PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 9]

Managed Care Organizations

The Department of Health (Department) proposes to amend Chapter 9 (relating to managed care organizations) by deleting the existing regulations in Subchapter A (relating to health care organizations), the statement of policy in Subchapter D (relating to PHOs, POs and IDSs) and the statement of policy in Subchapter E (relating to quality health care accountability and protection). The Department proposes to replace these regulations and statements of policy with the proposed rulemaking regulations in Annex A.

Purpose of the Proposed Rulemaking

The Department's regulations governing health maintenance organizations (HMOs) in Chapter 9 (HMO regulations) were adopted in 1983. The rapid growth in the industry of managed care and the changes in the entities that may deliver and finance health services in the managed care field have caused the Department to supplement those regulations over time through statements of policy. One statement of policy addresses an HMO's ability to contract for certain services through an integrated delivery system. See §§ 9.401—9.416. Another provides guidelines for the implementation of Article XXI of the Insurance Company Law of 1921 amended by the act of June 17, 1998 (P. L. 464, No. 68) (40 P. S. §§ 991.2101—991.2361) (Act 68). See §§ 9.501—9.519.

In 1996, Governor Ridge issued Executive Order 1996-1, which required all State agencies under the Governor's jurisdiction to review their existing regulations. In response to Executive Order 1996-1, the Department convened managed care policy work groups on the following seven topics: consumers; providers; special needs; behavioral health; data collection and standards; quality assurance, utilization and credentialing; and risk assignment, fiscal and financial issues. Included in the work groups were representatives from health plans, providers, purchasers and consumers, as well as Department staff and select staff from the Departments of Public Welfare, Aging, Insurance, Education and the Health Care Cost Containment Council. These groups met from July 1997 to December 1997 for the explicit purpose of providing public input to the Department regarding managed care public policy, in preparation for the revision of the HMO regulations.

In 1998, before revisions to the HMO regulations were completed, the General Assembly passed amendments to The Insurance Company Law of 1921. Act 68 set out specific requirements for managed care plans, which it specifically defined to include any health care plan using a gatekeeper to manage the utilization of health care services. See 40 P. S. § 991.2102 (definition of "managed care plan"). In October of 1998, the Department issued a statement of policy providing interim guidance on implementation of The Insurance Company Law of 1921 (Article XXI). The Department also stated that in 1999 it would adopt formal regulations facilitating the implementation of Article XXI. In May 1999, the Department provided to stakeholders draft regulations combining revisions to the HMO regulations and new provisions facilitating the implementation of Article XXI, and received comments from those entities. The Department has also received input, comments and suggestions from stakeholders concerning their experiences during the implementation stage of Article XXI.

In drafting its proposed regulations, the Department has taken into account the recommendations of the managed care work groups as well as the comments received on the draft regulations from stakeholders. The Department's proposed regulations are intended to address both those areas which specifically impact HMOs, and those requirements which managed care plans (other than managed care plans subject to ERISA) shall meet under Article XXI. These proposed regulations do not apply to traditional indemnity products or preferred provider organizations without gatekeepers, except with respect to proposed § 9.672 (relating to emergency services). Proposed § 9.742 (relating to CREs) reiterates the requirement of section 2151 of Article XXI (40 P. S. § 991.2152) concerning operational standards for utilization review (UR). Section 2151 requires licensed insurers and managed care plans with certificates of authority performing UR to comply with the operational standards for certified utilization review entities (CREs) in section 2152, although it does not require them to be certified by the Department. See 40 P. S. § 991.2151(e).

In proposing these regulations, the Department is attempting to address changes in the managed care industry, to include the statements of policy in regulation as necessary, and to implement the accountability and protection provisions of Act 68. Subchapter A is proposed to be repealed because the Department is updating its regulations governing health maintenance organizations. Subchapters D and E are proposed to be repealed, and relevant sections are being included in the proposed regulations.

Summary of the Proposed Rulemaking

Subchapter F. General

Section 9.601. Applicability.

This section would deal with new subject matter. Proposed § 9.601 defines the purpose of Chapter 9, and clarifies what entities are governed by the chapter. Chapter 9 is intended to apply to managed care plans as defined by Act 68, except when its application is specifically limited to HMOs. Chapter 9 would not apply to plans and HMOs exempted by the exception and preemption provisions of Act 68 (40 P. S. § 991.2193) and the HMO Act (40 P. S. § 1566). Generally, nothing in Chapter 9 is intended to prohibit plans from providing administrative services and health care provider networks to self-funded employers and other licensed insurers.

Subsection (a) would also put plans on notice that the Department also has pertinent regulations on these topics, and that plans shall be in compliance with both sets of regulations.

Subsection (b) would clarify that Chapter 9 applies to entities, including integrated delivery systems (IDS), which undertake plan functions through contracting arrangements. In some instances, the proposed regulations apply specifically to HMO-IDS arrangements.

Subsection (c) would clarify that Chapter 9 would not apply to licensed insurers, except with respect to those licensed insurers performing UR.

Subsection (d) would also clarify that Chapter 9 would not apply to ancillary services.

Section 9.602. Definitions.

The definition section would do two things: update and replace the current definitions relating to the HMO regulations in § 9.2 (relating to definitions); and add definitions relevant to the Department's responsibilities under Act 68.

In proposing changes to the current HMO regulations, the Department is proposing to eliminate outdated and unnecessary definitions, and to revise and add other definitions to reflect current industry trends. For example, the Department is proposing to delete the definitions of three types of HMOs: group practice HMOs, individual practice association HMOs and staff HMOs. Distinguishing these different types of HMOs by definition is no longer relevant for purposes of regulations; the Department applies the same regulations to all HMOs. Further, it is possible that listing only three types could give the impression that only three types of HMOs exist. That is not the case.

The Department is also proposing to delete the definition of the term, "Federally qualified health maintenance organization." Since Federal law no longer provides that a Federally qualified HMO may require an employer to offer it to employes, Federally qualified HMOs are no longer the dominant market force, and need not be addressed specifically in the Department's regulations.

The Department has attempted to recognize industry trends by proposing to add a definition for "IDS—integrated delivery system." An IDS is a method of provider contracting which has evolved since the passage of the HMO Act, and the promulgation of regulations under that act. This arrangement also allows a plan to delegate functions, including medical management oversight, to an entity more closely associated with and expert in those matters. An HMO-IDS arrangement also allows providers to benefit from the additional bargaining power provided by group activity. The Department's proposal to include IDSs in its proposed regulations is recognition that IDS arrangements exist, and are growing in size, scope and responsibility. The Department's responsibilities under the HMO Act require that it have the ability to regulate the arrangements and activities of these entities insofar as they perform the functions of and for HMOs.

The Department's proposal to add a definition for "medical management" is also intended to address the actual manner of doing business in the managed care industry. Medical management is a comprehensive term incorporating the full range of UR, quality assurance, and disease and case management activities. These services have been traditionally performed by HMOs, but with increasing frequency are being delegated by the HMO to IDSs and other entities, such as CREs.

The Department is also proposing to add definitions of terms used but not defined in the HMO Act. These terms include, "external quality assurance assessment," "external quality review organization," "foreign HMO," "inpatient services," "outpatient services," "preventive health care services," "provider network" and "service area." These definitions would add clarity to the regulations.

The Department is proposing to delete the term "primary care physician," and replace it with the term, "primary care provider." "Primary care provider" is the term used by Act 68. The term does not limit a primary care provider to a physician. By changing and broadening the term used, the Department intends to address concerns over enrollee access and availability to physicians in medically underserved areas, and to recognize the ability of licensed professionals other than physicians to perform certain primary care functions by the terms of their licenses.

The Department is proposing to add definitions for the following terms: "ancillary service plans," "complaint," "drug formulary," "emergency service," "grievance," health care provider," "health care service," "managed care plan," "utilization review" and "utilization review entity." These definitions are included in Act 68.

The Department is also proposing to add a definition for the term "ancillary services" since the industry usage of that term encompasses more than what is included by definition in the term "ancillary service plans."

Act 68 does not specifically define the term "gatekeeper." That term, however, is intrinsic to the determination of what entities are managed care plans for the purposes of the act. Act 68 specifically defines a managed care plan covered by the act as, among other things, "a health care plan that uses a gatekeeper . . . ." In proposing a definition for the term, "gatekeeper," the Department has attempted to include the description of a gatekeeper included in definition of "managed care plan." Further, the Department would define "gatekeeper" to include an agent of a managed care plan. These agents may be entities acting on behalf of the plan as well as natural persons.

Along with the proposed definition of "gatekeeper," the Department is proposing to include definitions for two types of managed care plans covered by Act 68: "gatekeeper PPOs" and "POS—point-of-service" plans.

Section 9.603. Technical advisories.

This section would deal with new subject matter. It is intended to provide the Department with the flexibility to address the issues of a rapidly changing industry. A technical advisory issued by the Department would be guidance from the Department on how to meet statutory and regulatory requirements, but would not in and of itself set legally binding standards.

Section 9.604. Plan reporting requirements.

This section would revise and replace current §§ 9.91 and 9.92 (relating to annual reports; and quarterly reports). The Department is proposing to expand the requirements of annual and quarterly reporting, currently applicable only to HMOs, to all managed care plans covered by Act 68. This will enable the Department to fulfill its monitoring and enforcement responsibilities under that article.

The Department is proposing to add several items to the list of reportable items included in § 9.91. Subsection (a)(1) would request enrollment and disenrollment data by product line and county, rather than simply request enrollment and disenrollment data, as does § 9.91. The Department does ask for similar data with this specificity and clarity at the current time. The proposed regulation would merely require what HMOs are now doing voluntarily. Similarly, subsection (a)(4) would require a plan to provide, in an annual report, copies of enrollee literature, including any documents that contain information concerning complaint and grievance rights and procedures. The Department currently requests this information so that the information is available to Department staff to aid enrollees calling for assistance. The proposed regulation would also enable the Department to fulfill its responsibilities relating to the complaint and grievance procedures under Act 68.

In subsection (a)(2), the Department is proposing to ask for utilization data annually as well as quarterly. The Department would also require the plan to provide a copy of its current provider directory, (see subsection (a)(5)) and a listing of all IDS arrangements and enrollment. See subsection (a)(7)). The former is required by section 2111(12) of Article XXI (40 P. S. § 991.2111(12)) concerning responsibilities of managed care plans. The latter is a necessary part of ensuring that the HMO entering into the arrangement remains in compliance with the HMO Act. Since IDSs perform functions originally required of the HMO, the Department must ensure that the HMO-IDS arrangement has sufficient resources and oversight to provide adequate services based on the population being served. Requiring and reviewing reports including specific enrollment and disenrollment data is one way of ensuring that compliance.

In subsection (a)(10), the Department is also proposing to add the requirement that a plan provide a listing of all CREs that perform UR for the plan or a contracted IDS. This would limit possible conflicts of interest by enabling the Department to determine whether a CRE assigned by the Department to review external grievances had provided services to the plan in the past.

Current § 9.91 requires the submission of copies of the HMO's quality assurance report and grievance resolution system. The Department is proposing to extend these requirements to all managed care plans by virtue of Act 68 and the PPO Act. Section 5.1(b)(1)(ii) of the HMO Act (40 P. S. § 1555.1(b)(1)(ii)) provides the Department with authority to determine whether an HMO has demonstrated it has arrangements for an ongoing quality of health care assurance program. Section 10(e) of the HMO Act (40 P. S. § 1560(e)), requires that an HMO establish and maintain a grievance resolution system satisfactory to the Secretary. Section 630 of The Insurance Company Law of 1921, known as the PPO Act (40 P. S. § 764a(e)), provides the Department with the authority to review and approve grievance resolution systems and to require quality and utilization controls of certain preferred provider organizations (PPOs).

The Department is proposing to delete references to Federally qualified HMOs since that distinction is no longer relevant.

Section 9.605. Department investigations.

This section would replace and revise § 9.94 (relating to Departmental investigation) of the HMO regulations. The Department is proposing to extend the section to managed care plans covered by Act 68, under the authority given to it by that act to ensure compliance. See 40 P. S. § 991.2181(d) concerning Departmental powers and duties and 40 P. S. § 2131(c)(2)(ii) concerning confidentiality and Department access to medical records.

Subsection (b) would also expand onsite inspection to any IDS with which an HMO has contracted. This provision is included since an IDS is taking over functions which could have been reviewed during an onsite inspection of the Department if those functions were still being performed by the HMO.

Subsection (d) would allow the Department access to medical records for the purposes of quality assurance, investigation of complaints or grievances, enforcement or other activities related to ensuring an HMO's compliance with Article XXI, the regulations and the laws of the Commonwealth. Section 2131(c)(2)(ii) of Article XXI (40 P. S. § 991.2131(c)(2)(ii)) provides for the Department's review of medical records for this purpose.

Section 9.606. Penalties and sanctions.

Authority for this provision is contained in, and the language is taken directly from, section 15 of the HMO Act (40 P. S. § 1565) and section 2182 of Article XXI (40 P. S. § 991.2182).

Subchapter G. HMOs

This subchapter would be applicable to any corporation that proposes to undertake to establish, maintain and operate an HMO within this Commonwealth, with the exception of an HMO exempted under sections 16 and 17(b) of the HMO Act (40 P. S. §§ 1566 and 1567(b)).

The proposed regulations in this subchapter would be, for the most part, revisions of the regulations in existing Chapter 9, Subchapter A (HMO regulations). The Department proposes to delete several of the provisions altogether. Section 9.31 of the HMO regulations, refers to the Certificate of Need process. Chapter 701 of the Health Care Facilities Act (35 P. S. §§ 448.701—448.712) sunset in December of 1996, therefore, this provision is no longer relevant.

Sections 9.55 and 9.95 (relating to alternative application format for Federally-qualified health maintenance organizatios; and Federally-qualified health maintenance organizations) would also be deleted as irrelevant. Since Federally-qualified HMOs are no longer relevant to the market, they no longer need to be regulated as a distinct entity.

Several of the current regulations add nothing to the Department's regulatory scheme. Retaining similar provisions in the new regulations would be unnecessary. Section 9.54 (relating to standards regarding approval of certificate of authority) merely states that an HMO must meet the minimum operating standards in the regulations. Section 9.71 (relating to operational standards), restates the HMO Act. The Department is proposing not to retain these provisions in the proposed rulemaking.

The Department is also proposing to not retain provisions in § 9.76 (relating to professional staffing) because specific staffing ratios contained in that section are obsolete. Staff model HMOs are no longer prevalent in the industry. Staffing requirements are dealt with at the individual HMO level through credentialing requirements, and provider network recruiting. The requirements for primary care physicians and health care providers would be incorporated into proposed §§ 9.678 and 9.681 (relating to primary care providers; and health care providers). So long as the HMO provides accessibility and access to personnel and facilities in a way that enhances the availability and accessibility of services, and provides for quality assurance mechanisms to ensure the safety of the enrollees, the Department would have no need to dictate staffing in this detail.

Section 9.622. Prohibition against uncertified HMOs.

This section would be substantially similar to current § 9.51 of the HMO regulations (relating to prohibition against uncertified health maintenance organizations). The Department proposes to clarify the language by adding provisions relating to foreign HMOs.

Section 9.623. Preapplication development activities.

This section would revise and replace current § 9.32 of the HMO regulations (relating to preapplication development activities). The revisions would not be substantive except for language stating that a certificate of authority would not be issued until the HMO is able to demonstrate that it has an adequate provider network. The Depart-

ment has been deeming applications complete even though the applicant has not provided all necessary relevant information relating to provider networks.

Application for Certificate of Authority

Section 9.631. Content of an application for an HMO certificate of authority.

This section would revise and replace current § 9.52 of the HMO regulations (relating to content of an application for certificate of authority). The proposed section would be substantially the same as § 9.52, with changes to reflect requirements of Act 68. For example, the Department would require the HMO to provide a copy of its policy on confidentiality (see § 9.631(10)), a description of its provider credentialing system, (see § 9.631(11)), and a description of its complaint and grievance systems. See § 9.631(7).

The Department is proposing to eliminate the requirement that the applicant provide a description of the manner in which subscribers would be selected to the HMO's board. The HMO Act requires that at least one-third of the board be subscribers. The Department is concerned with the outcome of the selection procedure, and not the procedure itself.

The Department is also proposing to eliminate current requirements that an HMO provide a detailed description or reasonable incentives for cost control within the structure and function of the HMO (§ 9.52(11) of the HMO regulations), a job description for the position of medical director, (§ 9.52(16) of the HMO regulations), a procedure for referral of subscribers to nonparticipating specialists (§ 9.52(17) of the HMO regulations), and written procedures for payment of emergency services provided by other than a participating provider (§ 9.52(18) of the HMO regulations). The Department has eliminated these requirements because they have been superceded by requirements in Act 68, or the Department believes they are no longer critical to the review of an applicant.

The Department also proposes to eliminate the requirement that HMOs provide a description of Federal grant or loan funds (§ 9.52(12) of the HMO regulations), since Federal qualification is no longer a relevant distinction.

The Department is also proposing to delete from its proposed regulations governing certificate of authority applications, requirements that the application include a copy of the applicant's most recent financial statement (§ 9.52(13) of the HMO regulations) and a copy of proposed subscriber literature § 9.52(15) of the HMO regulations. These two items are still required on the joint application developed by the Department and the Insurance Department. However, because they pertain to matters within the purview of the Insurance Department, the Department is proposing to remove them from its regulations.

Section 9.632. HMO certificate of authority review by the Department.

This section would be substantially similar to current § 9.53 of the HMO regulations (relating to review by the Department). This section would emphasize the fact that no application for a certificate of authority would be complete for purposes of the HMO Act until all requests for further information are adequately answered by the applicant, and there is evidence of a contracted and credentialed provider network of sufficient capacity to serve the proposed number of enrollees.

The Department is also proposing not to include in this section some of the language from § 9.53(f) of the HMO regulations (relating to public meetings on the application). Since the decision to hold a meeting is within the discretion of the Department, the time frames included in § 9.53(f), which are regulatory and not statutory, are unnecessary.

Section 9.633. HMO board requirements.

This section would be substantially the same as current § 9.96 of the HMO regulations (relating to board composition). The Department is proposing to remove the requirement that the board be composed of one-third enrollees within 1 year from the date of receipt of the certificate of authority, since this is an artificial deadline. The HMO is required to have a board made up of one-third enrollees by the HMO Act (40 P. S. § 1557). The board must reflect the requirements of the act as soon as an HMO has enrollees.

