licensed, board-certified or board-eligible physician who is qualified to practice in the area of medicine or in the specialty appropriate to treat an enrollee's life-threatening or disabling condition or disease who has recommended a service or treatment that is the subject of a request for external appeal. For enrollees covered by a health care plan with no out-of-network option, the attending physician must either participate in the enrollee's health care plan or must be a physician to whom the enrollee's health care plan referred the enrollee.
- (b) Confidential HIV related information means any information in the possession of a person who provides one or more health or social services or who obtains the information pursuant to a release of confidential HIV related information, concerning whether an individual has been the subject of an HIV related test, or has HIV infection, HIV related illness or AIDS, or information which identifies or reasonably could identify an individual as having one or more of such conditions, including information pertaining to such individual's contacts.
- (c) Final adverse determination means an adverse determination which has been upheld by a utilization review agent with respect to a proposed health care service following a standard appeal, or an expedited appeal where applicable, pursuant to section 4904 of the Public Health Law. If a health

care plan offers two levels of internal appeals, a final adverse determination shall mean the adverse determination of the first level appeal.

- (d) Material familial affiliation means any relationship as a spouse, child, parent, sibling, spouse's parent, spouse's child, child's parent, child's spouse, or sibling's spouse.
- (e) Material financial affiliation means any financial interest of more than five percent of total annual revenue or total annual income of a certified external appeal agent or officer, director, or management employee thereof; or clinical peer reviewer employed or engaged thereby to conduct any external appeal. The term "material financial affiliation" shall not include revenue received from a health care plan by:
 - (1) a certified external appeal agent to conduct an external appeal pursuant to section 4914 of Title II of Article 49 of the Public Health Law and the Insurance Law, or
 - (2) a clinical peer reviewer for health care services rendered to enrollees.
- (f) Material professional affiliation means any physician-patient relationship, any partnership or employment relationship, a shareholder or similar ownership interest in a professional corporation, or any independent contractor arrangement that constitutes a material financial affiliation with any expert or any officer or director of the independent organization.
- (g) Retrospective adverse determination means a determination for which utilization review was initiated after health care services have been provided. Retrospective adverse determination does not mean an initial determination involving continued or extended health care services or additional services for an enrollee undergoing a course of continued treatment prescribed by a health care provider pursuant to section 4903(3) of the Public Health Law.
- (h) Utilization review means the review to determine whether health care services that have been provided, are being provided or are proposed to be provided to a patient, whether undertaken prior to, concurrent with or subsequent to the delivery of such services, are medically necessary. A health care plan's denial of coverage of a health care service as defined in section 4900(5)(b) of the Public Health Law, whether made initially or on appeal under Title I of Article 49 of the Public Health Law, on the basis that the health care service is experimental or investigational, is a determination that the health care service is not medically necessary, provided however, that such health care service would otherwise be a covered benefit.

98-2.3 Standard description of the external appeal process.

- (a) Health care plans shall provide enrollees, and upon request, health care providers, with a copy of the standard description of the external appeal process developed jointly by the commissioner and superintendent, including a form and instructions for enrollees to request an external appeal. The standard description, request form and instructions for the external appeal process developed jointly by the commissioner and superintendent shall include, but not be limited to:
- (1) a statement of the enrollee's right to an external appeal of health care services denied pursuant to a utilization review determination by the enrollee's health care plan on the basis that the services are not medically necessary or that the services are experimental or investigational;
 - (2) a description of the eligibility criteria for an external appeal pursuant to section 4910 of the Public Health Law and Insurance Law and the following:
 - (i) Medicare cannot be the enrollee's only source of health services; and
 - (ii) Enrollees receiving benefits under both Medicaid and Medicare are eligible for the external appeal process only for denials of benefits that are covered under Medicaid;
 - (3) notification that enrollees receiving benefits under Medicaid may also file a complaint through the fair hearing process and that the determination in the fair hearing process will be the one that controls;
 - (4) notification of the timeframes within which the certified external appeal agent must make a determination on expedited and non-expedited external appeals;
 - (5) notification that enrollees requesting an expedited external appeal or an external appeal of a health care plan's denial because the requested health care service is considered to be experimental or investigational should forward the attending physician's attestation to the enrollee's attending physician to complete;
 - (6) notification that requests for external appeal must be accompanied by the appropriate fee, as determined by the enrollee's health care plan, or a statement that a waiver of the fee has been requested, in order to be eligible for an external appeal;
 - (7) a description of the responsibility of the enrollee's health care plan to send the enrollee's medical and treatment records to the certified external appeal agent, provided that the certified external appeal agent may request additional information from the enrollee, the enrollee's health care provider or the enrollee's health care plan at any time;
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- (8) a description of the right of the enrollee and the enrollee's health care provider to submit information to the certified external appeal agent, regardless of whether the agent has requested any information, within 45 days from when the enrollee received notice that the health care plan made a final adverse determination or within 45 days from when the enrollee received a letter from the health care plan affirming that both the enrollee and the enrollee's health care plan jointly agreed to waive the internal appeal process, provided that the external appeal agent has not yet rendered a determination on the appeal;
 - (9) a description of the process for notifying the enrollee and the enrollee's health care plan of the certified external appeal agent's determination;
 - (10) instructions for submitting the request for external appeal to the superintendent;
 - (11) instructions for contacting the state if the enrollee or health care provider has questions;
 - (12) notification that an enrollee or a person authorized pursuant to law to consent to health care for the enrollee must sign the request and consent to the release of medical and treatment records for an enrollee to be eligible for an external appeal; and
 - (13) a signature line for the enrollee's consent to the release of his or her medical and treatment records, including HIV, mental health and alcohol and drug abuse records, to the certified external appeal agent assigned to review the enrollee's external appeal, and the expiration date of the authority to release the enrollee's medical and treatment records in accordance with section 2782 of the Public Health Law for confidential HIV related information and sections 33.13 and 33.16 of the Mental Hygiene Law for mental health related information.
- (b) The commissioner and superintendent shall develop a separate form and instructions for an enrollee's health care provider to request an external appeal in connection with a retrospective adverse utilization review determination pursuant to section 4904 of the Public Health Law. The form must include notification that an enrollee or a person authorized pursuant to law to consent to health care for the enrollee must sign the request and consent to the release of medical and treatment records for the health care provider to be eligible for an external appeal.