Section 9.634. Location of HMO activities, staff and materials.

This section would deal with new subject matter. Paragraph (1) would require an HMO to make books, records and other documents relevant to it maintaining its certification and complying with Act 68, available to the Department at a location within this Commonwealth, within 48 hours of a Department request. This requirement would ensure that the Department has access to information necessary for it to perform its responsibilities, while allowing the HMO to run its operations as it finds its business requires. The Department is proposing, however, in paragraph (2), that the HMO's medical director responsible for overseeing UR and quality assurance activities would be licensed to practice in this Commonwealth, and qualified to oversee the delivery of health care services here. In paragraph (3), the Department is proposing that the HMO's quality assurance/improvement committee include Pennsylvania licensed health care providers. The Department believes these requirements would be essential for the provision of adequate services to enrollees of this Commonwealth.

Section 9.635. Delegation of HMO operations.

This section would deal with new subject matter. Subsection (a) would address a growing industry trend of the managed care organization delegating certain functions to a contractor with expertise in performing the function. HMOs have never been prohibited from this delegation. The Department asks for delegation information in § 9.52(7) of the HMO regulations (relating to content of application for a certificate of authority).

Although the "management" contracts are traditionally the province of the Insurance Department (see 40 P. S. § 1558(b)), they can impact upon the Department's ability to oversee the quality of health care services through review of provider contracts. See 40 P. S. § 1558(a) (The Secretary has the authority to require renegotiation of provider contracts when they are inconsistent with the purposes of the HMO Act). Subsection (a) would ensure that the Department is able to carry out its responsibilities under the HMO Act.

Further, the Department has the responsibility to ensure that an HMO can provide available and accessible services, and continuity of care. Since these are some of the responsibilities delegated to the contractor, the Department must have the same ability to oversee the contractor performing functions for which the HMO is responsible, as it would the HMO itself, if the functions were still performed directly by the HMO.

To ensure that delegation occurs in a controlled manner that protects both the enrollee and the participating

health care provider, the Department is proposing standards for delegation of this authority in proposed Subchapter H (relating to access and availability), and would require an HMO to meet these standards before a delegation contract would be approved.

Section 9.636. Issuance of a certificate of authority to a foreign HMO.

This section would deal with new subject matter. This proposed section tracks section 6.1 of the HMO Act (40 P. S. § 1556.1). The Department has received more inquiries in recent years from foreign HMOs seeking to do business in this Commonwealth. Therefore, the Department is proposing to include the HMO Act's requirements for a foreign HMO to obtain a certificate of authority in its regulations.

Operational Standards

Section 9.651. HMO provision and coverage of basic health services to enrollees.

Section 9.652. HMO provision of other than basic health services to enrollees.

These sections would revise and replace current § 9.72 of the HMO regulations (relating to basic health services). Section 9.72 implements the HMO Act's requirement that an HMO provide basic health services to the enrollee. See 40 P. S. § 1554. The Department is proposing to divide § 9.72 into several sections, one addressing the provision of basic health services, as defined by the HMO Act (see proposed § 9.651), and the other addressing nonbasic health services, as set out in § 9.72(d). See proposed § 9.652.

Section 9.651 would contain a listing of basic health services that the HMO Act requires an HMO to provide. The Department is proposing to eliminate the definitional language in § 9.72, and to expand, update and combine definitions when necessary. For example, the Department proposes to include physician services in the definition for "inpatient services." See proposed definition of "inpatient services" in proposed § 9.602 (relating to definition). The Department is also proposing to revise the definition of "emergency services" to reflect Act 68's definition of this term. See proposed definitions of "emergency care," "inpatient services," "outpatient services" and "preventive care services" in proposed § 9.602. Finally, the Department is proposing to insert the definitions, revised and updated, from current § 9.72 into proposed § 9.602.

The Department is also proposing to include the relevant material in § 9.72(b), which discusses co-pays and coinsurances, in a separate section specifically on those topics. See proposed § 9.653 (relating to use of co-payments and co-insurances in HMOs).

Section 9.653. Use of co-payments and co-insurances in HMOs.

This section would replace and revise § 9.72(b) of the HMO regulations (relating to basic health services). Section 9.72(b) prohibits unreasonable limitations as to time and cost on an HMO's provision of basic health services. It provides for the imposition of copayments only if those copayments do not exceed the maximum allowable percentages included in the regulations. The Department is proposing to eliminate those percentages because they are too confusing to be effective.

Section 9.654. HMO provision of limited networks to select enrollees.

This section would deal with new subject matter. In the current market, purchasers of health care looking to limit cost are willing to purchase limited networks of health care providers. The Department has the responsibility to ensure HMOs are able to provide access and availability of adequate health care services to enrollees. See 40 P. S. § 1555.1(b)(1)(i). The Department is proposing to add this section to ensure that the limited networks offered are not so circumscribed as to force enrollees out of network to obtain necessary services. If that were to happen, the enrollee could be continuously in a position of incurring maximum out-of-pocket expense for health care services. This situation would violate requirements of the HMO Act that the HMO be able to assure the accessibility and availability of adequate health care services.

In subsection (b)(1), the Department is proposing to require that enrollees in limited networks be fully informed by the HMO of out of network consequences. This would prevent enrollees from incurring unexpected costs.

Section 9.655. HMO external quality assurance assessment.

This section would replace and revise § 9.93 of the HMO regulations (relating to external quality assurance assessment). In subsection (a), the Department is proposing to increase the time frame in which the quality assurance assessment would be required of the HMO from 1 year from the date the HMO receives its certificate of authority to 18 months from that date. This change would be in accordance with standards of Nationally recognized accrediting bodies. In subsection (e), the Department is also proposing to increase the time frame in which an HMO is required to submit a copy of the external quality assurance assessment report to it from 10 business days from the date of receipt by the HMO to 15 days from that date.

Section 9.656. Standards for approval of point-of-service options by HMOs.

This section would deal with new subject matter. Subsection (a) would require an HMO to submit a formal filing in order to offer a POS option. In response to market forces and consumer demand, HMOs have developed benefit plans that provide for greater freedom of choice on the part of consumers. The Department has a responsibility to monitor POSs to ensure access and availability of provider networks to enrollees. The issues that could arise with POS plans would be the same as those that could arise from limited networks. There is the possibility that the primary care provider would perform an inadequate job of gatekeeping, so that enrollees would be forced to choose the higher-out-of pocket option. This situation would defeat the purpose of managed care, and would raise questions of violations of the HMO Act. In subsection (b), the Department is proposing to set out conditions under which POS options could be offered.

Subchapter H. Availability and Access

Section 9.671. Applicability.

This subchapter would be new, and would be derived mainly from the provisions of Act 68. Some sections would incorporate parts of the Department's current relating to HMOs; however, this subchapter would apply to all managed care plans as defined by Act 68, as well as to IDS arrangements with those managed care plans, for the services provided to enrollees of those plans.

Section 9.672. Emergency services.

This section would deal with new subject matter. It would be based on sections 2111(4) and 2116 of Article XXI (40 P. S. §§ 991.2111(4) and 991.2116). Section 2114(g) of Article XXI sets time frames in which emergency services must be provided. Section 2116 of Article XXI eliminates the need for prior authorization for emergency services, and sets out the requirement that the plan pay necessary costs. Subsections (b)—(e) would track these requirements and emphasize the need for the plan to apply the prudent layperson standard to the enrollee's presenting symptoms.

Subsection (f) would be derived from § 9.75(f) of the HMO regulations. Act 68 does not limit coverage for emergency services to participating plan providers. Subsection (f) would require the plan to pay for services provided by a nonparticipating provider at the same rate as it pays to a participating provider, when the services are determined by the plan to be necessary based on the prudent layperson standard.

Emergency services are also referenced in § 9.72 of the HMO regulations. The language included in Act 68 and proposed here would replace and revise the language in this provision.

Section 9.673. Plan provision of prescription drug benefits to enrollees.

Act 68 requires a plan to disclose to enrollees upon written request a description of the procedure by which prescribing providers may prescribe certain drugs. Subsection (c) would, among other things, clarify that a plan must have a procedure that allows for coverage of these prescriptions, and not merely a procedure for writing them.

The Department is also proposing, in subsection (b), to require that any refusal to permit an exception to the plan's formulary requirement would be handled by the plan as a grievance under Act 68. The Department is proposing this requirement because any decision not to provide a drug that is not on the formulary would be based on a determination that there is a prescription drug on the formulary that would be appropriate, and, therefore, would come within Act 68's definition of grievance. See 40 P. S. § 991.2102. Subsection (b) would require that a plan respond to an enrollee's written inquiry concerning whether a specific drug is on the formulary within 30 days of the receipt of the inquiry, and that the plan's response be in writing. This would aid the enrollee to prepare and timely file a grievance.

Section 9.674. Quality assurance standards.

This section would revise and replace § 9.74 of the HMO regulations (relating to quality assurance systems), and extend it to all plans covered by Act 68. The proposed revisions would more closely match the quality assurance standards of Nationally recognized accrediting bodies than the provisions of § 9.74. The Department is proposing standards for a plan's quality assurance program, which are intended to be a counterweight to the potential for underservice and undertreatment which exists in a managed care system. Managed care restricts access and availability of enrollees to a plan-selected network of health care providers. Financial mechanisms used in managed care (for example, capitation) potentially are incentives for underservice and underutilization resulting in poor quality service. The Department, because of its responsibilities under the HMO Act, Act 68 and the PPO Act, has an obligation to set standards for the mechanism by which the plan is to monitor itself for the effectiveness and quality of services being provided. Through subsection (b)(10), the Department proposes to monitor the plan's effectiveness in this area by requiring a copy of the plan's annual report of quality assurance activities.

Section 9.675. Delegation of medical management.

This section would deal with new subject matter. It would set standards for a plan's delegation of medical management authority. The section would ensure that delegation would occur in a controlled manner that would protect both the enrollee and the participating health care provider. The purpose of this type of delegation is, as previously stated, to allow the plan to delegate certain responsibilities to health care providers and those entities with specialized expertise in particular disease groups or populations. Because of the Department's responsibility to ensure the quality of health care services, cost effectiveness, and access to services, the Department must have the same oversight over a contractor, which is performing a service otherwise performed by the plan, as it would have over the plan.

Subsection (b) would require any contractor performing UR, unless the contractor is a licensed insurer or a plan with a certificate of authority, to be certified in accordance with section 2151 of Article XXI.

Section 9.676. Standards for enrollee rights and responsibilities.

This section would replace and revise § 9.77 of the HMO regulations (relating to subscriber rights), and would extend the requirement that an HMO have standards for enrollee rights to all managed care plans. Section 9.77 is a collection of personal rights provided enrollees by statutory and common law and regulation. This new section would require plans to develop procedures to implement enrollee rights and responsibilities. The Department is also proposing that a plan address the disclosure requirements in section 2136 of Article XXI (40 P. S. § 991.2136).

Section 9.677. Requirements of definitions of medical necessity.

This section would deal with new subject matter. Based on information provided to the Department by various work groups involved in the examination of the HMO regulations, it became clear that plans use differing definitions of medical necessity in various documents related to operations of the plan. The Department is proposing language requiring that all definitions of "medical necessity" would be the same to ensure uniformity and consistency of decision making concerning coverage and exclusions.

Section 9.678. Primary care providers.

This proposed section would be based upon the definitions in Act 68 relating to primary care providers. The Department has a similar requirement in § 9.75(c) of the HMO regulations (relating to assurance of access to care) that an HMO must make a primary care physician who is to supervise and coordinate the health care of the subscriber available to each subscriber. This section would establish minimum criteria for availability of a primary care provider to ensure that the provider would be able to fulfill responsibilities as a gatekeeper for the managed care plan. Failure of a primary care provider to perform adequately could seriously weaken the ability of the managed care plan to ensure access and availability of services.

Subsections (c) and (d) would allow a plan to consider, as a primary care provider, both a physician in a

nonprimary care specialty and a certified registered nurse practitioner, if those individuals meet certain standards, including the plan's certification requirements.

Subsection (f) would require plans to have in place policies and procedures allowing an individual to change a primary care provider.

Section 9.679. Access requirements in service areas.

This section would deal with new subject matter. This section would require a plan to have adequate and accessible provider networks by service area before enrollment could be undertaken in those areas. Subsection (c) would require a plan to maintain an adequate number and range of health care providers by specialty and service area to ensure that enrollees would have adequate access to and availability of health care services in each area covered by the plan. Subsection (d) would require a plan to report a change in a service area significant enough to affect a substantial number of enrollees in that area. The Department is proposing it be notified upon an alteration which would affect 10% of enrollees in the service area, 10% being a change significant enough to cause collapse of a delivery system or to stress the delivery system to the point when services are not adequately available. Subsection (e) would require services to be available to enrollees within 20 minutes or 20 miles in urban areas and 30 minutes or 30 miles in rural areas. These times and distances would reflect Federal Health Care Financing Administration (HCFA) requirements for access.

Section 9.680. Access for persons with disabilities.

This proposed section would be new, and would be taken directly from section 2111(11) of Article XXI.

Section 9.681. Health care providers.

This section would replace and revise § 9.75(b), (c) and (e) of the HMO regulations (relating to assurance of access to care). Subsection (a) would require a plan to have a provider directory and distribute it to enrollees. The Department proposes subsection (b) to ensure that an enrollee would be informed that a plan cannot guarantee continued access to a particular health care provider. Subsection (d), which would require a plan to have written procedures governing the accessibility and availability of the enumerated health care services, would replace § 9.75(e), although the Department proposes to make that requirement applicable to all managed care plans. Subsection (c), which would be a simplification of the requirements in § 9.75(d), would require a plan to provide coverage for health care services provided by nonparticipating health care providers according to the same terms and conditions as participating providers when there are no participating health care providers that are capable of performing the service. This subsection would prevent an enrollee from incurring out-of-pocket costs because the plan does not have an adequate network.

Section 9.682. Direct access for obstetrical and gynecological care.

This section would deal with new subject matter, and would be based on section 2111(7) of Article XXI. Subsection (d) would implement the requirements of direct access for obstetrical and gynecological care by requiring the plan's quality assurance committee to approve the terms and conditions under which a directly accessed provider could provide services without prior plan approval. Given the difficulty of defining clinical terms such as, "routine gynecological care" adequately and exhaustively in regulation, the Department proposes to refer the matter to the plan's committee of experts, the quality assurance committee.

Section 9.683. Standing referrals or specialists as primary care providers.

This section would deal with new subject matter, and would be based on section 2111(6) of Article XXI. Section 2111(6) of Article XXI allows an enrollee with a life threatening, degenerative or disabling disease or condition to request and receive an evaluation and, if the plan's established standards are met, receive either a standing referral to a specialist with clinical expertise in the area in question, or the designation of a specialist as the primary care provider. As in proposed § 9.682 (relating to direct access for obstetrical and gynecological care), subsection (b)(1) would require the plan to develop policies, procedures and clinical criteria for conducting evaluations and submit them to its quality assurance committee. In this way, the Department would avoid attempting to regulate clinical criteria, which could quickly become obsolete. The Department also proposes subsection (c) to require that the plan assess these standards annually to monitor the effectiveness of the polices and procedures, as well as the quality of the resultant services provided.

Further, the Department proposes to make a denial of the decision to authorize an arrangement a grievance, in accordance with the definition of grievance in Act 68. See 40 P. S. § 991.2102. Therefore, in subsection (b)(6) and (7) the Department would require that the plan issue its decision on the request in writing within 45 days and include information about the right to appeal the matter as a grievance in the decision.

Section 9.684. Continuity of care.

This section would deal with new subject matter and be based upon section 2117 of Article XXI (40 P. S. § 991.2117). Section 2117 of Article XXI sets out conditions in three circumstances under which a plan must allow for an enrollee to continue with a provider: (1) when the provider has been terminated by the plan, but has not been terminated by the plan for cause (see 40 P. S. § 991.2117(a)); (2) when the enrollee is entering into a plan in which the provider does not participate (see 40 P. S. § 991.2117(d)); and (3) when the new enrollee is pregnant. Id.

Subsection (a)(3) and (4) would facilitate implementation of section 2117 of Article XXI by requiring the plan to notify the enrollees it is able to identify through available data and, in that notification, provide the enrollee with written notice of how to exercise the option to continue care for a transitional period. These requirements would ensure that the enrollee is aware of the option as required by the act, and that the plan is aware of the enrollee's intention to exercise his option under the act.

Subsection (b) would require a new enrollee to notify the plan of the enrollee's intention to continue with a nonparticipating provider. Since the plan has the option under Act 68 to require nonparticipating providers to meet the same terms and conditions as participating providers, this notification requirement would provide the plan with the opportunity to negotiate terms. In addition, however, subsections (g) and (h) would require the plan to give a nonparticipating provider notice of its terms and conditions at the earliest possible opportunity, and to ascertain a terminated provider's willingness to continue with services prior to termination.

The Department has concerns over the possibility that a plan could continue to negotiate with a provider

throughout the 60-day transition period accorded to the enrollee by Act 68. If this were the case, since Act 68 provides that a plan may require a nonparticipating provider to meet the same terms and conditions as a participating provider, an enrollee continuing on with the ongoing course of treatment could find the plan ending negotiations and, therefore, not required to cover the services. To protect enrollees in this situation, subsection (i) would require that the plan hold the enrollee harmless during the period of negotiations with the nonparticipating provider, until the plan notifies the enrollee that the nonparticipating provider would not agree to its terms.

Subchapter I. Complaints and Grievances

Section 9.701. Applicability.

This subchapter applies to the review and appeal of complaints and grievances. This subchapter would be based upon the requirements of Act 68 relating to complaints and grievances. See 40 P. S. §§ 2141, 2142, 2161 and 2162. The Department derives its authority to approve the complaint and grievance process from Act 68, the HMO Act and the PPO Act. The HMO Act requires an HMO to have a grievance resolution process acceptable to the Secretary. See 40 P. S. § 1560(e). The PPO Act requires the Department of Insurance to consult with the Department to determine whether arrangements and provisions for a PPO which assumes financial risk which may lead to under-treatment or poor quality care are adequately addressed by a formal grievance system. See 40 P. S. § 764a(e). This subchapter would replace, in its entirety, the requirements in § 9.73 of the HMO regulations (relating to subscriber grievance systems) with new provisions required by Act 68. This section would clarify that.

Section 9.702. Complaints and grievances.

This section would deal with new subject matter. Subsection (a) would require a plan to provide copies of its complaint and grievance procedures to the Department for review prior to implementation. Subsection (b) would require the plan to correct noncompliant procedures at the Department's direction. Because the plan is given the ability by Act 68 to classify a matter as either a complaint or grievance, the possibility exists that the plan could classify a matter in such a way as to confer an advantage on itself. Subsection (c) would permit either the Insurance Department or the Department to become involved at the classification stage to prevent this problem from arising.

Subsection (d) would allow a plan to set up its own time frames in which the initial grievance must be filed. The Department is proposing to require a plan to allow an enrollee or a health care provider filing a grievance with the consent of the enrollee to have the same amount of time to file first and second level complaints and grievances as a plan is given by the act to consider them.

Section 9.703. Health care provider initiated grievances.

This section would deal with new subject matter. Act 68 allows for provider initiated grievances with the written consent of the enrollee. See 40 P. S. § 991.2161(a). Subsection (b) would protect the enrollee from coercion by not allowing the provider to require consent as a condition of service. Subsection (c) would require that once a provider assumes responsibility for a grievance, the provider must continue to prosecute the grievance through the second level review. Subsection (h) would allow the enrollee to rescind his consent at any time. Through these subsections, the Department would attempt to protect the enrollee from the provider that initially is willing to grieve the matter, but makes a determination during the process that the matter is no longer cost effective for it to pursue. The grievance issue, however, may still represent significant out-of-pocket expense to the enrollee. The Department is not proposing to allow the enrollee to begin the grievance at the initial review, however. Subsection (h) would allow an enrollee to take over the grievance at the point the provider chose to discontinue it. This provision would protect the interests of both parties, and would not be detrimental to the managed care plan.

The Department is also concerned with billing aspects of the provider grievance. Subsections (c) and (d) would prohibit the provider from billing the enrollee until there is an outcome to the grievance. Allowing the provider to bill the enrollee prior to the outcome could result in a double recovery for the provider, or could cause the enrollee to expend time and money affirmatively seeking a refund from that provider.

Finally, subsection (f) would require the provider to clearly disclose to the enrollee the consequences of the enrollee consenting to the provider filing a grievance, and subsection (g) would require the consent form used by the plan to inform the enrollee of the right to rescind consent.

Section 9.704. Internal complaint process.

This section would deal with new subject matter. Its requirements would be similar to those contained in section 2141 of Article XXI (40 P. S. § 991.2141). To ensure the fundamental fairness of the complaint review process, subsection (c)(1)(i) would require that the first level complaint review be made up of persons not involved in the initial decision. In the interests of fundamental fairness, subsection (c)(2)(ii) would require that the plan, during the second level review, provide reasonable flexibility in terms of the enrollee's time and travel distance when scheduling a second level review. The Department is also proposing that the plan provide the enrollee the opportunity to communicate with the review committee if the enrollee cannot attend. Finally, subsection (c)(2)(ii)(A) and (C) would require that the plan identify all persons present at the review for the enrollee. Subsection (c)(2)(iv) would require that the deliberations of the committee, including the enrollee's comments, either be transcribed verbatim or summarized, and forwarded to the Department as part of the complaint record. Subsection (c)(2)(vii) would specify what is to be included in the Act 68 notice to be sent to the enrollee. This information would be necessary for the individual to make a valid appeal to the Department. The Department is proposing that the plan be required to send the notice of the second level decision to the enrollee by a method which would permit the plan to document the enrollee's receipt of the decision. This would enable the Department to fulfill its responsibilities under section 2142 of Article XXI (40 P. S. § 991.2142) by determining whether the enrollee has appealed within 15 days of receipt of the decision.

Section 9.705. Appeal of a complaint decision.

This section would deal with new subject matter, and would include substantially the same information as contained in section 2142 of Article XXI. Subsection (b) would require that an enrollee provide to it certain information along with the appeal, for example, the name of the plan and a description of the issue involved.

Because Act 68 provides authority over complaints to both the Insurance Department and the Department, the Department is proposing in subsection (f) that both agencies jointly determine which agency will hear the appeal.

Lastly, it should be noted that the proposed regulations on the complaint appeal would provide for an appeal to the Department. The proposed regulations would not require that the Department provide the enrollee or the plan an administrative hearing. Subsection (g) would provide that, if either department believes that a hearing is necessary to the resolution of the appeal, it would be able to require and conduct a hearing.

Section 9.706. Enrollee and provider grievance system.

This section would deal with new subject matter. Its requirements would be similar to those contained in section 2161 of Article XXI (40 P. S. § 991.2161). To ensure the fundamental fairness of the process, subsection (c)(2)(ii) would impose similar requirements on the second level grievance review as it is proposing for the second level complaint review. Act 68 requires that the enrollee be afforded notice of the right to be present in the second level review committee meeting of both the complaint and the grievance process. Compare 40 P. S. § 991.2141(c)(2) with 40 P. S. § 991.2161(c)(2). Subsection (c)(2)(ii)(A)—(C) would require that the plan provide reasonable flexibility in terms of the enrollee's time and travel distance when scheduling the second level review, that it provide the enrollee the opportunity to communicate with the review committee if he cannot attend, and that it identify all persons present at the review for the enrollee. Subsection (c)(2)(iii) would require that the deliberations of the committee, including the enrollee's comments, either be transcribed verbatim or summarized, and forwarded to the CRE as part of the grievance record.

The provisions of Act 68 relating to internal grievances differ from those relating to internal complaints in a significant way, however. Act 68 requires inclusion in the first and second level grievance review of a licensed physician or, where appropriate, an approved licensed psychologist, in a same or similar specialty that typically manages or consults on the health care service in the first and second level grievance review. See 40 P. S. § 991.2161(d). To ensure that a plan would be able to obtain input of specialists most closely matched to the service in question, taking into account the calls on the specialist's time and practice, the Department has not read the term "include" to require the physical presence of the licensed physician or approved licensed psychologist referenced in section 2161(d) of Article XXI. Therefore, subsection (c)(3)(ii) proposes to allow this individual to be included in the review, discussion and decisionmaking by written report, telephone or video conference.

If the licensed physician or approved licensed psychologist would not be physically present, however, the Department is proposing in subsection (c)(3)(iii) to require the plan to provide that individual's report to the enrollee or health care provider in advance of the hearing, if the enrollee or health care provider requests the opinion in writing. The Department feels strongly that, to present the most comprehensive case, that the enrollee or the health care provider should be provided the opinion of the licensed physician or approved licensed psychologist prior to the date of the review. The Department is also proposing in subsection (c)(3)(iii) that the plan notify the enrollee or health care provider in advance of the review date of the fact that the licensed physician or approved licensed psychologist will not be physically present, and that that individual's report may be obtained in advance of the review.

Section 9.707. External grievance process.

This section would deal with new subject matter. It would help implement the requirement in Act 68 that a plan establish an external grievance review process, in which the Department participates by the appointment of a CRE to perform the review. See generally 40 P. S. § 991.2162. Subsection (b)(4) would implement this requirement by requiring the plan to provide the Department with two contacts with whom the Department may communicate. Subsection (b)(5) would require that a request for external review contain a certain set of minimum information to aid in the assignment of the CRE and the oversight of the external grievance.

Subsection (b)(7) would require that the plan provide the enrollee or health care provider with its description of the issue, the remedy it believes the enrollee or health care provider is seeking, and list of documents which it is to forward to the CRE. This information would be provided the enrollee within 15 days of the plan's receipt of the enrollee's or health care provider's request for an external grievance review. The Department proposes to require this exchange of information so that the enrollee or health care provider would know what information the plan has provided to the CRE, and would be able to determine whether additional information is necessary. The Department proposes this section in the interests of a full and fair resolution of the grievance without requiring the CRE to sift through duplicate documentation provided both by the plan and the enrollee or health care provider.

Subsection (g) would allow the parties the ability to challenge the appointment of a CRE based on conflict of interest. The parties would be able to object to the appointment until both parties agree on an acceptable CRE. Objection on the part of a plan to a CRE would not alleviate the proposed requirement that, or alter the time frames within which, the plan would be required to provide information to the enrollee. The Department's objective in proposing to allow objections to the appointment is to ensure that all parties agree that the services have been reviewed in an unbiased manner. The Department sees no benefit to having one party or the other believe a bias existed in the procedure. This would taint the outcome of the review and be more likely to force the matter to litigation.

Subsections (c) and (d) would provide for the Department to provide to the plan the name, address and telephone number of the appointed CRE. The plan would provide this information to the enrollee or health care provider. Subsection (e) allows either party, if they desire additional information, to request from the Department additional information from the CRE application. This would provide both parties with sufficient information with which to determine whether challenge of the appointment is necessary.

Subsection (f) would allow a plan to select a CRE if the Department is unable to do so within 2 business days of its receipt of the request. This would avoid inadvertent delay in the system. The enrollee would still be able to object to the plan's choice.

Section 9.708. Grievance reviews by CRE.

This section would deal with new subject matter. It would be base on the requirements for CRE review of an external grievance in section 2162(c)(2)—(5) of Article XXI. Subsections (a) and (b) would set out the time frame for the CRE decision, to whom the decision is to be sent, the basis and clinical rationale for the decision and the standard of review. These two proposed subsections would be based upon language included in section 2162(c)(5) of Article XXI. Subsection (c), which would set out information that the CRE is required to consider, would be based

upon section 2162(c)(2) and (3) of Article XXI. Subsection (d), which would set requirements for who can make the decision on the CRE's behalf, is taken from section 2162(c)(4) of Article XXI.

Subsection (e) would reiterate the applicable definition of "emergency services" which is to be used in reviewing the grievance decision.

Section 9.709. Expedited review.

This section would deal with new subject matter. Act 68 creates an expedited process for any enrollee whose life, health or ability to regain maximum function would be would be placed in jeopardy by the delay occasioned by the normal review process. See 40 P. S. § 991.2161(e). Subsections (a)—(d) would allow an enrollee to have access to an expedited review process at any time these extreme circumstances arise, regardless of whether the appeal would be classified as a complaint or grievance, or whether the review is an internal or external one.

Further, because of the intent to provide a rapid response due to the extreme circumstances, subsection (i) would require the external review agency to issue a rapid response. This would prevent severe and irreparable harm to the enrollee before the decision can be made.

In the interests of expediting the review, the Department is taking steps to ensure that its own processes for appointing CREs do not prohibit the use of an expedited system. Under subsection (f), the Department would make available to the plan methods by which a CRE may be contacted directly by the plan on weekends and State holidays.

Section 9.710. Approval of plan enrollee complaint and enrollee and provider grievance systems.

This section would deal with new subject matter. The Department is proposing to review the enrollee complaint and grievance systems to ensure these systems meet the approval of the Secretary.

Section 9.711. Alternative provider dispute resolution systems.

This section would deal with new subject matter. Prior to Act 68, issues involving procedural errors and administrative denials involving the level or type of health care services provided were handled strictly between the health care plan and the health care provider. The denials occur daily through the routine operations of the plan. With the passage of Act 68, these denials have been interpreted as grievances by some plans, requiring consent of the enrollee for the provider to challenge the denial. This draws the enrollee into an administrative dispute to which the enrollee had not previously been a party since services would generally already have been provided and the enrollee not billed. The Department is attempting to address these issues by proposing this § 9.711. In this section, the Department is proposing to allow for alternative dispute resolution procedures, subject to the Department's approval, (see 40 P. S. § 991.2162(f)), that create mechanisms for routine procedural errors and denials to be addressed by providers and plans without the need for enrollee consent. However, the provider may still opt to obtain enrollee consent and file a grievance.

Subchapter J. Health Care Provider Contracts

Section 9.721. Applicability.

This section would explain that Subchapter J applies to contracts between plans and health care providers, between HMOs and IDSs, and between IDSs and health care providers. The Department is proposing this subchapter, relating to health care provider contracts, under its authority to promulgate regulations relating to contractual relationships between the managed care plan and health care providers under Act 68, the HMO Act and the PPO Act. Section 2111(1) of Article XXI requires a managed care plan to assure availability and access of adequate health care providers to enable enrollees to have access to quality and continuity of care. Section 8(a) of the HMO Act (40 P. S. § 1558(a)) gives the Secretary the authority to require renegotiation of provider contracts when they require excessive payments, fail to include reasonable incentives or contribute to cost escalation.

The PPO Act also requires that the Insurance Department consult with the Department in determining whether arrangements and provisions for a PPO which assumes financial risk which may lead to undertreatment or poor quality care are adequately addressed by quality and utilization controls as well as by a formal grievance system. See 40 P. S. § 764a(e).

The Department's authority to review and approve IDS arrangements comes from these same provisions.

Section 9.722. Plan and health care provider contracts.

This section would deal with new subject matter. This section would inform a plan of what minimum requirements are necessary in a provider contract to make it acceptable to the Department, and to obviate the possibility that the plan will be required to renegotiate the document. Subsections (c) and (d) would include a requirement that provisions related to gag clauses are prohibited. Subsection (e) would require certain consumer protection language, for example, subsection (e)(1) would require a contract to include enrollee hold harmless language, before the contract could be approved. Subsection (e)(7) would require language relating to enrollee notice of plan termination of the provider contract, and language relating to reimbursement which would address the financial incentives prohibition of Act 68. See 40 P. S. § 991.2112.

Section 9.723. IDS.

Section 9.724. HMO-IDS provider contract.

Section 9.725. IDS provider contracts.

In 1996, the Department issued a policy statement addressing IDS. This policy statement, entitled, "PHOs, POs, and IDSs—Statement of Policy," (§§ 9.401—9.416), would be replaced by §§ 9.723—9.725 (relating to IDS; HMO-IDS provider contract; and IDS-provider contracts). The Department is proposing to combine certain provisions of that policy statement, and include those provisions in these sections as discussed as follows.

Section 9.723 would require that IDS contracts meet the terms and conditions of provider contracts in proposed § 9.722. Section 9.723 would require the HMO and its contracted IDS to notify the Department of any action occurring which would prevent the IDS's participating providers from ensuring adequate services. This is in keeping with the Department's responsibility to ensure the accessibility and availability of adequate personnel and facilities. See 40 P. S. § 1555.1(b)(1)(i).

Section 9.724(c)(5) would reinforce the fact that the HMO, as the regulated entity, would be responsible at all times for the services it contracts to have provided. Subsection (c)(6) and (7) would require the IDS to agree to be subject to monitoring by both the HMO and the Department.

Further, § 9.724 would protect the enrollee who is subject to a relationship. Subsection (c)(3) would prohibit the delay, reduction, denial or hindrance in any way of the provision of covered services to enrollees because of the contractual relationship between the IDS and the HMO. Subsection (c)(13) would require termination provisions that would be consistent with, and would enable enrollees to obtain the benefits of, the continuity of care requirements of Act 68. See 40 P. S. § 991.2117.

Section 9.725 would ensure that the contracts between the IDS and its providers make clear the chain of responsibility. This section would require language in the HMO—provider contracts that would ensure that all 3 parties, the provider, the IDS and the plan, would agree and concur that the HMO would have the ultimate responsibility. Further, the language would make clear that the Department would have the authority to review all 3 entities as it would the operations of HMO. Section 9.725 would prohibit language in the contract that would prevent the Department or the HMO from carrying out its functions and duties. Finally, paragraph (4) would require the inclusion in the contract of enrollee hold harmless language protecting enrollees from unexpected out-of-pocket costs.

Subchapter K. CREs

Section 9.741. Applicability.

This section would explain that this subchapter applies to entities seeking certification to practice as CREs in this Commonwealth. This section also applies to licensed insurers for a limited purpose. Sections 2151 and 2152 of Article XXI give the Department the authority to set standards for and approve certification of CREs.

Section 9.742. CREs.

This section would deal with new subject matter. It would reflect the requirements of Act 68 regarding the certification of CREs. See 40 P. S. § 991.2151. Subsection (c) would also clarify that licensed insurers and managed care plans with certificates of authority may perform UR in accordance with the requirements of Act 68, but that it need not obtain a certification from the Department to do so.

Section 9.743. Content of an application for certification as a CREs.

This section would deal with new subject matter. It would establish requirements for the certification application of an entity seeing to perform UR within this Commonwealth. Among other things, subsection (c) would require the applicant to submit information concerning its organization, structure and function, including information concerning location, officers, directors and senior management, and a list of the plans in this Commonwealth for whom the entity currently performs UR. The Department is proposing to have this information provided because the Department will need to communicate with these organizations during external reviews. Also, the Department will need information to prevent conflict of interest situations from arising when it appoints CREs to undertake external reviews.

This section would also require the applicant to describe how it would be able to meet the terms and conditions in section 2152 of Article XXI. For example, subsection (c)(5)(i)—(iv) and (vi) would require the applicant to describe its ability to respond to telephone calls within the period of time set out in the act, its reviewer credentialing process, its ability to arrange for a wide range of health care providers to conduct the reviews, its procedures for ensuring confidentiality and its capacity for maintaining written records for a 3-year period. Subsection (c)(5)(viii) and (ix) would also require the applicant to provide information relating to its experience, including the length of time it has operated in the Commonwealth, if applicable, and a list of three clients for whom the applicant has performed UR.

The Department wants the application to provide it with sufficient information to ensure the applicant is capable of providing the services in accordance with Act 68.

Further, section 2151(c) of Article XXI permits the Department to adopt the standards for certification of CREs of a Nationally recognized accrediting body to the extent the standards meet and exceed the standards set forth in Act 68. Subsection (c)(5)(vii) would require an entity seeking certification to provide evidence of this accreditation if the applicant has undergone the accreditation.

Section 9.744. CREs participating in internal and external grievance reviews.

This section would deal with new subject matter. The Department is proposing to set additional requirements for a CRE wishing to participate in external grievance reviews as contemplated by Act 68. See 40 P. S. § 991.2162. Since this entity may have to participate in expedited reviews, subsection (a)(4) would provide additional information relevant to its ability to conduct an external review.

Section 9.745. Responsible applicant.

This section would deal with new subject matter. This section would require an applicant to be a responsible person. Subsection (a) would define what this term would require. Subsection (b) would require the applicant to be able to utilize the appropriate standard of review in performing reviews, and would further require the applicant to be unbiased in its review.

Section 9.746. Fees for certification and recertification of CREs.