98-2.4 Certification of external appeal agents.

- (a) External appeal agents shall be certified jointly by the commissioner and superintendent pursuant to section 4912 of the Public Health Law, section 4912 of the Insurance Law and the following:

- (1) The applicant has demonstrated to the satisfaction of the commissioner and the superintendent that it has access to a pool of clinical peer reviewers sufficient to reasonably assure that appropriately qualified reviewers will be available on a timely basis for all appeals allowed by section 4910 of the Public Health Law and section 4910 of the Insurance Law and to avoid or minimize conflicts of interest pursuant to section 98-1.6 of this Subpart; and
 - (2) The applicant has demonstrated its capability to comply with all applicable laws, rules, regulations, contractual terms, policies and standards as set forth in section 4912 of the Public Health Law and section 4912 of the Insurance Law and as required by the commissioner and superintendent.
- (b) Applicants for certification as external appeal agents shall submit two originals and seven copies of the application to the commissioner in the form and manner prescribed jointly by the commissioner and the superintendent. Upon receipt of the application for certification, the commissioner shall transmit copies of such application to the superintendent for review.
- (c) No applicant shall be certified as an external appeal agent unless the applicant's proposed fees for external appeals are determined to be reasonable by the commissioner and superintendent.
- (d) In order to be certified as an external appeal agent, an applicant shall consent to cooperate in court proceedings relevant to its role as a certified external appeal agent.

98-2.5 Certification requirements. Applicants for certification as external appeal agents shall be required to submit a signed and notarized application to the commissioner, in the form and manner prescribed jointly by the commissioner and the superintendent. Such application shall include the requirements of section 4912 of the Public Health Law and Insurance Law and the following:

- (a) A description of the applicant's organizational structure and capability to operate a statewide external appeal program, including:
 - (1) certificate of incorporation, articles of organization and by-laws or operating agreement of the applicant and, as applicable, the applicant's holding company or parent company;
 - (2) the applicant's organizational chart; and
 - (3) any existing or proposed relationships between the applicant and any health care services entities, health care providers and management service organizations. A certified external appeal agent shall not

delegate any management function related to external appeal activities pursuant to Title II of Article 49 of the Public Health Law and the Insurance Law to a management service organization or any other entity.

- (b) Identification of management staff and a description of such management staff's responsibilities. Each member of the management staff shall provide personal qualifying information, in the form and manner prescribed jointly by the commissioner and the superintendent.
 - (c) The chief executive officer of the external appeal agent shall complete an attestation, also described in section 98-2.6(b) of this Subpart, which affirms, under penalty of perjury, that:
 - (1) the applicant for certification as an external appeal agent does not own or control, is not owned or controlled by and does not exercise common control with any national, state or local illness, health benefit or public advocacy group, society or association of hospitals, physicians or other providers of health care services or association of health care plans; and
 - (2) the external appeal entity, including the medical director and all owners, officers, directors and management employees of such entity has no material professional affiliation, material familial affiliation, material financial affiliation or other affiliation proscribed by section 98-2.6 of this Subpart with any health care plan, any owner, officer, director or management employee of any health care plan, any health care provider, physician's medical group, independent practice association or provider of pharmaceutical products or services or durable medical equipment, any health care facility, or any developer or manufacturer of health services, except as specifically listed in an attachment to the attestation.
 - (d) Information concerning the governing board of the applicant, including roles and responsibilities, identification of the board members and a description of their qualifications.
 - (e) A description of the clinical peer reviewer network, including an assessment of the network's adequacy to provide statewide external appeal services.
 - (f) The current financial condition of the applicant, including a certified financial statement, a statement of revenues and expenses, a balance sheet and methods to repay any indebtedness, sources of capitalization and documentation of accounts, assets, reserves and deposits.
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- (g) The process for ensuring that clinical peer reviewers, when making an external appeal determination concerning medical necessity, consider the clinical standards of the health care plan, the information provided concerning the enrollee, the attending physician's recommendation and applicable generally accepted practice guidelines developed by the federal government, national or professional medical societies, boards and associations.
- (h) Policies and procedures for processing external appeals, including:
 - (1) a description and a chart or diagram of the sequence of steps through which an external appeal will move from receipt of the external appeal by the certified external appeal agent through notification to the enrollee and the enrollee's health care plan regarding the external appeal determination. Such description shall take into account the requirements of section 4914 of the Public Health Law and Insurance Law and subdivisions (a) through (h) and (k) of section 98-2.10 of this Subpart; and
 - (2) procedures for ensuring that no prohibited material affiliation exists with respect to the clinical peer reviewer(s) assigned to each external appeal, pursuant to section 98-2.6 of this Subpart. Such procedures shall include, for each clinical peer reviewer assigned to review the external appeal, a requirement for a duly signed and notarized attestation which affirms, under penalty of perjury, that no prohibited material affiliation exists with respect to such clinical peer reviewer's participation in the review of the external appeal pursuant to subdivisions (e), (f) and (h) of section 98-2.6 of this Subpart. Such attestation shall be in such form as prescribed by the commissioner and superintendent and must be maintained on file with the certified external appeal agent.
- (i) A description of the fees which shall reflect the total amount that will be charged by the certified external appeal agent for external appeals, inclusive of indirect costs, administrative fees and incidental expenses, and a description of the methodology used to calculate the fees. Fees shall be approved for use for two years. Any proposed change in fees must be prior approved by the commissioner and the superintendent.
- (j) A description of the certified external appeal agent's ability to accept requests for external appeals, provide requisite notifications, screen for material affiliations, respond to calls from the State and meet other requirements on a seven day per week basis.