This section would deal with new subject matter. The Department has the authority to establish fees for certification and recertification applications under section 2151(d) of Article XXI. Subsection (a) would require a fee of $1,000 for the initial application for an entity seeking to perform internal URs, and an additional $1,000 for any entity seeking to perform external reviews as well. Subsection (b) would require a fee of $500 for any recertification application. These fees would be commensurate with the amount of administrative time and resources required to review and verify the information in the application (including site visits) and to periodically monitor compliance with the standards.

Section 9.747. Department review and approval of a certification request.

This section would deal with new subject matter. This section would clarify the Department's authority to obtain additional information, inspect the books and records of the applicant and to perform site visits as it finds necessary to determine the applicant's compliance with Act 68 and the regulations. In lieu of a site visit by the Department, subsection (b) would permit the applicant to provide evidence of accreditation by a Nationally recognized accrediting body whose standards meet or exceed the standards of Act 68. If the applicant is not accredited, subsection (c) provides the applicant with the option to undergo a site inspection by a Nationally recognized

accrediting body whose standards meet or exceed the standards of Act 68. The cost of a site visit would be borne by the applicant.

Section 9.748. Maintenance and renewal of CRE certification.

This section would deal with new subject matter. It would allow the Department to monitor a CRE during the 3-year certification period to ensure compliance with Act 68 and proposed regulations, and for purposes of renewal of certification. Subsection (a) would provide for monitoring in several ways: periodic onsite inspections, proof of the CRE's continuing accreditation by a Nationally recognized accrediting body whose standards meet or exceed the standards of Act 68 or an onsite inspection by an accrediting body.

Subsection (b) would require the CRE to submit a renewal application to the Department 60 days prior to the end of the 3-year certification period. The renewal application would include evidence of the CRE's continued accreditation by a Nationally recognized accrediting body whose standards meet or exceed the standards of Act 68, a certification that the CRE has complied with and will continue to comply with Act 68 and the regulations and an updating of the CRE's originally filed list of conflicts of interest and list of CRE contracts with plans. The Department could perform the onsite inspection, or the CRE could opt to have the onsite inspection done by a Nationally recognized accrediting body.

Subchapter L. Credentialing

Section 9.761. Provider credentialing.

This section would deal with new subject matter. It would contain standards that would be modeled after standards utilized by a Nationally recognized accrediting body. The proposed standards would create a process by which a plan may critically evaluate credentials of new health care providers, and reevaluate the credentials and performance of currently contracted health care providers. Because managed care plans limit access to plan-selected and credentialed health care providers, these standards would ensure that the plan has an objective process by which it establishes and monitors its health care provider network. This further would ensure the provision of quality health care services to enrollees.

Affected Parties

The proposed regulations would affect HMOs certified to do business in this Commonwealth; managed care plans as defined by Act 68; including certified HMOs, and enrollees served by and providers who participate in these managed care plans. The proposed regulations would also affect entities, which conduct or want to conduct internal or external URs, since Act 68 requires these CREs to be certified by the Department. Licensed insurers would also be affected by proposed § 9.742. Licensed insurers and managed care plans with certificates of authority performing UR are required to comply with section 2152 of Article XXI. See 40 P. S. § 991.2151(e). Licensed insurers and managed care plans with certificates of authority are not required to seek certification.

Cost and Paperwork Estimates

A. *Cost*

The proposed regulations would have no measurable fiscal impact on local governments or the general public. The members of the general public enrolled in managed care plans governed by the regulations may ultimately experience some increase in health care costs due to the statutory requirements, and the concurrent increase in monitoring of those plans by the Department and the Department of Insurance.

The replacement and revision of the current regulations in Chapter 9 would create no additional cost to the Commonwealth, since these revisions are intended to reflect the current operations of the Department. There will be no additional cost to the Commonwealth, however, there may be additional monitoring duties placed on the Department by Act 68. Those duties are reflected in provisions of the proposed regulations relating to health care accountability and access, complaints and grievances, provider contracts, accreditation of CREs and credentialing.

The proposed regulations relating to HMOs should not have a significant fiscal impact upon HMOs since comprehensive revision and updating of the HMO regulations should make compliance with those regulations easier. With respect to the requirements of Act 68, which the Department proposes to implement through its proposed regulations, there may be some increased cost to managed care plans. The proposed regulations and Act 68 would require a certain composition of review committees, which may add to the cost of the review. The additional disclosure requirements of Act 68 may also have a fiscal impact upon managed care plans, including HMOs.

The proposed regulations would also create a fiscal impact on entities wishing to be certified as CREs. Act 68 authorizes the Department to adopt an application fee for entities requesting certification. The Department is proposing to do so in its proposed regulations. This certification requirement would not apply either to licensed insurers wishing to perform this function, or managed care entities with certificates of authority.

B. *Paperwork*

There would be changes in paperwork requirements associated with the proposed regulations. While the proposed regulations relating solely to HMOs would not alter paperwork requirements for those entities to obtain and maintain certificates of authority, the proposed regulations intended to implement Article XXI would require submission of documents from entities not previously regulated. These requirements would impact the Department, which would be required to review additional contracts and grievance and complaint procedures submitted by managed care plans, and requests for certification from CREs. The Department would also coordinate the external review procedure in Act 68, which would require the Department to appoint and oversee the operations of the CRE conducting the review.

There may be additional paperwork for managed care plans that are not HMOs, since they would be required for the first time to submit complaint and grievance procedures and data to the Department. HMOs are required by current regulations to make these submissions. Act 68 itself creates additional paperwork, since the plans must comply with the mandated complaint and grievance systems detailed in that act. Depending upon how plans operated their grievance systems prior to Act 68, that act and the Department's proposed regulations could require additional paperwork of the plans. Further, again depending upon how managed care plans operated prior to Act 68, that act's requirement that certain disclosures be made to enrollees could result in an increase in paperwork.

Act 68 also creates additional paperwork for CREs. Under Act 68, CREs are required to obtain certification

from the Department to perform utilization reviews of health care services delivered or proposed to be delivered in this Commonwealth. Prior to the passage of Act 68, this requirement did not exist.

Act 68 and the proposed regulations might also create some different or additional paperwork for those members of the general public who obtain health care through managed care plans covered by Act 68. Depending upon the dispute resolution system established by plans prior to Act 68, there might be alterations in the manner in which an enrollee must utilize these procedures.

Effective Dates/Sunset Date

The proposed regulations will become effective upon publication of final-form regulations in the *Pennsylvania Bulletin*. No sunset date has been established. The Department will continually review and monitor the effectiveness of these regulations.

Statutory Authority

The Department's authority to promulgate these proposed regulations is based upon three statutes: the HMO Act (40 P. S. §§ 1551—1567); section 630 of The Insurance Company Law of 1921, known as the PPO Act (40 P. S. § 764a(e)); and Act 68.

The Department has authority to promulgate regulations relating to the certification and operations of HMOs under section 14 of the HMO Act (40 P. S. § 1564). Section 5.1(a) of the HMO Act provides the Department with the authority to determine what information to require in a corporation's application for certification as an HMO. Section 5.1(b)(1)(i) of the HMO Act provides the Department with authority to determine whether an HMO has demonstrated potential ability to assure both availability and accessibility of adequate personnel and facilities in manner enhancing availability, accessibility and continuity of services. Section 5.1(b)(1)(ii) of the HMO Act provides the Department with authority to determine whether an HMO has demonstrated it has arrangements for an ongoing quality of health care assurance program. Section 5.1(b)(1)(iii) of the HMO Act provides the Department with authority to determine whether an HMO has appropriate mechanisms to effectively provide or arrange for provision of basic health care services on a prepaid basis. Section 8(a) of the HMO Act (40 P. S. § 1558(a)) allows the Secretary to require renegotiation of provider contracts when those contracts provide for excessive payments, fail to include reasonable incentives or contribute to escalation of costs of health care services to enrollees. Section 8(a) of the HMO Act also permits the Secretary to require renegotiation when determined that the contracts are inconsistent with the purposes of the HMO Act. Section 10(e) of the HMO Act (40 P. S. § 1560(e)) requires that an HMO establish and maintain a grievance resolution system satisfactory to the Secretary. Section 11(c) of the HMO Act (40 P. S. § 1561(c)) provides the Secretary and his agents with free access to all books, records, papers and documents that relate to the nonfinancial business of the HMO. Finally, section 15 of the HMO Act (40 P. S. § 1565) provides the Department with the authority to suspend or revoke an HMO's certificate of authority, or to fine the HMO for violations of the HMO Act.

The Department has authority to promulgate regulations relating to the health care accountability and protection provisions of Act 68 under section 2181(e) of Article XXI (40 P. S. § 991.2181(e)). Act 68 governs managed care plans, which include, by definition, HMOs and gatekeeper PPOs. See the definition of "managed care plan" in 40 P. S. § 991.2102. Act 68 also regulates CREs operating or wishing to operate in this Commonwealth. See 40 P. S. §§ 991.2151 and 991.2152. The Department has authority to enforce compliance with Article XXI under section 2181(d) of Article XXI (40 P. S. § 991.2181(d)), and to impose fines, obtain injunctions, require plans of correction and ban enrollment under section 2182 of Article XXI (40 P. S. § 991.2182).

Section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)) provides the Department with general authority to promulgate its regulations.

The Department also has authority to review and approve grievance resolution systems and to require quality and utilization controls of certain PPOs under the PPO Act. Section 630 of The Insurance Company Law of 1921 requires that the Insurance Department consult with the Department in determining whether arrangements and provisions for a PPO which assumes financial risk which may lead to undertreatment or poor quality care are adequately addressed by quality and utilization controls as well as by a formal grievance system.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on December 8, 1999, the Department submitted a copy of this proposed rulemaking to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. In addition to submitting the proposed rulemaking, the Department has provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed rulemaking, it will notify the Department by February 17, 2000. The notifications shall specify the regulatory review criteria, which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the regulation by the Department, the General Assembly and the Governor, of objections raised.

Contact Person

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulations to Stacy Mitchell, Director, Bureau of Managed Care, Pennsylvania Department of Health, P. O. Box 90, Harrisburg, PA 17108-0090 (717) 787-5193, within 30 days after publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Persons with a disability who wish to submit comments, suggestions or objections regarding the proposed rulemaking to Ms. Mitchell may do so in an alternative format (such as, audio tape, Braille) or by using V/TT (717) 783-6514 for speech or hearing impaired persons or the Pennsylvania AT&T Relay Service at (800) 654-5984[TT]. Persons who require an alternative format of this document may contact Ms. Mitchell at the above address or telephone numbers so that necessary arrangements may be made.

ROBERT S. ZIMMERMAN, Jr.,
Secretary

Fiscal Note: 10-160. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART I. GENERAL HEALTH

CHAPTER 9. MANAGED CARE ORGANIZATIONS

Subchapter A. (Reserved)

(*Editor's Note:* Sections 9.1, 9.2, 9.31, 9.32, 9.51—9.55, 9.71—9.77 and 9.91—9.97 as they appear in 28 Pa. Code pages 9-2 to 9-18, serial pages (248720), (229397) to (229399), (213093) to (213096), (248721) to (248722), (213099) to (213104) and (239541) to (239542) are proposed to be deleted in their entirety.)

§ 9.1. (Reserved).

§ 9.2. (Reserved).

§ 9.31. (Reserved).

§ 9.32. (Reserved).

§§ 9.51—9.55. (Reserved).

§§ 9.71—9.77. (Reserved).

§§ 9.91—9.97. (Reserved).

Subchapter D. (Reserved)

(*Editor's Note:* Sections 9.401—9.415 as they appear at 28 Pa. Code pages 9-41 to 9-53, serial pages (213130), (248723) to (248724), (213133) to (213140) and (248725) as proposed to be deleted in their entirety.)

§§ 9.401—9.416. (Reserved).

Subchapter E. (Reserved)

(*Editor's Note:* Sections 9.501—9.519 as they appear at 28 Pa. Code pages 9-54 to 9-70, serial pages (248726) to (248742).)

§§ 9.501—9.519. (Reserved).

Subchapter F. GENERAL

Sec.
9.601. Applicability.
9.602. Definitions.
9.603. Technical advisories.
9.604. Plan reporting requirements.
9.605. Department investigations.
9.606. Penalties and sanctions.

§ 9.601. Applicability.

(a) This chapter applies to managed care plans as defined by section 2102 of the act (40 P. S. § 991.2102) unless expressly stated otherwise. Plans are advised to consult the regulations of the Insurance Department on these topics. See 31 Pa. Code Chapters 154 and 301 (relating to quality health care accountability and protection; and health maintenance organizations) to ensure complete compliance with Commonwealth requirements.

(b) An entity, including an IDS, subcontracting with a managed care plan to provide services to enrollees shall meet the requirements of Article XXI of the act and Subchapters H—L for services provided to those enrollees.

(c) Section 9.742 (relating to CREs) applies to licensed insurers and managed care plans with certificates of authority.

(d) This chapter does not apply to ancillary service plans.

§ 9.602. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Act—The Insurance Company Law of 1921 (40 P. S. §§ 361—991.2361).

Act 68—The act of June 17, 1998 (P. L. 464, No. 68) (40 P. S. §§ 991.2001—991.2361) which added Articles XX and XXI of the act.

Ancillary service plan—

(i) An individual or group health insurance plan, subscriber contract or certificate, that provides exclusive coverage for dental services or vision services.

(ii) The term also includes Medicare Supplement Policies subject to section 1882 of the Social Security Act (42 U.S.C.A. § 1395ss) and the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) supplement.

Ancillary services—A health care service that is not directly available to enrollees but is provided as a consequence of another covered health care service, such as radiology, pathology, laboratory and anesthesiology.

Article XXI—Sections 2101—2193 of the act (40 P. S. §§ 991.2101—991.2193) relating to health care accountability and protection.

Basic health services—The health care services in § 9.651 (relating to HMO provision and coverage of basic health care services to enrollees).

Certificate of authority—The document issued jointly by the Secretary and the Commissioner that permits a corporation to establish, maintain and operate an HMO.

CRE—Certified utilization review entity. An entity certified under this chapter to perform UR on behalf of a plan.

Commissioner—The Insurance Commissioner of the Commonwealth.

Complaint—

(i) A dispute or objection by an enrollee regarding a participating health care provider, or the coverage (including contract exclusions and noncovered benefits), operations or management policies of a managed care plan, which has not been resolved by the managed care plan and has been filed with the plan or the Department or the Insurance Department.

(ii) The term does not include a grievance.

Department—The Department of Health of the Commonwealth.

Drug formulary—A listing of a managed care plan's preferred therapeutic drugs.

Emergency service—

(i) A health care service provided to an enrollee after the sudden onset of a medical condition that manifests itself by acute symptoms of sufficient severity or severe pain so that a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in one or more of the following:

(A) Placing the health of the enrollee or, with respect to a pregnant woman, the health of the woman or her unborn child in serious jeopardy.

(B) Serious impairment to bodily functions.

(C) Serious dysfunction of any bodily organ or part.

(ii) Transportation and related emergency care provided by a licensed ambulance service shall constitute an emergency service if the condition is as described in subparagraph (i).

Enrollee—A policyholder, subscriber, covered person, member or other individual who is entitled to receive health care services under a managed care plan.

External quality assurance assessment—A review of an HMO's ongoing quality assurance program and operations conducted by a nonplan reviewer such as a Department-approved external quality review organization.

External quality review organization—An entity approved by the Department to conduct an external quality assurance assessment of an HMO.

Foreign HMO—An HMO incorporated, approved and regulated in a state other than the Commonwealth.

Gatekeeper—A health care provider, managed care plan or agent of a managed care plan, from which an enrollee must receive referral or approval for covered health care services as a requirement for payment of the highest level of benefits.

Gatekeeper PPO—A PPO requiring enrollee use of a gatekeeper from which an enrollee must receive referral or approval for covered health care services as a requirement for payment of the highest level of benefits.

Grievance—

(i) A request by an enrollee, or a health care provider with the written consent of the enrollee, to have a managed care plan or CRE reconsider a decision solely concerning the medical necessity and appropriateness of a health care service. If the managed care plan is unable to resolve the matter, a grievance may be filed regarding the decision that does one of the following:

(A) Disapproves full or partial payment for a requested health service.

(B) Approves the provision of a requested health care service for a lesser scope or duration than requested.

(C) Disapproves payment of the provision of a requested health care service but approves payment for the provision of an alternative health care service.

(ii) The term does not include a complaint.

HMO—Health maintenance organization—An organized system that combines the delivery and financing of health care and which provides basic health services to voluntarily enrolled members for a fixed prepaid fee.

HMO Act—The Health Maintenance Organization Act (40 P. S. §§ 1551—1568).

Health care provider—A licensed hospital or health care facility, medical equipment supplier or person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth, including a physician, podiatrist, optometrist, psychologist, physical therapist, certified nurse practitioner, registered nurse, nurse midwife, physician's assistant, chiropractor, dentist, pharmacist or an individual accredited or certified to provide behavioral health services.

Health care service—A covered treatment, admission, procedure, medical supply, equipment or other service, including behavioral health, prescribed or otherwise provided or proposed to be provided by a health care provider to an enrollee under a managed care plan contract.

IDS—Integrated delivery system—A partnership, association, corporation or other legal entity which does each of the following:

(i) Enters into a contractual arrangement with a plan.

(ii) Employs or contracts with health care providers.

(iii) Agrees under its arrangement with the plan to provide or arrange for the provision of covered health care services to enrollees.

(iv) Assumes under the arrangement with the plan full or partial responsibility for conducting any or all of the following activities: quality assurance, UR, credentialing, provider relations or enrollee services.

Inpatient services—Care at a licensed hospital, skilled nursing or rehabilitation facility, including preadmission testing, diagnostic testing performed during an inpatient stay, nursing care, room and board, durable medical equipment, ancillary services, inpatient drugs, meals and special diets, use of operating room and related facilities, use of intensive care and cardiac units and related services.

Licensed insurer—An individual, corporation, association, partnership, reciprocal exchange, inter-insurer, Lloyds insurer and other legal entity engaged in the business of insurance; fraternal benefit societies as defined in the Fraternal Benefit Societies Code (40 P. S. §§ 1142-101—1142-701), and PPOs as defined in section 630 of the act (40 P. S. § 764a).

Managed care plan or *plan*—

(i) A health care plan that uses a gatekeeper to:

(A) Manage the utilization of health care services.

(B) Integrate the financing and delivery of health care services to enrollees by arrangements with health care providers selected to participate on the basis of specific standards.

(C) Provide financial incentives for enrollees to use the participating health care providers in accordance with procedures established by the plan.

(ii) A managed care plan includes health care arranged through an entity operating under any of the following:

(A) Section 630 of the act.

(B) The HMO Act.

(C) The Fraternal Benefit Society Code.

(D) 40 Pa.C.S. §§ 6102—6127 which relates to hospital plan corporations.

(E) 40 Pa.C.S. §§ 6301—6334 which relates to professional health services plan corporations.

(iii) The term includes an entity, including a municipality, whether licensed or unlicensed, that contracts with or functions as a managed care plan to provide health care services to enrollees.

(iv) The term does not include ancillary service plans or an indemnity arrangement which is primarily fee for service.

Medical management—A function that includes any aspect of UR, quality assurance, case management and disease management and other activities for the purposes of determining, arranging, monitoring or providing effective and efficient health care services.

Member—An enrollee.

Outpatient services—Outpatient medical and surgical, emergency room and ancillary services including ambula-

tory surgery and all ancillary services pursuant to ambulatory surgery, outpatient laboratory, radiology and diagnostic procedures, emergency room care that does not result in an admission within 24 hours of the delivery of emergency room care and other outpatient services covered by the plan.

Outpatient setting—A physician's office, outpatient facility, ambulatory surgical facility or a hospital when a patient is not admitted for inpatient services.

PCP—Primary care provider—A health care provider who, within the scope of the provider's practice, supervises, coordinates, prescribes or otherwise provides or proposes to provide health care services to an enrollee; initiates enrollee referral for specialist care; and maintains continuity of enrollee care.

POS plan—Point-of-service plan—

(i) A health care plan which requires an enrollee to select and utilize a gatekeeper to obtain the highest level of benefits with the least amount of out-pocket expense for the enrollee.

(ii) A POS plan may be provided by an HMO or by a gatekeeper PPO.

PPO—A preferred provider organization.

Preventive health care services—

(i) Services provided by the plan to provide for the prevention, early detection and minimization of the ill effects and causes of disease or disability.

(ii) The services include prenatal and well baby care, immunizations and periodic physical examinations.

Provider network—The health care providers designated by a plan to provide health care services to enrollees.

Secretary—The Secretary of Health of the Commonwealth.

Service area—The geographic area in which the plan has received approval to operate from the Department.

UR—Utilization review—

(i) A system of prospective, concurrent or retrospective UR, performed by a utilization review entity or health care plan, of the medical necessity and appropriateness of health care services prescribed, provided or proposed to be provided to an enrollee.

(ii) The term does not include any of the following:

(A) Requests for clarification of coverage, eligibility or health care service verification.

(B) A health care provider's internal quality assurance or UR process unless the review results in denial of payment for a health care service.

§ 9.603. Technical advisories.

The Department may issue technical advisories to assist plans in complying with the HMO Act, Article XXI and this chapter. The technical advisories do not have the force of law or regulation, but will provide guidance on how a plan may maintain compliance with the HMO Act, Article XXI and this chapter.

§ 9.604. Plan reporting requirements.

(a) *Annual reports.* A plan shall submit to the Department on or before April 30 of each year, a detailed report of its activities during the preceding calendar year. The plan shall submit the report in a format specified by the Department in advance of the reporting date, and shall include, at a minimum, the following information:

(1) Enrollment and disenrollment data by product line—for example, commercial, Medicare and Medicaid and by county.

(2) Health care services utilization data.

(3) Data relating to complaints and grievances.

(4) A copy of the current enrollee literature, including subscription agreements, enrollee handbooks and any mass communications to enrollees concerning complaint and grievance rights and procedures.

(5) A copy of the plan's current provider directory.

(6) A statement of the number of physicians leaving the plan and of the number of physicians joining the plan.

(7) A listing of all IDS arrangements and enrollment by each IDS.

(8) Copies of the currently utilized generic or standard form health care provider contracts including copies of any deviations from the standard contracts and reimbursement methodologies.

(9) A copy of the quality assurance report submitted to the plan's Board of Directors.

(10) A listing, including contacts, addresses and phone numbers, of the contracted CREs that perform UR on behalf of the plan or a contracted IDS.

(11) Other information which the Department may request, upon advance notice to the plan.

(b) *Quarterly reports.* Four times per year, a plan shall submit to the Department two copies of a brief quarterly report summarizing key utilization, enrollment, and complaint and grievance system data. Each quarterly report shall be filed with the Department within 45 days following the close of the preceding calendar quarter. The plan shall submit each quarterly report in a format specified by the Department for that quarterly report.

§ 9.605. Department investigations.

(a) The Department may investigate information contained in annual, quarterly or special reports, enrollee complaints relating to quality of care or service, or the deficiencies identified in the course of external quality reviews.

(b) Investigation may include onsite inspection of an HMO's facilities and records, and may include onsite inspection of the facilities and records of any IDS subcontractor.

(c) The Department or its agents shall have free access to all books, records, papers and documents that relate to the business of the HMO, other than financial business.

(d) The Department will have access to medical records of HMO enrollees for the sole purpose of determining the quality of care, investigating complaints or grievances, enforcement, or other activities relating to ensuring compliance with Article XXI, this chapter or other laws of the Commonwealth.

(e) The Department may request submission by the HMO of a special report detailing any aspect of its operations relating to the provision of health care services to enrollees, provider contracting or credentialing, operation of the enrollee complaint and grievance system, or quality assessment.

§ 9.606. Penalties and sanctions.

(a) For violations of Article XXI and this chapter, the Department may take one or more of the following actions:

(1) Impose a civil penalty of up to $5,000 per violation.

(2) Maintain an action in the name of the Commonwealth for an injunction to prohibit the activity that violates the provisions.

(3) Issue an order temporarily prohibiting the plan from enrolling new members.

(4) Require the plan to develop and adhere to a plan of correction approved by the Department which the plan shall make available to enrollees upon written request. The Department will monitor compliance with the plan of correction.

(b) For violations of the HMO Act and this chapter, the Department may suspend or revoke a certificate of authority or impose a penalty of not more than $1,000 for each unlawful act committed if the Department finds that one or more of the following conditions exist:

(1) The HMO is providing inadequate or poor quality care, either directly, through contracted providers or through the operations of the HMO, thereby creating a threat to the health and safety of its enrollees.

(2) The HMO is unable to fulfill its contractual obligations to its enrollees.

(3) The HMO has advertised its services in an untrue, misrepresentative, misleading, deceptive or unfair manner either directly or through any person on its behalf.

(4) The HMO has substantially failed to comply with the HMO Act.

(c) Before the Department may act under subsection (b), the Department will provide the HMO with written notice specifying the nature of the alleged violation and fixing a time and place, at least 10 days thereafter, when a hearing of the matter shall be held. Hearing procedures and appeals shall be conducted in accordance with 2 Pa.C.S. (relating to administrative law and procedure).

(d) A plan may appeal the decision to impose a penalty under subsection (a)(1) or to issue an order under subsection (a)(3) under 2 Pa.C.S. Chapter 5, Subchapter A (relating to practice and procedure of Commonwealth agencies).

Subchapter G. HMOS

GENERALLY

Sec.

APPLICATION FOR CERTIFICATE OF AUTHORITY

OPERATIONAL STANDARDS

GENERALLY

§ 9.621. Applicability.

(a) This subchapter applies to corporations that propose to undertake to establish, maintain and operate an HMO within this Commonwealth, with the exception of an HMO exempted under sections 16 and 17(b) of the HMO Act (40 P. S. §§ 1566 and 1567(b)).

(b) This subchapter is intended to ensure that HMOs certified by the Commonwealth offer increased competition and consumer choice which serve to advance quality assurance, cost effectiveness and access to health care services.

§ 9.622. Prohibition against uncertified HMOs.

(a) A corporation may not, within this Commonwealth, solicit enrollment of members, enroll members or deliver prepaid basic health services, by or through an HMO, unless it has received a certificate of authority from the Secretary and Commissioner to operate and maintain the HMO.

(b) A foreign HMO may not, within this Commonwealth, solicit enrollment of members, enroll members or deliver prepaid basic health care services unless it has received a certificate of authority from the Secretary and the Commissioner to operate and maintain an HMO.

§ 9.623. Preapplication development activities.

The Department will, upon request, provide technical advice and assistance to persons proposing to develop an HMO, including review of health care services provider contracts to be used to establish and maintain an acceptable health care services provider network. A network is required for approval of a certificate of authority.

APPLICATION FOR CERTIFICATE OF AUTHORITY

§ 9.631. Content of an application for an HMO certificate of authority.

An application for a certificate of authority under the HMO Act shall include completed application forms as the Secretary and Commissioner may require. An application for a certificate of authority will not be deemed complete unless it includes at least the following information:

(1) Organizational information including a copy of the applicant's articles of incorporation, bylaws that include a description of the manner by which subscribers will be selected and appointed to the board of directors, an organization chart and clear disclosure of the relationship between the applicant and any affiliated entities owned or controlled by the applicant or which directly or indirectly own or control the applicant.

(2) A list of names, addresses and official positions of the board of directors of the applicant, and of persons who are responsible for the affairs of the applicant, including: President/Chief Executive Officer; Medical Director; Chief Financial Officer; Chief Operating Officer; Directors of Quality Assurance, Utilization Review, Provider Relations, Member Services; and the Director of the Enrollee Complaint and Grievance Process if this responsibility does not fall under one of the previous directorships listed. Resumes shall be included for Chairperson of the Board and the positions listed in this paragraph.

(3) The address of the registered office, in this Commonwealth, where the HMO can be served with legal process.

(4) A copy of each proposed standard form health care services provider contract and each IDS contract includ-

ing a detailed description of the types of financial incentives that the HMO may utilize.

(5) A copy of the HMO's proposed contracts with individual enrollees and groups of enrollees describing the health care coverage to be provided to each individual or group.

(6) A description of the proposed plan services area by county, including demographic data of prospective enrollees and location of contracted providers.

(7) A detailed description of the applicant's proposed enrollee complaint and grievance systems.

(8) A detailed description of the applicant's proposed system for ongoing quality assurance.

(9) A detailed description of the applicant's proposed UR system.

(10) A copy of the applicant's proposed confidentiality policy.

(11) A detailed description of the applicant's proposed provider credentialing system, and standards for ongoing recredentialing activities incorporating quality assurance, UR and enrollee satisfaction measures.

(12) A description of the applicant's capacity to collect and analyze necessary data related to utilization of health care services and to provide the Department with the periodic reports specified in § 9.604 (relating to plan reporting requirements), including a description of the system whereby the records pertaining to the operations of the applicant, including membership and utilization data, are identifiable and distinct from other activities the entity undertakes.

(13) If the applicant intends to delegate any UR functions to a subcontractor, evidence of the subcontractor's certification as a CRE under Subchapter K (relating to CREs) if the certification is required.

(14) A detailed description of the applicant's ability to assure both the availability and accessibility of adequate personnel and facilities to serve enrollees in a manner enhancing access, availability and continuity of covered health care services.

(15) A copy of each contract with an individual or entity for the performance on the HMO's behalf of necessary HMO functions, including marketing, enrollment and administration, and each contract with an insurance company, hospital plan corporation or professional health services corporation for the provision of insurance or indemnity or reimbursement against the cost of health care services provided by the HMO.

(16) A detailed description of the applicant's incentives and mechanisms for cost-control within the structure and function of the applicant.

(17) Other information the applicant may wish to submit for consideration.

(18) Other information the Department requests as necessary to review the applicant's application for compliance with the HMO Act, Act 68 and this chapter.

§ 9.632. HMO certificate of authority review by the Department.

(a) The applicant shall submit a complete application to both the Department and the Insurance Department.

(b) Upon receipt of a complete application for a certificate of authority the Department will publish notification of receipt in the *Pennsylvania Bulletin*. The Department will accept public comments, suggestions or objections to the application for 30 days after publication. The Department may hold a public meeting concerning the application, with appropriate notification to the applicant, and notice to the public through publication of notice in the *Pennsylvania Bulletin*.

(c) Within 45 days of receipt of the application, the Department will notify the applicant of additional information required to complete the application, and of any part of the application which must be corrected by the applicant to demonstrate compliance with the HMO Act or this chapter. A copy of any requests for information sent to the applicant will be sent to the Commissioner.

(d) The Department will review the completed application for compliance with the HMO Act and this chapter. The application will not be considered complete until the required information is provided to the Department in writing, including evidence of a contracted and credentialed provider network of sufficient capacity to serve the proposed number of enrollees.

(e) The Department may visit or inspect the site or proposed site of the applicant's facilities or facilities of the applicant's contractors and its provider network, to ascertain its capability to comply with the HMO Act, Act 68 and this chapter.

(f) The Department will complete its review within 90 days of submission of the completed application.

(g) Within 90 days of receipt of a completed application for a certificate of authority, the Secretary and Commissioner will jointly take action as set forth in paragraph (1) or (2). A disapproval of an application may be appealed in accordance with 2 Pa.C.S. (relating to administrative law and procedure).

(1) Approve the application and issue a certificate of authority.

(2) Disapprove the application and specify in writing the reasons for the disapproval.

§ 9.633. HMO board requirements.

(a) A corporation that has received a certificate of authority shall, within 1 year of its receipt of the certificate, establish and maintain a board of directors at least one-third of whom are enrollees of the HMO. The process to select enrollee members of the board shall be structured to prevent undue influence in the selection process by nonenrollee members of the board and to obtain diverse representation of broad segments of the enrollees covered under HMO contracts issued by the corporation.

(b) A member of the board shall execute a conflict of interest statement certifying that the board member will not engage in forms of self-dealing including the sale, exchange, leasing or furnishing of property, goods, services or facilities between the HMO and the board member, the board member's employer or an organization substantially controlled by the board member, in a manner more favorable to the board member or to the HMO than would be provided to the general public.

(c) The board of the HMO shall be responsible for the operations of the HMO, and shall have the ability to take corrective action when deficiencies are noted in any of its functions regardless of where and by whom the function is performed.

(d) The board shall review and approve the quality assurance plan of the HMO on an annual basis.

§ 9.634. Location of HMO activities, staff and materials.

To demonstrate its ability to assure both availability and accessibility of adequate personnel and facilities to effectively provide or arrange for the provision of basic health services in a manner enhancing access, availability and continuity of care, the HMO shall meet the following minimum standards:

(1) The HMO shall make available for review at a location within in this Commonwealth, by the Department or an agent of the Department, the books and records of the corporation and the essential documents as the Department may require, including signed provider contracts, credentialing files, complaint and grievance files, committee meeting (quality assurance and credentialing) minutes and hearing transcriptions. Documents need not be permanently maintained in this Commonwealth but shall be made available within this Commonwealth within 48 hours.

(2) The HMO shall ensure that the medical director responsible for overseeing the UR and quality assurance activities regarding coverage and services provided to enrollees who are residents of this Commonwealth is appropriately licensed in this Commonwealth, and qualified to oversee the delivery of health care services in this Commonwealth.

(3) The HMO's quality assurance/improvement committee shall include health care providers licensed in this Commonwealth.

§ 9.635. Delegation of HMO operations.

(a) An HMO may contract with any individual, partnership, association, corporation or organization for the performance of HMO operations. A contract for delegation of HMO operations shall be filed with the Commissioner and does not in any way diminish the authority or responsibility of the board of directors of the HMO, or the ability of the Department to monitor quality of care and require prompt corrective action of the HMO when necessary.

(b) An HMO shall delegate medical management authority in accordance with § 9.675 (relating to the delegation of medical management).

§ 9.636. Issuance of a certificate of authority to a foreign HMO.

(a) A foreign HMO may be authorized by issuance of a certificate of authority to operate or to do business in this Commonwealth if the Department is satisfied that it is fully and legally organized and approved and regulated under the laws of its state and that it complies with the requirements for HMOs organized within and certified by the Commonwealth.

(b) A foreign HMO shall submit a completed Commonwealth application for a certificate of authority in accordance with §§ 9.631 and 9.632 (relating to content of an application for an HMO certificate of authority; and HMO certificate of authority review by the Department).

(1) In lieu of the Commonwealth application, a foreign HMO may submit to the Department and the Insurance Department a copy of the application submitted and approved for certificate of authority or licensure in another state with cross references to requirements contained in the Commonwealth's application.

(2) The foreign HMO shall provide, along with the out-of-State application, documentation of any change or modification occurring since that certificate of authority or license was approved.

(3) The foreign HMO shall otherwise affirm that the information submitted to the Department remains current and accurate at the time of submission.

(c) The Department may waive or modify its requirements under the HMO Act and this chapter following a written request from the foreign HMO for the modification or waiver and upon determination by the Department that the requirements are not appropriate to the particular foreign HMO, and that the waiver or modification will be consistent with the purposes of the HMO Act, and that it would not result in unfair discrimination in favor of the HMO of another state.

(d) Foreign HMOs are required to comply on the same basis as Commonwealth certified HMOs with all ongoing reporting and operational requirements, including external quality assurance assessments.

OPERATIONAL STANDARDS

§ 9.651. HMO provision and coverage of basic health services to enrollees.

(a) An HMO shall maintain an adequate network of health care providers through which it provides coverage for basic health services to enrollees as medically necessary and appropriate without unreasonable limitations as to frequency and cost.

(b) An HMO may exclude coverage for the services as are customarily excluded by indemnity insurers, except to the extent that a service is required to be covered by State or Federal law.

(c) An HMO shall provide and cover the following basic health services as the HMO determines to be medically necessary and appropriate according to its definition of medical necessity:

(1) Emergency services on a 24-hour-per-day, 7-day-per-week basis. The plan may not require an enrollee, or a participating health care provider advising the enrollee regarding the existence of an emergency, to utilize a participating health care provider for emergency services, including ambulance services.

(2) Outpatient services.

(3) Inpatient services.

(4) Preventive services.

(d) An HMO shall provide other benefits as may be mandated by State and Federal law.

§ 9.652. HMO provision of other than basic health services to enrollees.

An HMO may provide coverage for other than basic health services including dental services, vision care services, prescription drug services, durable medical equipment or other health care services, provided:

(1) The HMO establishes, maintains and operates a network of participating health care providers sufficient to provide reasonable access to and availability of the contracted nonbasic health services to enrollees.

(2) The health care provider contracts it uses to contract with participating providers meets the requirements of § 9.722 (relating to plan and health care provider contracts).

(3) The provision of those health services is subject to the same complaint and grievance procedures applicable to the provision of basic health services.