98-2.6 Conflict of interest.

- (a) No entity shall be qualified for certification as an external appeal agent if it owns or controls, is owned or controlled by, or exercises common control with any of the following:
 - (1) any national, state or local illness, health benefit or public advocacy group;
 - (2) any national, state or local society or association of hospitals, physicians, or other providers of health care services, or;
 - (3) any national, state or local association of health care plans.

 - (b) An applicant for certification as an external appeal agent shall submit a sworn statement setting forth that none of the control affiliations proscribed in subdivision (a) above apply to the applicant, and that the applicant, its medical director and each of its owners, officers, directors and management employees, either:
 - (1) has no material familial, financial or professional affiliation, as those terms are defined in subdivisions (d) through (f) of section 98-2.2 of this Subpart, with any person or entity listed in subparagraphs (i) through (v) of paragraph (2) of this subdivision; or
 - (2) provides a list of those material familial, financial and professional affiliations, each of which may, upon certification, result in a prohibited conflict of interest in connection with an external appeal because of such affiliation with:
 - (i) any health care plan; or
 - (ii) any owner, officer, director, or management employee of any health care plan; or
 - (iii) any health care provider, physician's medical group, independent practice association, or provider of pharmaceutical products or services or durable medical equipment; or
 - (iv) any facility at which a health service would be provided; or
 - (v) any developer or manufacturer of a health service.

 - (c) Following certification:
 - (1) if an external appeal agent acquires ownership or control of, or becomes owned or controlled by, or acquires and begins to exercise common control with any entity described in paragraphs (1) through (3) of subdivision (a) of this section, the external appeal agent shall notify the Departments of Health and Insurance in writing within five business days of such acquisition or exercise of control. Such notice
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shall be sufficient basis for the revocation of certification without a hearing; and

- (2) the sworn statement required by subdivision (b) of this section shall be amended and resubmitted to the Departments of Health and Insurance within five business days of the addition or deletion of any material affiliation as described in subparagraphs (i) through (v) of paragraph (2) of subdivision (b) of this section.
- (d) The applicant shall submit a detailed written description of its policies, processes and procedures for ensuring, in accordance with the criteria set forth in subdivisions (b) and (c) and paragraphs (2) through (4) of subdivision (e) of this section and paragraph (2) of subdivision (h) of section 98-2.5 of this Subpart, that appeals will be conducted by impartial clinical peer reviewers, for the reporting and review of clinical peer reviewer conflicts of interest and for assigning or reassigning an appeal where a conflict or potential conflict is identified and further, that the applicant, its medical director and each of its owners, officers, directors, management employees and clinical peer reviewers have no material familial, financial or professional affiliation with the enrollee whose health care service is the subject of an appeal assigned to it subsequent to certification as an external appeal agent or with the enrollee's designee.
 - (e) Unavoidable conflicts; minimization. Notwithstanding any other provision of law and in accordance with section 4913(2) of the Public Health Law and section 4913(b) of the Insurance Law:
 - (1) If the superintendent determines in the course of assigning an external appeal that a conflict is unavoidable because all external appeal agents certified pursuant to this Subpart or their medical director, owners, officers, directors and/or management employees have a disqualifying material affiliation with one or more of the persons or entities listed in subparagraphs (i) through (v) of paragraph (2) of subdivision (b) of this section in relation to the appeal to be assigned, the superintendent shall make a random assignment of the appeal in accordance with section 98-2.8 of this Subpart, provided, however, that the certified external appeal agent assigned shall, within two (2) business days of the assignment or for an expedited appeal, within 24 hours of the assignment, certify to the superintendent by sworn statement that the clinical peer reviewer(s) who will review the external appeal have been assigned in accordance with paragraph (2) of this subdivision and subdivision (f) of this section. When an appeal must be assigned pursuant to this paragraph, the superintendent shall notify the enrollee that all certified agents have a proscribed material affiliation(s), of the need to randomly assign the appeal to one of the external appeal agents certified by the state in order that a determination of the appeal be

obtained and of the nature of the affiliation(s) involving the certified external appeal agent assigned to the appeal, and shall inform the enrollee that, in no event shall the agent's clinical peer reviewer(s) who reviews the appeal have any affiliation proscribed by this section.