§ 9.653. Use of co-payments and co-insurances in HMOs.

Upon the request of the Insurance Department, the Department will review requests by an HMO to incorporate co-payments and co-insurance in the HMO benefit structure, to determine whether these requests would detract from availability, accessibility or continuity of services and to ensure that the request constructively advances the purposes of quality assurance, cost-effectiveness and access.

§ 9.654. HMO provision of limited networks to select enrollees.

(a) An HMO that wants to offer limited subnetworks which include only selected health care providers, shall request approval from the Department to do so.

(b) The Department will approve a request to offer limited subnetworks if the proposal meets the following requirements:

(1) There is adequate disclosure to potential enrollees of the limitations in the number of the HMO's participating providers.

(2) If a covered service is not available within the limited network, the HMO shall provide or arrange for the provision of the service at no additional cost to the enrollee, other than the routine co-payments which would have been applicable if the service had been provided within the limited network.

(3) The limited network has an adequate number and distribution of network providers to provide care which is available and accessible to enrollees within a defined area.

(4) Enrollment is limited to enrollees within a reasonable traveling distance to limited participating network providers.

§ 9.655. HMO external quality assurance assessment.

(a) Within 18 months of receipt of a certificate of authority, and every 3 years thereafter unless otherwise required by the Department, an HMO shall have an external quality assessment conducted using an external quality review organization acceptable to the Department. Department personnel may participate in the external quality assurance assessment.

(b) Costs for the required external review shall be paid by the HMO.

(c) An HMO may combine the external quality assurance assessment with an accreditation review offered by an external quality review organization acceptable to the Department, if the review adequately incorporates assessment factors required by the Department, and allows for Department staff to actively participate in the external review process.

(d) The assessment shall study the quality of care being provided to enrollees and the effectiveness of the quality assurance program established by the HMO.

(e) The external quality review organization shall issue a copy of its findings to the HMO's senior management. It is the responsibility of the HMO to ensure that a copy of all interim and final reports regarding the external quality assessment are filed within 15 days with the Department, either directly by the HMO, or by the external quality review organization.

§ 9.656. Standards for approval of point-of-service options by HMOs.

(a) An HMO shall submit a formal product filing for a POS product to the Department and the Insurance Department.

(b) An HMO may offer POS options to groups and enrollees, if the HMO:

(1) Has a system for tracking, monitoring and reporting enrollee self-referrals for the following purposes:

(i) Periodically informing an enrollee's primary care provider of enrollee self-referred services.

(ii) Promptly investigating any PCP practice in which enrollees are utilizing substantially higher levels of non-PCP referred care than average, to ensure that enrollee self-referrals are not a reflection of access or quality problems on the part of the PCP practice.

(2) Provides clear disclosure to enrollees of out-of-pocket expenses.

(3) Does not directly or indirectly encourage enrollees to seek care without a PCP referral or from out-of-network providers due to an inadequate network of participating providers in any given specialty.

Subchapter H. AVAILABILITY AND ACCESS

Sec.

§ 9.671. Applicability.

This subchapter is applicable to managed care plans, including HMOs and gatekeeper PPOs, and subcontractors of managed care plans, including IDSs, for services provided to enrollees.

§ 9.672. Emergency services.

(a) A plan shall utilize the definition of "emergency service" in section 2102 of the act (40 P. S. § 991.2102) in administering benefits, adjudicating claims and processing complaints and grievances.

(b) A plan may not deny any claim for emergency services on the basis that the enrollee did not receive permission, prior approval, or referral from a gatekeeper or the plan itself prior to seeking emergency service.

(c) A plan may apply the prudent layperson standard to the enrollee's presenting symptoms and services provided in adjudicating related claims for emergency services.

(d) Coverage for emergency services shall include emergency transportation and related emergency care provided by a licensed ambulance service. Use of an ambulance as transportation to an emergency facility for a condition that does not satisfy the definition of "emergency service" does not constitute an emergency service and does not require coverage as an emergency service.

(e) A plan may not require an enrollee to utilize any particular emergency transportation services organization

or a participating emergency transportation services organization for emergency care.

(f) A plan shall cover emergency services provided by a nonparticipating health care provider at the same level of benefit as that provided by a participating health care provider when the plan determines the emergency services were necessary based on the prudent layperson standard.

§ 9.673. Plan provision of prescription drug benefits to enrollees.

(a) A plan providing prescription drug benefit coverage to enrollees, either as a basic benefit or through the purchase of a rider or additional benefit package, and using a drug formulary which lists the plan's preferred therapeutic drugs, shall clearly disclose in its marketing material and enrollee literature that restrictions in drug availability may result from use of a formulary.

(b) An enrollee or a prospective enrollee may make a written inquiry to a plan asking whether a specific drug is on the plan's formulary. The plan shall respond in writing to the request within 30 days from the date of its receipt of the request.

(c) A plan utilizing a drug formulary shall have a written policy that includes an exception process by which a health care provider may prescribe and obtain coverage for the enrollee for specific drugs, drugs used for an off-label purpose, biologicals and medications not included in the formulary for prescription drugs or biologicals when the formulary's equivalent has been ineffective in the treatment of the enrollee's disease or if the drug causes or is reasonably expected to cause adverse or harmful reactions to the enrollee.

(d) The plan shall distribute its policy and process to each participating health care provider who prescribes.

(e) If the plan does not approve a health care provider's request for an exception, the enrollee or the health care provider with the written consent of the enrollee may file a grievance under Subchapter I (relating to complaints and grievances).

§ 9.674. Quality assurance standards.

(a) A plan shall have an ongoing quality assurance program that includes review, analysis and assessment of the access, availability and provision of health care services. The quality assurance program shall provide for a mechanism allowing feedback to be reviewed and used for continuous quality improvement programs and initiatives by the plan.

(b) The quality assurance program shall meet the following standards:

(1) The plan shall maintain a written description of its quality assurance program, documenting studies undertaken, evaluation of results, subsequent actions recommended and implemented, and aggregate data, and shall make this information available to the Department upon request.

(2) The plan shall document all quality assurance activities and quality improvement accomplishments.

(3) The activities of the plan's quality assurance program shall be overseen by a quality assurance committee that includes plan participating physicians in active clinical practice.

(4) The plan's quality assurance structures and processes shall be clearly defined, with responsibility assigned to appropriate individuals.

(5) The plan shall demonstrate dedication of adequate resources, in terms of appropriately trained and experienced personnel, analytic capabilities and data resources for the operation of the quality assurance program.

(6) The plan shall ensure that all participating health care providers maintain current and comprehensive medical records which conform to standard medical practice.

(7) The plan's review of quality shall include consideration of clinical aspects of care, access, availability and continuity of care.

(8) The plan's quality assurance program shall have mechanisms that provide for the sharing of results with health care providers in an educational format to solicit input and promote continuous improvement.

(9) The plan shall provide to the Department a description of the annual quality assurance work plan, or schedule of activities, which includes the objectives, scope and planned projects or activities for the year.

(10) The plan shall present a report of the plan's quality assurance activities annually to the plan's board of directors, and shall provide a copy of the report to the Department.

§ 9.675. Delegation of medical management.

(a) A plan may contract with an entity for the performance of medical management relating to the delivery of health care services to enrollees. The plan shall submit the medical management contract to the Department for review and approval prior to implementation.

(b) If the contractor is to perform UR, the contractor shall be certified in accordance with Subchapter K (relating to utilization review entities).

(c) To secure Department approval, a medical management contract shall include the following:

(1) Reimbursement methods being used to reimburse the contractor which complies with section 2152(b) of the act (40 P. S. § 991.2152(b)) which relates to operational standards for CREs compensation.

(2) The standards for the plan's oversight of the contractor.

(d) Acceptable plan oversight shall include:

(1) Written review and approval by the plan of the explicit standards to be utilized by the contractor in conducting quality assurance, UR or related medical management activities.

(2) Reporting by the contractor to the plan regarding the delegated activities on at least a quarterly basis and the impact of the delegated activities on the quality and delivery of health care to the plan's enrollees.

(3) Random sample re-review and validation of the results of delegated responsibilities to ensure that the decisions made and activities undertaken by the contractor meet the agreed-upon standards in the contract.

(4) A written description of the relationship between the plan's medical management staff and the contractor's medical management staff.

(5) A requirement that the contractor submit written reports of activities and accomplishments to the plan's quality assurance committee on at least a quarterly basis.

(e) With respect to medical management arrangements involving an HMO, the medical management contract shall include a statement by the contractor agreeing to submit itself to review as a part of the HMO's external

quality assurance assessment. See § 9.655 (relating to HMO external quality assurance assessment). A contractor may receive a separate review of its operations by an external quality review organization approved by the Department. The Department will consider the results of the review in its overall assessment provided the review satisfies the requirements of § 9.674 (relating to quality assurance standards).

§ 9.676. Standards for enrollee rights and responsibilities.

The plan shall adopt policies and procedures to assure implementation of enrollee rights and responsibilities which shall include:

(1) Access to the information required by Act 68 and the Insurance Department regulations pertaining to enrollee disclosures.

(2) Instructions as to how non-English speaking and visually-impaired enrollees may obtain the information in an alternative format.

(3) An affirmation that enrollees have the right to be treated with dignity and respect, that medical records will be maintained in a confidential manner, and that enrollees have the right to information and participation with decisionmakers concerning their health care services regardless of whether or not the services are benefits covered by the plan.

(4) Other rights and responsibilities mandated by State and Federal law.

§ 9.677. Requirements of definitions of "medical necessity."

The definition of "medical necessity" shall be the same in the plan's provider contracts, enrollee contracts and other materials used to evaluate appropriateness and to determine coverage of health care services.

§ 9.678. Primary care providers.

(a) A plan shall make available to each enrollee a primary care provider to supervise and coordinate the health care of the enrollee.

(b) A primary care provider shall meet the following minimum standards, unless a specialty health care provider is approved by the plan to serve as a designated primary care provider as provided for in § 9.683 (relating to standing referrals or specialists as primary care providers):

(1) Provide office hours of a minimum of 20 hours-per-week.

(2) Be available directly or through on-call arrangements with other qualified plan participating health care providers, 24 hours-per-day, 7 days-per-week for urgent and emergency care and to provide triage and appropriate treatment or referrals for treatment.

(3) Maintain medical records in accordance with plan standards and accepted medical practice.

(4) Maintain hospital admitting privileges or an alternate arrangement for admitting an enrollee, approved by the plan, that provides for timeliness of information and communication to facilitate the admission, treatment, discharge and follow-up care necessary to ensure continuity of services and care to the enrollee.

(5) Possess an unrestricted license to practice in this Commonwealth.

(c) A plan may consider a physician in a nonprimary care specialty as a primary care provider if the physician meets the plan's credentialing criteria and has been found by the plan's quality assurance committee to demonstrate, through training, education and experience, equivalent expertise in primary care.

(d) A plan may consider a certified registered nurse practitioner (CRNP), practicing in an advanced practice category generally accepted as a primary care area, as a primary care provider, if the CRNP meets the plan's credentialing criteria and practices in accordance with State law.

(e) A plan shall include in its provider directory a clear and adequate disclosure of the applicable referral limitations caused by the choice of a given provider as a primary care provider.

(f) A plan shall establish and maintain a policy and procedure to permit an enrollee to change a designated primary care provider with appropriate advance notice to the plan.

§ 9.679. Access requirements in service areas.

(a) A plan shall provide services to enrollees only in those service areas in which it has been approved to operate by the Department.

(b) A plan seeking to expand its service area beyond that which was initially approved shall file with the Department a service area expansion request.

(c) A plan shall demonstrate at all times that it has an adequate number and range of health care providers by specialty and service area to ensure that enrollees have adequate access to and availability of health care services covered by the plan.

(d) A plan shall immediately report to the Department any serious potential change in the plan's ability to provide services in a particular service area through termination, cancellation or nonrenewal of health care provider contracts potentially affecting 10% or more of the plan's enrollees in the service area.

(e) A plan shall ensure that services for hospitalization, primary care and frequently utilized specialty services shall be available to enrollees within 20 minutes or 20 miles in urban areas, and 30 miles or 30 minutes in rural areas, or based on the availability of health care providers, unless otherwise approved by the Department.

§ 9.680. Access for persons with disabilities.

(a) A plan shall file with the Department its policies, plans and procedures for ensuring that it has within its provider network participating health care providers that are physically accessible to people with disabilities, in accordance with Title III of the Americans with Disabilities Act of 1990 (42 U.S.C.A. §§ 12181—12188.)

(b) A plan shall file with the Department its policies, plans and procedures for ensuring that it has within its provider network participating health care providers who can communicate with individuals with sensory disabilities, in accordance with Title III of the Americans with Disabilities Act of 1990.

§ 9.681. Health care providers.

(a) A plan shall provide to enrollees a provider directory that shall include the name, address and telephone number of each participating health care provider by speciality.

(b) A plan shall include a clear disclaimer in the provider directories it provides to enrollees that the plan cannot guarantee continued access during the term of the enrollee's enrollment to a particular health care provider,

and that if a participating health care provider used by the enrollee ceases participation, the plan will provide access to alternative providers with equivalent training and experience.

(c) A plan that has no participating health care providers available to provide covered health care services shall arrange for and provide coverage for services provided by a nonparticipating health care provider. The plan shall cover the nonnetwork services at the same level of benefit as if a network provider had been available.

(d) A plan shall have written procedures governing the availability and accessibility of frequently utilized health care services, including the following:

(1) Well-patient examinations and immunizations.

(2) Emergency telephone consultation on a 24 hour-per-day, 7 day-per-week basis.

(3) Treatment of acute emergencies.

(4) Treatment of acute minor illnesses.

§ 9.682. Direct access for obstetrical and gynecological care.

(a) The plan shall permit an enrollee direct access to participating health care providers for maternity and gynecological care without referral from a primary care provider.

(b) A plan may not require prior authorization for these services or any aspect of services considered as a routine part of obstetrical and gynecological care including related laboratory or diagnostic procedures.

(c) A plan may require that directly accessed participating health care providers seek prior plan authorization for nonroutine procedures or services and elective inpatient hospitalization.

(d) A plan shall develop policies and procedures that describe the terms and conditions under which a directly accessed health care provider may provide and refer for health care services with and without obtaining prior plan approval. The plan shall have these policies and procedures approved by its quality assurance committee. The plan shall provide these terms and conditions to all health care providers who may be directly accessed for maternity and gynecological care.

§ 9.683. Standing referrals or specialists as primary care providers.

(a) A plan shall adopt and maintain procedures whereby an enrollee with a life-threatening, degenerative or disabling disease or condition shall, upon request, receive an evaluation by the plan and, if the plan's established standards are met, the procedures shall allow for the enrollee to receive either a standing referral to a specialist with clinical expertise in treating the disease or condition, or the designation of a specialist to assume responsibility to provide and coordinate the enrollee's primary and specialty care.

(b) The plan's procedures shall:

(1) Ensure the plan has established standards, including policies, procedures and clinical criteria for conducting the evaluation and issuing or denying the request, including a process for reviewing the clinical expertise of the requested specialist. The plan shall have its standards approved by its quality assurance committee.

(2) Provide for evaluation by appropriately trained and qualified personnel.

(3) Be under a treatment plan approved by the plan and provided in writing to the specialist who will be serving as the primary care provider or receiving the standing referral.

(4) Be subject to the plan's utilization management requirements and other established utilization management and quality assurance criteria.

(5) Ensure that a standing referral to, or the designation of a primary care provider as, a specialist will be made to participating specialists when possible. Nonparticipating specialists may be utilized as appropriate.

(6) Ensure the plan issues a written decision regarding the request for a standing referral or designation of a specialist as a primary care provider within a reasonable period of time taking into account the nature of the enrollee's condition, but within 45 days after the plan's receipt of the request.

(7) Ensure the written decision denying the request provides information about the right to appeal the decision through the grievance process.

(c) A plan shall have mechanisms in place to review the effect of this procedure, and shall present the results to its quality improvement committee on an annual basis.

§ 9.684. Continuity of care.

(a) Provider terminations initiated by the plan shall be governed as follows:

(1) An enrollee may continue an ongoing course of treatment, at the option of the enrollee, for 60 days from the date the enrollee is notified by the plan of the termination or pending termination of a participating health care provider.

(2) If the terminating provider is a primary care provider, the plan shall provide written notice of the termination to each enrollee assigned to that primary care provider and shall request and facilitate the enrollee's transfer to another primary care provider.

(3) If the terminating provider is not a primary care provider, the plan shall notify the affected enrollees identified through referral and claims data.

(4) Written notice from the plan shall include instructions as to how to exercise the continuity of care option, including qualifying criteria, the procedure for notifying the plan of the enrollee's intention and how the enrollee will be notified that a continuing care arrangement has been agreed to by the provider and the plan.

(b) A new enrollee seeking to continue care with a nonparticipating provider shall notify the plan of the enrollee's request to continue an ongoing course of treatment for the transitional period.

(c) The transitional period for an enrollee who is a woman in the second or third trimester of pregnancy as of the effective date of coverage, if she is a new enrollee, or as of the date the termination notice was provided by the plan, shall extend through the completion of postpartum care.

(d) The transitional period may be extended by the plan if extension is determined to be clinically appropriate. The plan shall consult with the enrollee and the health care provider in making this determination.

(e) A plan shall cover health care services provided under this section under the same terms and conditions as applicable for services provided by participating health care providers.

(f) A plan may require nonparticipating health care providers to meet the same terms and conditions as participating health care providers with the exception that a plan may not require nonparticipating health care providers to under go full credentialing.

(g) A plan shall provide the nonparticipating health care provider with written notice of the terms and conditions to be met at either the earliest possible opportunity following notice of termination to the provider, or immediately upon request from an enrollee to continue services with a nonparticipating health care provider.

(h) A plan shall use best efforts to ascertain the health care provider's willingness to continue to provide health care services for the transitional period prior to the actual termination date.

(i) An enrollee shall be held harmless by the plan for services provided by nonparticipating providers post-termination of a participating provider, during the period of negotiations between the plan and the health care provider under subsection (f) up to the time affected enrollees are notified by the plan in writing that agreement is not possible.

(j) This section does not require a plan to provide health care services that are not covered under the terms and conditions of the plan.

(k) If the plan terminates a participating health care provider for cause, the plan will not be responsible for the health care services provided to the enrollee following the date of termination.

Subchapter I. COMPLAINTS AND GRIEVANCES

Sec.

§ 9.701. Applicability.

This subchapter applies to the review and appeal of complaints and grievances under Act 68.

§ 9.702. Complaints and grievances.

(a) *General.*

(1) A plan shall have a two-level complaint and a two-level grievance procedure which meets the requirements of sections 2141, 2142, 2161 and 2162 of Article XXI of the act (40 P. S. §§ 991.2141, 991.2142, 991.2161 and 991.2162) and this subchapter and is satisfactory to the Secretary.

(2) The plan may not incorporate administrative requirements, time frames or tactics to directly or indirectly discourage the enrollee from, or disadvantage the enrollee in utilizing the procedures.

(3) A plan shall provide copies of its complaint and grievance procedures to the Department for review and approval. The Department will use the procedures as a reference when assisting enrollees who contact the Department directly.

(b) *Correction of plan.* A plan shall immediately correct any procedure found by the Department to be noncompliant or to create unacceptable administrative burdens on the enrollee.

(c) *Complaints versus grievances.*

(1) The plan may not classify the appeal as either a complaint or a grievance with the intent to adversely affect or deny the enrollee's access to the process.

(2) If there is any doubt as to whether the appeal is a complaint or a grievance, the plan shall consult with the Department or the Insurance Department as to the most appropriate classification.

(3) An enrollee may contact the Department or the Insurance Department directly for consideration and intervention with the plan, if the enrollee disagrees with the plan's classification of an appeal.

(4) If the Department determines that a grievance has been improperly classified as a complaint, the Department will notify the plan and the enrollee and the case will be redirected to the appropriate level of grievance review. Filing fees shall be waived by the plan.

(5) If the Department determines that a complaint has been improperly classified as a grievance, the Department will notify the plan and the enrollee, and the case will be redirected to the appropriate level of complaint review.

(6) The Department will monitor plan reporting of complaints and grievances and may conduct audits and surveys to verify compliance with Article XXI and this subchapter.

(d) *Time frames.*

(1) A plan may not impose unreasonable time limitations on an enrollee's ability to file an appeal or grievance.

(2) If a plan establishes a time limit for an enrollee to file the initial complaint or grievance, the plan shall allow the enrollee at least 30-calendar days to file the complaint or grievance from the date of the occurrence of the issue being complained about.

(3) If a plan establishes a time frame for an enrollee to file a second level complaint or grievance, the plan shall allow the enrollee at least 45 days to file the second level complaint or grievance from the date of the enrollee's receipt of notice of the plan's decision.

(4) A health care provider seeking to file a grievance with enrollee consent under § 9.703 (relating to health care provider initiated grievances) shall have the same time frames in which to file as an enrollee.

§ 9.703. Health care provider initiated grievances.

(a) A healthcare provider may, with the consent of the enrollee, file a written grievance with a plan.

(b) A health care provider may not require an enrollee to sign an document authorizing the health care provider to file a grievance as a condition of providing a health care service.

(c) Once a health care provider assumes responsibility for filing a grievance, the health care provider may not refuse to grieve the issue through the second level grievance review.

(d) The health care provider may not bill the enrollee for services provided that are the subject of the grievance until the external grievance review has been completed.

(e) If the health care provider elects to appeal an adverse decision of a CRE, the health care provider may not bill the enrollee for services provided that are the subject of the grievance until it chooses not to appeal an adverse decision to a court of competent jurisdiction.

(f) A health care provider, seeking to obtain written consent from an enrollee to file a grievance on behalf of the enrollee, shall clearly disclose to the enrollee in writing that the consent precludes the enrollee from filing a grievance on the same issue unless the enrollee, during the course of the grievance, rescinds in writing the previous written consent.

(g) The written consent form shall inform the enrollee in writing of the right to rescind a consent at any time during the grievance process.

(h) The enrollee may rescind consent to a health care provider, to file a grievance on behalf of the enrollee, at any time during the grievance process. If the enrollee rescinds consent, the enrollee may continue with the grievance at the point at which consent was rescinded. The enrollee may not file a separate grievance. An enrollee who has filed a grievance may, at any time during the grievance process, choose to provide consent to a health care provider to allow the health care provider to continue with the grievance instead of the enrollee.

§ 9.704. Internal complaint process.

(a) A plan shall establish, operate and maintain an internal complaint process which meets the requirements of section 2141 of the act (40 P. S. § 991.2141), and this subchapter, and is acceptable to the Secretary. The process shall address complaints concerning matters including participating health care providers, health plan coverage, plan operations and plan management policies.

(b) A plan shall permit an enrollee to file with it a written or oral complaint.

(c) A plan's internal complaint process shall include the following standards:

(1) *First level review.*

(i) The first level complaint review shall be performed by an initial review committee which shall include one or more employes. The members of the committee may not have been involved in a prior decision to deny the enrollee's complaint.

(ii) A plan shall permit an enrollee to provide written data or other material in support of the complaint. The enrollee may specify the remedy or corrective action being sought.

(iii) The plan shall complete its review and investigation of the complaint within 30 days of receipt of the complaint.

(iv) The plan shall notify the enrollee in writing of the decision of the initial review committee within 5 business days of the committee's decision. The notice shall include the basis for the decision and the procedures and time frame to file a request for a second level review of the decision of the initial review committee.

(2) *Second level review.*

(i) The second level complaint review shall be performed by a second level review committee made up of three or more individuals who did not participate in the first level review. At least one third of the second level review committee may not be employes of the plan. The members of the second level review committee shall have the duty to be unbiased in their review and decision.

(ii) The plan shall notify the enrollee in writing of the right to appear before the second level review committee. The second level review committee shall satisfy the following:

(A) The plan shall provide reasonable flexibility in terms of time and travel distance when scheduling a second level review to facilitate the enrollee's attendance.

(B) If an enrollee cannot appear in person at the second level review, the plan shall provide the enrollee the opportunity to communicate with the review committee by telephone or other appropriate means.

(C) Attendance at the second level review shall be limited to members of the review committee; the enrollee or the enrollee's representatives, or both; the enrollee's provider or applicable witnesses; and appropriate representatives of the plan. Persons attending the second level review and their respective roles at the review shall be identified for the enrollee.

(iii) The decision of the second level review committee shall be binding upon the parties unless appealed by the enrollee.

(iv) The deliberation of the second level review committee, including the enrollee's comments, shall be either by transcribed verbatim or summarized, and maintained as a part of the complaint record to be forwarded to the Department or the Insurance Department upon appeal.

(v) The plan shall complete the second level review within 45 days of the plan's receipt of the enrollee's request for review.

(vi) The plan shall notify the enrollee of the decision of the second level review committee in writing, within 5 business days of the committee's decision.

(vii) The plan shall include in its notice to the enrollee the basis for the decision and the procedures and time frame for the enrollee to file an appeal to the Department or the Insurance Department, including the addresses and telephone numbers of both agencies. The decision shall be sent in a manner so that the plan can document the enrollee's receipt of the decision.

(d) The Department of Health address for purposes of this section is: Bureau of Managed Care, Pennsylvania Department of Health, P. O. Box 90, Harrisburg, PA 17108, (717) 787-5193. The Department may change this address upon prior notification in the *Pennsylvania Bulletin*.

§ 9.705. Appeal of a complaint decision.

(a) An enrollee shall have 15 days from receipt of the second level review decision of a complaint to file an appeal of the decision, in writing, with either the Department or the Insurance Department.

(b) The appeal from the enrollee shall include the following:

(1) The enrollee's name, address and telephone number.

(2) Identification of the plan.

(3) The enrollee's plan ID number.

(4) A brief description of the issue being appealed.

(5) Correspondence from the plan concerning the complaint.

(c) Upon receipt of the appeal, the Department will verify with the plan that the appeal was submitted within

15 days of the enrollee's receipt of the notice of the decision by the second level review committee.

(d) The plan shall forward the complaint file within 5 business days of the Department's request. Upon confirmation that the appeal was filed within the appropriate time frame, the Department will request the complaint file from the plan.

(e) The plan and the enrollee may provide additional information for review and consideration as appropriate.

(f) Both the Department and the Insurance Department will determine the appropriate agency for the review.

(g) The Department may decide to hold an administrative hearing on the appeal. The hearing shall be conducted in accordance with the procedures in 1 Pa. Code Part II (relating to General Rules of Administrative Practice and Procedure).

(h) The enrollee may be represented by an attorney or other individual before the Department.

§ 9.706. Enrollee and provider grievance system.

(a) A plan shall establish, operate and maintain an internal enrollee grievance system in compliance with sections 2161 and 2162 of the act (40 P. S. §§ 991.2161 and 991.2162) and this subchapter and acceptable to the Secretary, for the purposes of reviewing a denial of coverage for a health care service on the basis of medical necessity and appropriateness.

(b) The enrollee, or a health care provider with written consent of the enrollee, may file a written grievance with the plan.

(c) The plan's grievance process shall include the following standards:

(1) *First level review.*

(i) The first level grievance review shall be performed by an initial review committee which shall include one or more individuals selected by the plan. The members of the committee may not have been involved in any prior decision relating to the grievance.

(ii) The plan shall permit the enrollee or the health care provider to provide written data or other material in support of the grievance. The enrollee or health care provider may specify the remedy or corrective action being sought.

(iii) The investigation and the review of the grievance shall be completed within 30 days of receipt of the grievance.

(iv) The plan shall notify the enrollee or the health care provider of the decision of the internal review committee in writing, within 5 business days of the committee's decision. The notice shall include the basis and clinical rationale for the decision and the procedures and time frame for the enrollee or provider to file a request for a second level review of the decision of the initial review committee.

(2) *Second level review.*

(i) The second level review committee reviewing a grievance appealed to the second level of review shall be made up of 3 or more individuals who did not previously participate in the decision to deny coverage or payment for health care services. The members of the second level review committee have the duty to be unbiased in their review and decision.

(ii) The plan shall notify the enrollee or health care provider in writing of the right to appear before the second level review committee. The second level review committee shall satisfy the following:

(A) The plan shall provide reasonable flexibility in terms of time and travel distance when scheduling a second level review to facilitate the enrollee's attendance.

(B) If an enrollee or health care provider cannot appear in person at the second level review, the plan shall provide the enrollee or the health care provider the opportunity to communicate with the review committee by telephone or other appropriate means.

(C) Attendance at the second level review shall be limited to members of the review committee; the enrollee, or the enrollee's representatives, or both; the health care provider; applicable witnesses; and appropriate representatives of the plan. Persons attending and their respective roles at the review shall be identified for the record.

(iii) The deliberation of the second level review committee, including the enrollee's comments, shall be either transcribed verbatim or summarized, and maintained as a part of the grievance record to be forwarded upon appeal.

(iv) The plan shall complete the second level grievance review within 45 days of receipt of the request for the review.

(v) The plan shall notify the enrollee, or in the case of a grievance filed by a health care provider, the provider, of the decision of the second level review committee in writing within 5 business days of the committee's decision.

(vi) The plans shall include the basis and clinical rationale for the decision, and the procedures and time frames for the enrollee or the health care provider to file a request for an external grievance review in its response to the enrollee or health care provider. The decision shall be sent in a manner so that the plan can document the enrollee's or health care provider's receipt of the decision.

(3) *Same or similar specialty.*

(i) Both the initial and second level grievance review committees shall include a licensed physician or an approved licensed psychologist, in the same or similar specialty as that which would typically manage or consult on the health care service in question.

(ii) The physician or approved licensed psychologist, in the same or similar specialty, need not personally attend at the review, but shall be included in the hearing, discussion and decisionmaking by written report, telephone or videoconference.

(iii) If the licensed physician or approved licensed psychologist, in the same or similar specialty, will not be present or included by telephone or videoconference at the review attended by the enrollee or health care provider, the plan shall notify the enrollee or health care provider of that fact in advance of the review and of the enrollee or health care provider right to request a copy of the report. The plan shall provide the enrollee or the health care provider, upon written request, a copy of the report of the licensed physician or approved licensed psychologist at least 7 days prior to the review date.

§ 9.707. External grievance process.

(a) The plan shall establish and maintain an external grievance process by which an enrollee, or a health care provider with the written consent of the enrollee, may

appeal the denial of a second level grievance following receipt of the second level grievance review decision.

(b) The external grievance process shall adhere to the following standards:

(1) An enrollee or health care provider shall have 15 days from receipt of the second level grievance review decision to file an appeal of the decision with the plan.

(2) Within 5 business days of receiving the external grievance request, the plan shall notify the Department, the enrollee or health care provider, and a CRE that conducted the internal grievance review that a request for an external grievance review has been filed.

(3) The plan's notification to the Department shall include a request for assignment of a CRE.

(4) Along with the request, and the information in subsection (k), the plan shall provide the Department with the name, title and phone numbers of both a primary and alternative external grievance coordinator. One of these individuals shall be available to the Department so that expeditious communication may be had regarding the assignment of a CRE both for the purpose of performing external grievance reviews and of tracking the status of the reviews.

(5) The request to the Department shall include the following:

(i) The enrollee's name, address and telephone number.

(ii) If the external grievance is being filed by a health care provider, the health care provider shall provide both the name of the enrollee involved, and its own identifying information.

(iii) The name of the plan.

(iv) The enrollee's plan ID number.

(v) A brief description of the issue being appealed.

(vi) The remedy being sought.

(vii) Correspondence from the plan relating to the matter in question.

(viii) Other reasonably necessary supporting documentation.

(ix) If the external grievance is being requested by a health care provider, verification that the plan and the health care provider have both established escrow accounts in the amount of half the anticipated cost of the review.

(6) Within 15 days of receipt of the external grievance, the plan or the CRE that conducted the internal grievance review shall forward to the CRE the written documentation regarding the denial, including the following:

(i) The decision.

(ii) All reasonably necessary supporting information.

(iii) A summary of applicable issues.

(iv) The contractual language supporting the denial including the plan's definition of "medical necessity" used in the internal grievance reviews.

(7) Within the same 15-day period as provided by paragraph (6), the plan shall provide the enrollee or the health care provider with its description of the issue, the remedy being sought by the enrollee and the list of documents being forwarded to the CRE for the external review.

(8) The enrollee or the health care provider, within 15 days of receipt of notice of appeal sent by the plan, may supply additional information for consideration in the external review but shall route it through the plan to the CRE so that the plan has an opportunity to consider the additional information. The plan shall expeditiously provide the enrollee's or health care provider's information to the CRE.

(c) Within 2 business days of receiving a request for an external grievance review, the Department will assign a CRE from its list of CREs on a rotation basis and will provide notice of the assigned CRE to the plan and CRE.

(d) The plan shall notify the enrollee or health care provider with the name, telephone number and address of the CRE assigned within 2 business days of its receipt of that information from the Department.

(e) The Department will make available additional information from the CRE's accreditation application to the plan, the enrollee or health care provider upon request.

(f) If the Department fails to select a CRE within 2 business days of receipt of the external grievance, the plan may designate a CRE to conduct a review from the list of CREs approved by the Department. A CRE affiliated directly or indirectly with the plan may not be selected by the plan to review the external grievance.

(g) Either party may have 3 business days from the date of its receipt of the notice of assignment of the CRE to object to the CRE assigned based on conflict of interest, and may request the assignment of another CRE. If the plan chooses to object to the CRE, this does not eliminate its responsibility to provide the required information to the enrollee or health care provider within the time frames in this section.

(h) If a party objects, the Department will assign a second CRE in accordance with this subsection. The parties may object to the second CRE in accordance with this subsection.

(i) If either party objects to the second CRE assigned, the 60-day time period allowed for the CRE's review will be calculated from the date on which the CRE is accepted by both parties.

(j) The Department will assign a uniform tracking number, which shall be utilized by the plan, CRE, enrollee and health care provider to communicate with or report data to the Department.

(k) The plan shall authorize a health care service and pay a claim determined to be medically necessary and appropriate by the CRE whether or not the plan has appealed the CRE's decision to a court of competent jurisdiction.

(l) If the health care provider that filed the external grievance is not the prevailing party, the health care provider shall pay the fees and costs associated with the external grievance. If the plan is not the prevailing party, the plan shall pay the fees and costs associated with the external grievance review regardless of the identity of the grievant. For purposes of this section, fees do not include attorney's fees.

§ 9.708. Grievance reviews by CRE.

(a) The assigned CRE shall review and issue a written decision within 60 days of the filing of the request for an external grievance review request. The decision shall be sent to the enrollee, health care provider, plan and the Department. The decision shall include the basis and clinical rationale for the decision.

(b) The assigned CRE shall review the second level grievance review decision based on whether the health care service denied by the internal grievance process is medically necessary and appropriate under the terms of the plan.

(c) The assigned CRE shall review all information considered by the plan in reaching any prior decision to deny coverage for the health care service in question, and information provided under § 9.707 (relating to external grievance process).

(d) The assigned CRE's decision shall be made by either of the following:

(1) One or more physicians certified by a board approved by the American Board of Medical Specialties or the American Board of Osteopathic Specialties, practicing within the same or similar specialty that typically manages or recommends treatment for the health care service being reviewed.

(2) One or more licensed physicians or approved licensed psychologists in active clinical practice or in the same or similar specialty that typically manages or recommends treatment for the health care service being reviewed.

(e) In reviewing a grievance decision relating to emergency services, the CRE shall utilize the emergency service standards of Act 68 and this chapter, and the definition of "medical necessity" and "emergency" in the enrollee's certificate of coverage.

§ 9.709. Expedited review.

(a) A plan shall make an expedited review procedure available to an enrollee if the enrollee's life, health or ability to regain maximum function would be placed in jeopardy by delay occasioned by the review process in this subchapter. An enrollee may request from the plan an expedited review at any stage of the plan's review process.

(b) The plan's internal expedited review process shall be bound by the same rules and procedures as the second level grievance review process with the exception of time frames. It is the responsibility of the enrollee or the health care provider to provide information to the plan in an expedited manner to allow the plan to conform to this section.

(c) A plan shall conduct an expedited internal review and issue its decision within 48 hours of the enrollee's request for an expedited review.

(d) The notification to the enrollee shall state the basis for the decision, including any clinical rationale and the procedure for obtaining an expedited external review.

(e) The enrollee has 2 business days from the receipt of the expedited internal review decision to contact the plan to request an expedited external review.

(f) Within 1 business day of the enrollee request, the plan shall submit a request for an expedited external review to the Department by Fax transmission or telephone call. The Department will make information available to the plan to enable the plan to have direct access to a CRE on weekends and State holidays.