- (2) An agent assigned pursuant to this Subpart shall not assign an appeal to a clinical peer reviewer(s) which has a material affiliation with any of those persons listed in subparagraphs (i) through (v) of paragraph (2) of subdivision (b) of this section or to a clinical peer reviewer(s) which has a material familial, financial or professional affiliation with the enrollee whose health care service is the subject of the appeal, or with the enrollee's designee.
 - (3) Where a clinical peer reviewer has a material affiliation with a health maintenance organization or line of business thereof, such affiliation alone shall not constitute a disqualifying conflict with respect to an appeal involving an affiliated health maintenance organization or line of business with respect to which the clinical peer reviewer has no material affiliation.
 - (4) Where a clinical peer reviewer has a material affiliation with a hospital or other licensed provider which is an affiliate of a larger hospital or other provider system or network, such affiliation alone shall not constitute a disqualifying conflict with respect to an appeal involving another hospital or other provider affiliated with such hospital or provider system with respect to which the clinical peer reviewer has no material affiliation.
- (f) No appeal shall be assigned to an external appeal agent or clinical peer reviewer that participated in or issued an internal utilization review decision or the final adverse utilization review determination which is the basis for an external appeal.
- (g) Any appeal assigned to an external appeal agent or clinical peer reviewer which is subsequently determined to involve a disqualifying material affiliation, or prior involvement of the external appeal agent or clinical peer reviewer in the underlying internal utilization review decision or final adverse utilization review determination, shall be immediately returned for reassignment to the superintendent, or the external appeal agent, respectively. If the appeal is being returned to the superintendent, the certified external appeal agent shall also immediately notify the superintendent, by telephone or fax, that the appeal is being returned.
- (h) Notwithstanding any other provision of this Subpart, a certified external appeal agent may assign an appeal to a clinical peer reviewer with unique expertise and experience with respect to a health care service which is relevant to an appeal for reasons which may include, but shall not necessarily be limited to:

- (1) the development or participation in the development of a service, procedure or related equipment; and/or
- (2) prior training and participation in the diagnosis or treatment of a condition rarely encountered or rarely encountered in the geographic area in which the enrollee resides, provided, however, that such clinical peer reviewer did not participate in the internal utilization review decision or the final adverse determination which is the basis for the external appeal.

98-2.7 Screening of requests for external appeal.

- (a) Requests for external appeals shall be submitted to the superintendent. Upon receipt of such requests completed in the form and manner prescribed by the commissioner and superintendent, the requests shall be screened by the superintendent to determine eligibility for external appeal pursuant to the criteria detailed in section 4910(2) of the Public Health Law and section 4910(b) of the Insurance Law and the following:
 - (1) The enrollee submitting the request or on whose behalf a request for external appeal was submitted, or in the case of a retrospective adverse determination, on whose behalf a health care service is delivered, is not covered exclusively by Title XVIII of the federal Social Security Act; and
 - (2) If the enrollee submitting the request or on whose behalf a request for external appeal was submitted, or in the case of a retrospective adverse determination, on whose behalf a health care service is delivered, is receiving benefits under both Title XVIII and Title XIX of the federal Social Security Act, the health care service being requested is a covered benefit under Title XIX.
 - (3) The request is substantially complete as appropriate for the type of determination to be appealed and contains the following:
 - (i) a copy of the final adverse determination letter from the health care plan notifying the enrollee that their request for health care services was denied on appeal; or
 - (ii) a copy of a letter from the health care plan to the enrollee indicating a joint agreement to waive any internal appeal offered by the health care plan; or
 - (iii) in the case of a retrospective adverse determination, a copy of the final adverse determination letter from the health care plan;
 - (iv) payment of a fee, if applicable, or a statement that a waiver of the fee has been requested;

- (v) the signature of the enrollee, or a person authorized pursuant to law to consent to health care for the enrollee, authorizing release of medical and treatment information; and
 - (vi) in the case of a retrospective adverse determination, if the enrollee's health care provider is requesting an external appeal and the enrollee's acknowledgment of the external appeal request and consent for release of the enrollee's medical records to a certified external appeal agent is obtained at the time health care services are provided, a copy of a letter sent by the enrollee's health care provider to the enrollee notifying the enrollee that an external appeal of a retrospective adverse determination has been requested and that the enrollee's medical records will be released to a certified external appeal agent.
- (4) As applicable, the enrollee's attending physician attestation is fully and appropriately completed by the attending physician in the form and manner prescribed by the commissioner and superintendent, or the enrollee has indicated that the attending physician attestation has been transmitted to the enrollee's attending physician. An application shall not be considered incomplete or untimely solely on the basis of failure by the attending physician to submit such documentation within the enrollee's 45 day timeframe for initiation of an external appeal request pursuant to section 4914(2)(a) of the Public Health Law, provided however, the application will not be forwarded to an external appeal agent until the attestation is submitted.
- (5) If the attending physician is recommending that the enrollee participate in a clinical trial, the attending physician attests that:
- (i) the enrollee has a life-threatening or disabling condition or disease, as defined in subdivision 7-a of section 4900 of the Public Health Law;
 - (ii) the enrollee meets the eligibility criteria for the clinical trial;
 - (iii) the clinical trial is open to the enrollee; and
 - (iv) the enrollee has been or will likely be accepted into the clinical trial.
- (6) The external appeal request was submitted, in the form and manner prescribed by the commissioner and superintendent, to the superintendent within 45 days from the date the enrollee or, for provider initiated retrospective appeals, the enrollee's health care provider, received notice that the health care plan made a final adverse determination or within 45 days from when the enrollee received a letter from the health care plan affirming that both the enrollee and the enrollee's health care plan jointly agreed to waive

the internal appeal process. Unless otherwise demonstrated, it shall be presumed that the enrollee, or the enrollee's health care provider for provider initiated retrospective appeals, received the notice of final adverse determination or letter agreeing to waive the internal appeal process within eight days of the date on the notice of final adverse determination or the date on the letter agreeing to waive the internal appeal process.

- (b) Screening of expedited appeals shall be initiated by the superintendent within 24 hours of receipt of the request. Screening of standard appeals shall be initiated by the superintendent within five business days of receipt of the request.
- (c) In the event that additional information is required to process a request, the superintendent shall contact the initiator of the request, the enrollee's health care plan or the enrollee's attending physician, as appropriate, by the most efficient means available, to request the necessary information.
- (d) A copy of appropriately completed requests for appeals of final adverse utilization review determinations made by entities certified under Article 44 of the Public Health Law that are determined to be eligible for external appeal shall be transmitted to the commissioner immediately after assignment to a certified external appeal agent.
- (e) The superintendent shall notify the enrollee and the enrollee's health care plan if a request is determined to be eligible for external appeal within seven days of receipt of a complete request for a standard appeal and within 48 hours of receipt of a complete request for an expedited appeal. Such notification shall include:
 - (1) identification of the certified external appeal agent assigned to the appeal;
 - (2) notification to the enrollee of any unavoidable material affiliations concerning the certified external appeal agent assigned to the appeal, including a brief explanation of the nature of the material affiliation(s) pursuant to paragraph (1) of subdivision (e) of section 98-2.6 of this Subpart;
 - (3) for purposes of notifying the enrollee's health care plan, a copy of the enrollee's signed release of medical and treatment information, completed in a manner as prescribed jointly by the commissioner and superintendent and in accordance with section 2782 of the Public Health Law for confidential HIV related information and sections 33.13 and 33.16 of the Mental Hygiene Law for mental health related information; and

- (4) for purposes of notifying the enrollee's health care plan, as applicable, a copy of the attending physician's attestation.
- (f) If a fee is submitted and the health care plan's determination is upheld by the external appeal agent, the superintendent shall forward the fee to the health care plan within seven days of receipt of the external appeal agent's determination.
- (g) If a fee is submitted and the health care plan's determination is overturned in whole or in part by the external appeal agent, the superintendent shall return the fee to the enrollee or, in the case of a provider initiated retrospective appeal, the enrollee's health care provider, within seven days of receipt of the external appeal agent's determination.
- (h) Those requests determined to be ineligible for external appeal shall be returned to the enrollee or, in the case of a provider initiated retrospective appeal, the enrollee's health care provider, by the superintendent, with notification to the enrollee's health care plan and attending physician, as appropriate, accompanied by an explanation as to why the request was determined to be ineligible for external appeal within seven days of receipt of a complete request for a standard appeal and within 48 hours of receipt of a complete request for an expedited appeal.

98-2.8 Random assignment of external appeals. Requests for external appeals that have been determined to be eligible for external appeal shall be randomly assigned by the superintendent to a certified external appeal agent according to a process prescribed by the commissioner and superintendent. Such process must take into account conflicts of interest pursuant to section 4913 of the Public Health Law and Insurance Law and section 98-2.6 of this Subpart.

98-2.9 Responsibilities of health care plans. Health care plans shall be responsible for compliance with all applicable requirements of Article 49 of the Public Health Law and with the following:

- (a) Enrollee requests for experimental or investigational health care services that would otherwise be a covered benefit except for the health care plan's determination that the health care service is experimental or investigational shall be subject to utilization review pursuant to Title I of Article 49 of the Public Health Law.
- (b) If a health care plan requires information necessary to conduct a standard internal appeal pursuant to section 4904 of the Public Health Law, the health care plan shall notify the enrollee and the enrollee's health care provider, in writing, within fifteen (15) days of receipt of the appeal, to identify and request the necessary information. In the event that only a portion of such

necessary information is received, the health care plan shall request the missing information, in writing, within five business days of receipt of the partial information. In the case of expedited appeals, the health care plan shall immediately notify the enrollee and the enrollee's health care provider by telephone or facsimile to identify and request the necessary information, followed by written notification. The period of time to make an appeal determination under section 4904 of the Public Health Law begins upon a health care plan's receipt of necessary information.

- (c) If a health care plan offers two levels of internal appeals, the health care plan may not require the enrollee to exhaust the second level of internal appeal to be eligible for an external appeal.
- (d) Notices of final adverse determinations shall comply with all requirements of Article 49 of the Public Health Law and with all applicable federal laws and rules.
- (e) Each notice of a final adverse determination of an expedited or standard utilization review appeal under section 4904 of the Public Health Law shall be in writing, dated and include the following:
 - (1) a clear statement describing the basis and clinical rationale for the denial as applicable to the enrollee;
 - (2) a clear statement that the notice constitutes the final adverse determination;
 - (3) the health care plan's contact person and his or her telephone number;
 - (4) the enrollee's coverage type;
 - (5) the name and full address of the health care plan's utilization review agent;
 - (6) the utilization review agent's contact person and his or her telephone number;
 - (7) a description of the health care service that was denied, including, as applicable and available, the dates of service, the name of the facility and/or physician proposed to provide the treatment and the developer/manufacture of the health care service;
 - (8) a statement that the enrollee may be eligible for an external appeal and the timeframes for requesting an appeal; and
 - (9) for health care plans that offer two levels of internal appeals, a clear statement written in bolded text that the 45 day timeframe for requesting an external appeal begins upon receipt of the final adverse determination of the first level appeal, regardless of whether or not a second level appeal is requested, and that by choosing to request a second level internal appeal, the time may expire for the enrollee to request an external appeal.

- (f) A written notice of final adverse determination concerning an expedited utilization review appeal under section 4904 of the Public Health Law shall be transmitted to the enrollee within 24 hours of the rendering of such determination.
- (g) If the enrollee and the health care plan have jointly agreed to waive the internal appeal process offered by the health care plan, the information required in subdivision (e) of this section must be provided to the enrollee simultaneously with the letter agreeing to such waiver. The letter agreeing to such waiver and the information required in subdivision (e) of this section must be provided to the enrollee within 24 hours of the agreement to waive the health care plan's internal appeal process.
- (h) Health care plans shall facilitate the prompt completion of external appeal requests, including but not limited to, the following:
 - (1) Health care plans shall provide the enrollee with a copy of the standard description of the external appeal process as developed jointly by the commissioner and superintendent, including a form and instructions for requesting an external appeal along with a description of the fee, if any, charged to enrollees for an external appeal, criteria for determining eligibility for a waiver of such fees based on financial hardship, and the process for requesting a waiver of such fees based on financial hardship:
 - (i) simultaneous with a notice of a final adverse determination that a health care service is not medically necessary, including on the grounds that the health care service is experimental or investigational; or
 - (ii) simultaneous with the written confirmation of agreement between the health care plan and the enrollee to waive the health care plan's internal appeal process; and
 - (iii) within three business days of a request by an enrollee or an enrollee's designee.
 - (2) Transmitting enrollee medical and treatment records pursuant to an appropriately completed release or releases signed by the enrollee or by a person authorized pursuant to law to consent to health care for the enrollee and, in the case of medical necessity appeals, transmitting the clinical standards used to determine medical necessity for health care services within three business days of receiving notification of the external appeal from the certified external appeal agent to which the subject appeal is assigned, or in the case of an expedited appeal, within 24 hours of receiving

notification of the external appeal from the certified external appeal agent to which the subject appeal is assigned;

- (3) Providing information requested by the assigned certified external appeal agent as soon as is reasonably possible, but in no event shall the health care plan take longer than two business days to provide the requested information for standard appeals. Requests for information relative to expedited appeals must be provided to the certified external appeal agent within 24 hours; and
- (4) Providing a form and instructions, developed jointly by the commissioner and superintendent, for an enrollee's health care provider to request an external appeal in connection with a retrospective adverse utilization review determination under section 4904 of the Public Health Law, within three business days of a health care provider's request for a copy of the form. For retrospective adverse determinations, health care plans may charge the appealing health care provider up to \$50 for each appeal, provided however, that no fee may be charged to an enrollee for a health care provider's external appeal of a retrospective adverse determination and provided further, that in the event a retrospective adverse determination is overturned on external appeal, the full amount of the fee shall be refunded to the appealing health care provider.
 - (i) In the event an adverse determination is overturned on external appeal, or in the event that the health care plan reverses a denial which is the subject of external appeal, the health care plan shall provide, arrange to provide or make payment for the health care service(s) which is the basis of the external appeal to the enrollee to the extent that such health care service(s) is provided while the enrollee has coverage with the health care plan. Nothing herein shall be construed to require the health care plan to provide any health care services to an individual who is no longer an enrollee of that health care plan at the time of an external appeal agent's reversal of a health care plan's utilization review denial.
 - (j) Health care plans shall establish the fee, if any, to be charged to enrollees for an external appeal and shall have a methodology for determining an enrollee's eligibility for a waiver of the fee requirement for an external appeal based on financial hardship pursuant to section 4910(3) of the Public Health Law and section 4910(c) of the Insurance Law.
 - (k) Nothing in this Subpart shall be construed to relieve the health care plan of financial responsibility for external appeals that have been assigned to a certified external appeal agent. In the case of a health care plan reversing a

denial which is the subject of an external appeal after assignment of the appeal to a certified external appeal agent, but prior to assignment of clinical peer reviewer(s), the health care plan shall be assessed an administrative fee as prescribed by the commissioner and superintendent.

98-2.10 Responsibilities of certified external appeal agents.

- (a) Within 24 hours of receiving assignment from the superintendent of a request for external appeal, certified external appeal agents shall send notification of such assignment to the enrollee requesting an external appeal or on whose behalf an external appeal is requested, the enrollee's health care plan, the attending physician, as applicable, and, in the case of a provider initiated appeal of a retrospective adverse determination, the enrollee's health care provider. The certified external appeal agent shall include in such notification:
 - (1) a request for any additional documentation that may be available to support the appeal;
 - (2) the address to which any required or additional documentation should be sent;
 - (3) whether the appeal is a standard or expedited appeal; and
 - (4) for purposes of notifying the enrollee's health care plan, as applicable, copies of the documents relied upon by the enrollee's attending physician to establish medical and scientific evidence that the recommended health care service(s) is likely to be more beneficial to the enrollee than any covered standard health care service or procedure.

- (b) Certified external appeal agents shall make a final determination on non-expedited external appeals within 30 days of receiving the request for external appeal from the superintendent, provided that, in the event that the certified external appeal agent requests additional documentation from the enrollee, the enrollee's health care plan, the enrollee's attending physician or health care provider, other than the documentation requested pursuant to subdivision (a) of this section, the certified external appeal agent shall have an additional five business days from receipt of the request for external appeal from the superintendent within which to make a final determination. Certified external appeal agents shall notify the superintendent if additional documentation has been requested.

- (c) Certified external appeal agents shall make a final determination on expedited external appeals within 3 days of receiving the request for external appeal from the superintendent.

- (d) In addition to the requirements in section 4914(2)(d) of the Public Health Law and section 4914(b)(4) of the Insurance Law, the external appeal agent shall consider any documentation submitted by the enrollee or the enrollee's designee, the enrollee's attending physician, the enrollee's health care plan or the enrollee's health care provider that is pertinent to the external appeal under review provided that such documentation is submitted by the earlier of:
- (1) within 45 days from when the enrollee or, in the case of a provider initiated retrospective appeal, the enrollee's health care provider received notice that the health care plan made a final adverse determination or within 45 days of the date from when the enrollee received a letter from the health care plan affirming that both the enrollee and the enrollee's health care plan jointly agreed to waive the internal appeal process; or
 - (2) prior to the external review agent's final determination on the appeal. A certified external appeal agent may not reconsider an appeal for which a final determination has been made based upon receipt of additional information subsequent to such final determination.
- (e) The certified external appeal agent shall forward to the enrollee's health care plan any documentation received by the certified external appeal agent that is pertinent to an appeal that has been referred to the agent by the superintendent. Any such documentation that, in the opinion of the certified external appeal agent, constitutes a material change from the documentation upon which the utilization review agent based its adverse determination or upon which the health care plan based its denial shall be forwarded immediately, but no later than 24 hours after receipt of such documentation, to the enrollee's health care plan, with notification that such documentation represents a material change, for consideration pursuant to section 4914(2)(a) of the Public Health Law and section 4914(b)(1) of the Insurance Law. In the event of receipt of such material documentation, for other than expedited appeals, the certified external appeal agent shall not issue a determination for up to three (3) business days or until the health care plan has considered such documentation and amended, reversed or confirmed the adverse determination, whichever is earlier.
- (f) For each external appeal determination made by a certified external appeal agent, the medical director of the certified external appeal agent shall certify that:
- (1) the certified external appeal agent and each clinical peer reviewer assigned to review the external appeal followed appropriate procedures as defined in section 4914 of the Public Health Law and Insurance

- Law, section 98-2.10 of this Subpart and the certified external appeal agent's application and, as applicable, conditions for certification;
- (2) all clinical peer reviewers met the criteria for conducting the external review pursuant to subdivision 2 of section 4900 of the Public Health Law and subdivision (b) of section 4900 of the Insurance Law; and
 - (3) or each clinical peer reviewer assigned to review the external appeal, a duly signed and notarized attestation which affirms, under penalty of perjury, that no prohibited material affiliation exists with respect to such clinical peer reviewer's participation in the review of the external appeal pursuant to subdivisions (e), (f) and (h) of section 98-2.6 of this Subpart, is on file with the certified external appeal agent. Such attestation shall be in such form as prescribed by the commissioner and superintendent.
- (g) Certified external appeal agents shall forward copies of appeal determination notification letters sent to health care plans and enrollees pursuant to section 4914(2)(b) and (c) of the Public Health Law and section 4914(b)(2) and (3) of the Insurance Law to the enrollee's health care provider, if applicable, and to the commissioner and superintendent. Such notification letters shall include:
- (1) a clear statement of the health care plan's responsibility in regard to provision of the contested health care service(s) to the enrollee;
 - (2) a statement attesting that no prohibited material affiliation existed with respect to the clinical peer reviewers; and
 - (3) with respect to a medical necessity appeal determination, the reasons for the determination, which shall include a discussion of the health care plan's clinical standards, the information provided concerning the patient, the attending physician's recommendation, and applicable generally accepted practice guidelines developed by the federal government, national or professional medical societies, boards and associations which were used in making the determination; or
 - (4) with respect to an experimental or investigational treatment or service appeal determination, a statement as to whether the proposed health service or treatment is likely to be more beneficial than any standard treatment or treatments for the enrollee's life-threatening or disabling condition or disease; or
 - (5) with respect to a clinical trial appeal determination, a statement as to whether the clinical trial is likely to benefit the enrollee in the treatment of the enrollee's condition or disease.
- (h) Certified external appeal agents shall enclose a request for payment with the copy of the appeal notification letter sent to the health care plan.

- (i) Certified external appeal agents shall not be relieved of responsibility for making a determination with respect to an assigned external appeal on the basis that the enrollee no longer has coverage with the health care plan that denied the health care service(s) that is the subject of the appeal. However, a health care plan will not be required to pay the patient costs of any health service(s) or procedure(s) that is the subject of an external appeal for enrollees who no longer have coverage with such health care plan unless and to the extent that such health care service(s) was provided while the enrollee had coverage with the health care plan.
 - (j) In addition to the information required by section 4916(2) of the Public Health Law and section 4916(b) of the Insurance Law, certified external appeal agents shall include in the annual report a description of each external appeal assigned to such certified external appeal agent by the superintendent, including a summary of the clinical justification for the agent's determination, and any other information required by the commissioner and/or superintendent.
 - (k) In no event shall the certified external appeal agent provide the health care plan with a copy of the enrollee's application for an external appeal or divulge to the health care plan, the enrollee, the enrollee's attending physician or health care provider the names of the clinical peer reviewers assigned to the appeal. However, such information shall be made available upon request to and upon audit or examination by the commissioner and superintendent. Nothing herein is intended to preclude access to such information during court proceedings.
- (l)(1) Upon requesting an external appeal, the enrollee, the enrollee's designee or the enrollee's health care provider shall acknowledge that the determination of the external appeal is binding on the plan and the enrollee, and shall agree not to commence any legal proceeding against an external appeal agent or clinical peer reviewer to review a determination made by such external appeal agent or clinical peer reviewer pursuant to Article 49 of the Public Health Law or Article 49 of the Insurance Law; provided, however, that the foregoing shall not limit any rights the enrollee, the enrollee's designee or the enrollee's health care provider may have with respect to bringing an action for damages for bad faith or gross negligence or with respect to bringing an action against the enrollee's health care plan.
- (2) As specified in Public Health Law section 4914(3) and Insurance Law section 4914(c), no external appeal agent or clinical peer reviewer conducting an external appeal shall be liable in damages to any person for any opinions rendered by such external appeal agent or clinical peer reviewer upon completion of an external appeal conducted pursuant to Article 49 of the Public Health Law or Article 49 of the Insurance Law, unless such opinion was rendered in bad faith or involved gross negligence.

98-2.11 Enrollee rights and responsibilities.

- (a) Enrollees shall be responsible for:
 - (1) Exhausting the health care plan's internal appeal process under section 4904 of the Public Health Law, provided however, that if a health care plan has two levels of internal appeals, the enrollee must only exhaust the first level of appeal. In the alternative, the enrollee and the enrollee's health care plan may jointly agree to waive the internal appeal process;
 - (2) Ensuring that requests for external appeals are filed and completed within the time frames provided for in subdivision (4) of this section, except in the case of transmittal of medical and treatment records, which shall be the responsibility of the enrollee's health care plan;
 - (3) As applicable, providing the attending physician with the documents necessary to complete the physician attestation component of the external appeal request, and, as necessary, providing evidence to the superintendent that such has occurred; and
 - (4) Ensuring that, to the extent possible, all supporting documentation, including but not limited to diagnostic test results and medical literature, is submitted to the assigned certified external appeal agent within the earlier of:
 - (i) 45 days from the date of the enrollee's receipt of a final adverse determination notice or within 45 days of receiving a letter from the health care plan affirming that both the enrollee and the enrollee's health care plan jointly agreed to waive the internal appeal process; or
 - (ii) prior to the date the external appeal determination is finalized by the certified external appeal agent.
 - (5) responding to the superintendent's requests for information concerning an incomplete external appeal request in a timely manner.
- (b) Enrollees whose health benefits are provided through both Title XVIII and XIX of the federal Social Security Act are eligible to request an external appeal only for those health care services covered through Title XIX.
- (c) Enrollees whose health benefits are provided through Title XIX of the federal Social Security Act and who request an external appeal pursuant to Title II of Article 49 of the Public Health Law or the Insurance Law may additionally apply to the Department of Health for a fair hearing pursuant to the terms and within the time frames prescribed by sections 22 and 364-j of the Social Services Law and applicable regulations. Pursuant to section

4910(4) of the Public Health Law and section 4910(d) of the Insurance Law, a fair hearing determination prevails over an external appeal determination; therefore, any appeal for which a determination has been made pursuant to the fair hearing process shall not be considered for external appeal.

- (d) Enrollees, except for those whose health benefits are provided through Title XIX of the federal Social Security Act and Title 1-A of Article 25 of the Public Health Law, are responsible for enclosing a fee with the request for an external appeal to the superintendent in accordance with the fee prescribed by the enrollee's health care plan. The enrollee is responsible for requesting a waiver of the fee requirement from the health care plan if such fee will pose a financial hardship for the enrollee. Enrollees shall not be responsible for paying a fee for any external appeal requested by a health care provider relative to a retrospective adverse determination.

98-2.12 Confidentiality.

- (a) No health care plan may share an enrollee's medical and treatment records or any other confidential information, including HIV related and mental health related information, with a certified external appeal agent or a clinical peer reviewer designated by such certified external appeal agent unless the enrollee, or a person authorized pursuant to law to consent to health care for the enrollee, has signed a specific release of information for HIV, mental health and drug and alcohol abuse or otherwise appropriate release in a manner and in such form as prescribed by the commissioner and superintendent in accordance with section 2782 of the Public Health Law for confidential HIV related information and sections 33.13 and 33.16 of the Mental Hygiene Law for mental health related information and as required by any applicable federal law or regulation.
- (b) No certified external appeal agent or clinical peer reviewer designated by such certified external appeal agent shall, except as specifically authorized by an appropriate release signed by the enrollee or by a person authorized pursuant to law to consent to health care for the enrollee, divulge confidential medical and treatment information or other information obtained through the review of an external appeal to any individual or group except the certified external appeal agent to whom the appeal was assigned and, as necessary, the commissioner and superintendent.

98-2.13 Audits and examinations.

- (a) The commissioner or superintendent or their representative(s) may examine at any time each certified external appeal agent, including any entities under contract with the certified external appeal agent for the purpose of carrying out the requirements of Title II of Article 49 of the Public Health Law or

Title II of Article 49 of the Insurance Law and this Subpart, as to compliance with such requirements and the quality of services offered.

- (b) All external appeal case records shall be subject to audit and examination for a period of six years from the date of the certified external appeal agent's final determination on the appeal. All documentation relating to the case shall be kept and maintained by the certified external appeal agent for no less than six years from the date of the certified external appeal agent's final determination on the appeal. Such documentation shall include, but not be limited to:
 - (1) procedures for credentialing clinical peer reviewers;
 - (2) procedures for selecting clinical peer reviewers for the case, including procedures for ensuring the absence of any prohibited material affiliation relative to clinical peer reviewers;
 - (3) enrollee's medical and treatment records;
 - (4) any other documentation received by the certified external appeal agent relative to the case;
 - (5) notes, comments and determinations of each clinical peer reviewer assigned to the case;
 - (6) written justification when more than three clinical peer reviewers are assigned to a particular case;
 - (7) letter of notification to the enrollee and the enrollee's health care plan and, as applicable, the enrollee's health care provider of the final determination;
 - (8) the names and qualifications of the clinical peer reviewer(s) that reviewed the external appeal; and
 - (9) a signed and notarized attestation from each clinical peer reviewer assigned to an external appeal that no prohibited material affiliation exists with respect to such external appeal.
- (c) The commissioner or superintendent or their representative(s) may examine at any time each health care plan to determine compliance with the requirements of Title II of Article 49 of the Public Health Law or Title II of Article 49 of the Insurance Law and this Subpart.
- (d) All external appeal case records shall be subject to audit and examination for a period of six years from the date of the certified external appeal agent's final determination on the appeal. All documentation relating to the case shall be kept and maintained by the health care plan for no less than six years from the date of the certified external appeal agent's final determination on the appeal. Such documentation shall include, but not be limited to:
 - (1) record of fees collected and waived;

- (2) all correspondence and any other documentation received by and submitted to the certified external appeal agent assigned to the case;
- (3) a copy of the notice provided by the health care plan to the enrollee or, as applicable, the enrollee's health care provider regarding the final utilization review adverse determination and the enrollee's right to request an external appeal; and
- (4) a copy of the letter or other documentation of agreement between the health care plan and the enrollee to waive the health care plan's internal utilization review processes.