(g) The case will be referred to an external review entity and the Department will assign a CRE within 1 business day of receiving the request for an expedited review.

(h) When assigning a CRE, the Department will rely on information provided by the CRE as to any affiliations or contractual relationships with plans to avoid conflicts of interest.

(i) In all cases, the plan will transfer a copy of the case file to the review entity for receipt on the next business day and the CRE has 2 business days to issue a response.

(j) External expedited review decisions may be appealed to a court of competent jurisdiction.

§ 9.710. Approval of plan enrollee complaint and enrollee and provider grievance systems.

(a) The Department will review the plan's enrollee complaint and grievance systems under its authority to review the operations of the plan and its quality assurance systems, and complaint and grievance resolution systems, to ensure that they are satisfactory to the Secretary.

(b) If changes are made by the plan in procedure or in the description of the enrollee and provider complaint and grievance systems to ensure continued compliance, the plan shall submit a copy of the proposed changes to the Department for prior review.

(c) Complaint and grievance procedures for special populations, such as Medicaid and Medicare HMO enrollees, shall comply with Act 68 to the extent permitted by Federal law and regulation.

§ 9.711. Alternative provider dispute resolution systems.

(a) A plan and a health care provider may agree to an alternative dispute resolution system for the review and resolution of disputes between the health care provider and the plan. These disputes include denials based on procedural errors and administrative denials involving the level or types of health care service provided.

(b) Procedural errors and administrative denials in which the enrollee is held harmless by virtue of the provider contract or when the enrollee has never been advised by the plan in writing that continued health care services would not be covered benefits, will not be automatically viewed as grievances for the purposes of this subchapter and may be addressed by alternate dispute systems.

(c) The alternative dispute resolution procedure shall be included in the health care provider contract with the plan, and shall be enforceable. The contract shall contain a provision that a decision from the alternative dispute resolution system shall be final and binding on both the plan and health care provider.

(d) Nothing in this subchapter precludes a plan and its participating health care providers from creating and maintaining informal dispute resolution systems aimed at expediting the review and determination of problems prior to utilization of the formal grievance procedure.

(e) To be acceptable to the Department, a proposed alternative dispute solution system shall:

(1) Be impartial.

(2) Include specific and reasonable time frames in which to initiate appeals, receive written information, conduct hearings and render decisions.

(3) Provide for final review and determination of provider grievances.

(f) An alternative dispute resolution system may not be utilized for any external grievance filed by an enrollee.

Subchapter J. HEALTH CARE PROVIDER CONTRACTS

Sec.
9.721. Applicability.
9.722. Plan and health care provider contracts.
9.723. IDS.
9.724. HMO-IDS provider contract.
9.725. IDS-provider contracts.

§ 9.712. Applicability.

This subchapter applies to provider contracts between managed care plans subject to Act 68 and health care providers; HMOs subject to the HMO Act and IDSs; and IDSs and health care providers.

§ 9.722. Plan and health care provider contracts.

(a) A plan shall submit the standard form of each type of health care provider contract to the Department for review and approval prior to implementation.

(b) The plan shall submit any change or amendment to a health care provider contract to the Department 10 days prior to implementation of the change or amendment.

(c) To be approved by the Department, a health care provider contract may not contain provisions permitting the plan to sanction, terminate or fail to renew a health care provider's participation for any of the following reasons:

(1) Advocating for medically necessary and appropriate health care services for an enrollee.

(2) Filing a grievance on behalf of and with the written consent of an enrollee, or helping an enrollee to file a grievance.

(3) Protesting a plan decision, policy or practice the health care provider believes interferes with its ability to provide medically necessary and appropriate health care.

(4) Taking another action specifically permitted by section 2113 the act (40 P. S. § 991.2113).

(d) To be approved by the Department, a health care provider contract may not contain any provision permitting the plan to penalize or restrict a health care provider from discussing any of the information health care providers are permitted to discuss under section 2113 of the act or other information the health care provider reasonably believes is necessary to provide to an enrollee full information concerning the health care of the enrollee.

(e) To be approved by the Department, a health care provider contract shall include the following consumer protection provisions:

(1) Enrollee hold harmless language which survives the termination of the health care provider contract regardless of the reason for termination, and includes the following:

(i) A statement that the hold harmless language is construed for the benefit of the enrollee.

(ii) A statement that the hold harmless language supersedes any written or oral agreement currently in existence, or entered into at a later date, between the health care provider and enrollee, or persons acting in their behalf.

(iii) Language to the following effect:

"In no event including, but not limited to, nonpayment by the plan, plan insolvency, or a breach of this contract, shall the provider bill, charge, collect a deposit from, seek compensation or reimbursement from, or have any recourse against the enrollee or persons other than the plan acting on the behalf of the enrollee for services listed in this agreement. This provision does not prohibit collecting supplemental charges or co-payments in accordance with the terms of the applicable agreement between the plan and the enrollee."

(2) Language stating that enrollee records shall be kept confidential by the plan and the health care provider in accordance with section 2131 of the act (40 P. S. § 991.2131) and applicable State and Federal laws and regulations, which include:

(i) Language permitting the Department, the Insurance Department, and, when necessary, the Department of Public Welfare, access to records for the purpose of quality assurance, investigation of complaints or grievances, enforcement or other activities related to compliance with Article XXI, this chapter and other laws of the Commonwealth.

(ii) Language which states that records are only accessible to Department employes or agents with direct responsibilities under subparagraph (i).

(3) Language requiring the health care provider to participate in and abide by the decisions of the plan's quality assurance, UR and enrollee complaint and grievance systems.

(4) Language addressing any alternative dispute resolution systems.

(5) Language requiring the health provider to adhere to State and Federal laws and regulations, including State reporting requirements concerning communicable and noncommunicable diseases and conditions.

(6) Language concerning prompt payment of claims.

(7) Language requiring that the health care provider give at least 60 days advance written notice to the plan of termination of the provider contract.

(f) To be approved by the Department, a health care provider contract shall satisfy the following:

(1) Include the reimbursement method being used to reimburse a participating provider under the contract. If a provider reimbursement is subject to variability due to economic incentives, including bonus incentive systems, withhold pools or similar systems, the plan shall describe the systems and the factors being employed by the plan to determine reimbursement when the contract is submitted to the Department for review.

(2) Include no incentive reimbursement system for licensed professional health care providers which shall weigh utilization performance as a single component more highly than quality of care, enrollee services and other factors collectively.

(3) Include no financial incentive that compensates a health care provider for providing less than medically necessary and appropriate care to an enrollee.

§ 9.723. IDS.

(a) IDS contracts between the IDS and the HMO and between the IDS and the health care provider shall meet the standards of health care provider contracts in § 9.722 (relating to plan and health care provider contracts).

(b) An HMO and an IDS entering into an arrangement under this subchapter shall notify the Department in writing at least 60 days in advance of any proposed action which would result in the IDS's participating providers being unavailable to provide covered services to enrollees,

including institution of litigation, termination or nonrenewal notice by either party.

§ 9.724. HMO-IDS provider contract.

(a) An HMO may contract with an IDS for the provision of care by IDS participating health care providers to HMO enrollees.

(b) To avoid the necessity of renegotiation under section 8(a) of the HMO Act (40 P. S. § 1558(a)), the HMO shall provide a copy of the HMO-IDS contract for review and approval prior to implementation.

(c) Along with the HMO-IDS contract, the HMO shall provide copies of contracts between the IDS and its participating health care providers for the Department's review and approval. For the Department to approve a contract between the HMO and the IDS, the contract shall meet the following standards:

(1) An IDS, assuming financial risk from a HMO, is not required to obtain its own license to assume the risk, provided that the ultimate responsibility for provision of care to enrollees remains, as set forth in the enrollee contract, the responsibility of the HMO, unless the IDS does the following:

(i) Solicits or enrolls members in a plan that will deliver prepaid basic health care services.

(ii) Delivers prepaid basic health care services to those members.

(2) If a person or entity is delivering prepaid basic health care services to enrollees, but not soliciting or enrolling members in a plan, that person or entity is not required to obtain a certificate of authority. If the person or entity is delivering prepaid basic health care services and performing administrative services or other similar functions, but not soliciting or enrolling HMO members, that person or entity is not required to obtain a certificate of authority.

(3) The IDS shall acknowledge and agree that under no circumstance shall provision of covered services to enrollees be delayed, reduced, denied or otherwise hindered because of the financial or contractual relationship between the HMO and the IDS or between the IDS and the participating health care providers.

(4) The IDS shall acknowledge and agree that only those IDS participating health care providers who meet the HMO's credentialing and provider contracting standards may participate and provide services to enrollees and that the ultimate authority to approve or terminate IDS health care providers is retained by the HMO.

(5) The IDS shall acknowledge and agree that the HMO is required to establish, operate and maintain a health care services delivery system, quality assurance system, provider credentialing system, enrollee complaint and grievance system, and other systems meeting Department standards and that the HMO is directly accountable to the Department for compliance with the standards and for provision of high quality, cost-effective care to HMO enrollees. Nothing in the HMO-IDS contract may limit the HMO's authority or responsibility to meet standards or to take prompt corrective action to address a quality of care problem, resolve an enrollee complaint or grievance, or to comply with a regulatory requirement of the Department.

(6) The IDS shall agree to provide the HMO and the Department with access to medical and other records concerning the provision of services to enrollees by the IDS through its participating health care providers. The IDS shall agree to permit and cooperate with onsite reviews by the Department for purposes of monitoring the effectiveness of the IDS performance of any HMO-delegated functions.

(7) The IDS shall agree that any delegation of authority or responsibility, in part or in full, for provider credentialing and relations, quality assessment, UR and other HMO functions to the IDS shall be subject to performance monitoring by the HMO and Department, and is subject to independent validation by the HMO, the Department, or an independent quality review organization or CRE approved by the Department.

(8) The IDS shall agree to collect and provide the HMO with utilization, financial and other data for the purposes of monitoring and comparative performance analysis.

(9) The IDS shall agree to comply with data reporting requirements, including encounter, utilization and reimbursement methodology required by the Department.

(10) The IDS shall obtain and maintain Department certification as a CRE if performing UR activities in Subchapter F (relating to CREs) and sections 2151 and 2152 of the act (40 P. S. §§ 991.2151 and 991.2152).

(11) The HMO-IDS contract shall contain enrollee financial hold-harmless provisions acceptable to the Department which prevent the IDS and IDS participating health care providers from billing HMO enrollees for covered services (other than authorized co-payments, coinsurance or deductibles) under any circumstances including insolvency of the HMO or the IDS.

(12) The HMO-IDS contract shall safeguard patient access to care and avoid significant disruption of service delivery by adequately providing for continuation of services by IDS participating health care providers to HMO enrollees if the HMO-IDS contractual agreement is in any way jeopardized, suspended, terminated or unexpectedly not renewed. In the event of termination, the HMO shall ensure continuity of care for those affected enrollees, under Act 68 and § 9.684 (relating to continuity of care).

(13) The HMO-IDS contract shall contain a provision allowing either party to terminate without cause upon at least 60 days prior written notice.

(14) Any delegation of medical management shall meet the requirements of § 9.675 (relating to delegation of medical management).

§ 9.725. IDS-provider contracts.

In addition to the HMO-IDS contract, the health care provider contracts between the IDS and its participating health care providers shall be submitted for review and approval to the Department. To secure Department approval of a contract between the HMO and the IDS, an IDS-health care provider contract shall meet the following standards:

(1) The health care provider shall acknowledge and agree that nothing in the IDS-provider contract limits the following:

(i) The authority of the HMO to ensure the health care provider's participation in and compliance with the HMO's quality assurance, utilization management, enrollee complaint and grievance systems and procedures or limits.

(ii) The Department's authority to monitor the effectiveness of the HMO's system and procedures or the extent to which the HMO adequately monitors any function delegated to the IDS, or to require the HMO to

take prompt corrective action regarding quality of care or consumer grievances and complaints.

(iii) The HMO's authority to sanction or terminate a health care provider found to be providing inadequate or poor quality care or failing to comply with HMO systems, standards or procedures as agreed to by the IDS.

(2) An IDS health care provider shall acknowledge and agree that any delegation by the HMO to the IDS for performance of quality assurance, utilization management, credentialing, provider relations and other medical management systems shall be subject to the HMO's oversight and monitoring of IDS performance.

(3) An IDS health care provider shall acknowledge and agree that the HMO, upon failure of the IDS to properly implement and administer the systems, or to take prompt corrective action after identifying quality, enrollee satisfaction or other problems, may terminate its contract with IDS, and that as a result of the termination, the health care provider's participation in the HMO may also be terminated.

(4) The IDS provider contract shall contain enrollee financial hold-harmless provisions acceptable to the Department which prevent the IDS and an IDS participating health care provider from billing HMO enrollees for covered services (other than authorized co-payments, coinsurance, or deductibles) under any circumstances including insolvency of the HMO or the IDS.

Subchapter K. CREs

Sec.
9.741. Applicability.
9.742. CREs.
9.743. Content of an application for certification as a CRE.
9.744. CREs participating in internal and external grievance reviews.
9.745. Responsible applicant.
9.746. Fees for certification and recertification of UR entities.
9.747. Department review and approval of a certification request.
9.748. Maintenance and renewal of CRE certification.

§ 9.741. Applicability.

This subchapter sets standards for the certification of CREs and the maintenance of that certification.

§ 9.742. CREs.

(a) To conduct UR activities, including review of health care services delivered or proposed to be delivered in this Commonwealth for or on behalf of a plan, an entity shall be certified as a CRE by the Department.

(b) Certification shall be renewed every 3 years unless otherwise subjected to additional review, suspended or revoked by the Department. The Department may subject a CRE to additional review, suspend or revoke certification if it determines that the CRE is failing to comply with Act 68 and this chapter.

(c) A licensed insurer or a plan with a certificate of authority shall comply with section 2152 of the act (40 P. S. § 991.2152), but is not required to obtain separate certification as a CRE.

§ 9.743. Content of an application for certification as a CRE.

(a) A CRE seeking certification shall submit two copies of the Department's application to the Department's Bureau of Managed Care.

(b) The Department may make changes to the application form. The changes shall be published in the *Pennsylvania Bulletin* at least 30 days prior to the effective date of the changes.

(c) The application shall contain the following:

(1) The name, address and telephone number of the entity as it should appear on the Department's official list of certified CREs.

(2) Information relating to its organization, structure and function, including the following:

(i) The location of the principal office handling UR.

(ii) The articles of incorporation and bylaws, or similar documents regulating the internal affairs of the applicant.

(iii) The name of each owner of more than 5% of the shares of the corporation, if the applicant is a public corporation.

(iv) A chart showing the internal organization of the applicant's management and administrative staff.

(3) The names and resumes of each officer, director and senior management.

(4) A listing of each plan in this Commonwealth for which the applicant currently conducts UR.

(5) A description of the applicant's:

(i) Ability to respond to each telephone call received as required by section 2152 of the act (40 P. S. § 991.2152), including toll-free telephone numbers and the applicant's system to provide access during nonbusiness hours.

(ii) Acceptable selection and credentialing procedures and criteria for physician and psychologist clinical peer reviewers.

(iii) Ability to arrange for a wide range of health care providers to conduct reviews. The applicant shall have access to a pool of clinical peer reviewers sufficient to reasonably assure that appropriately qualified reviewers will be available on a timely basis.

(iv) Procedures for protecting the confidentiality of medical records and certification that the applicant will comply with the confidentiality provisions in section 2131 of the act (40 P. S. § 991.2131) and other applicable State and Federal laws and regulations imposing confidentiality requirements.

(v) Procedures to ensure that a health care provider is able to verify that an individual requesting information on behalf of the plan is a representative of the plan.

(vi) Capacity to maintain a written record of UR decisions adverse to enrollees for at least 3 years, including a detailed justification and the required notifications to the health care provider and enrollee.

(vii) Evidence of approval, certification or accreditation received by a Nationally recognized accrediting body in the area of UR, if it has secured the approval, certification or accreditation.

(viii) The length of time the applicant has been operating in this Commonwealth, if applicable.

(ix) A list of three clients for which the applicant has conducted UR including the name, address, position and telephone number of a contact person for each client. The Department may contact these references for an assessment of the applicant's past performance and its ability to meet the timeframes for prospective, concurrent and retrospective UR in section 2152 of the act.

(d) The applicant shall certify that:

(1) Decisions resulting in a denial shall be made by a licensed physician in a same or similar specialty to the health care provider of the service in question.

(2) An approved licensed psychologist in a same or similar specialty to the health care provider of the service

in question, if the review is of behavioral health services within the psychologist's scope of practice, and the psychologist's clinical experience provides sufficient experience to review that specific behavioral health car service. A licensed psychologist may not review the denial of payment for a health care service involving inpatient care or a prescription drug.

(3) Compensation from a plan to a CRE, employe, consultant or other person performing UR on its behalf does not contain incentives, direct or indirect, to approve or deny payment for the delivery of any health care service.

§ 9.744. CREs participating in internal and external grievance reviews.

(a) To be certified to review internal and external grievances, the applicant shall supply the following additional information to the Department for review, along with the application:

(1) The name and type of business of each corporation, affiliate or other organization that the applicant controls; the nature and extent of the affiliation or control; and a chart or list clearly identifying the relationship between the applicant and affiliates.

(2) The name, title, address and telephone number of a primary and at least one backup designee with whom the Department may communicate regarding assignment of external grievances and other issues.

(3) A disclosure of any potential conflict of interest which would preclude its review of an external grievance—for example, ownership of or affiliation with a competing plan or other health insurance company.

(4) A description of the applicant's:

(i) Capacity and procedures for notifying the health care provider of additional facts or documents required to complete the UR within 48 hours of receipt of the request for review.

(ii) Systems and procedures, including staffing and resources, to meet the time frames for decisions as specified in section 2152 of the act (40 P. S. § 991.2152). The applicant shall have access to a pool of clinical peer reviewers sufficient to reasonably assure that appropriately qualified reviewers will be available on a timely basis for internal and external grievance reviews.

(iii) Capability and agreement to receive and decide all external grievances, or just behavioral health grievances if so desired, and 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.

(iv) The capacity, procedures and agreement to maintain the information obtained in the review of the grievances, including outcomes, for at least 3 years in a manner that is confidential and unavailable to any affiliated entity or person who may be a direct or indirect competitor to the plan being reviewed.

(v) A fee schedule for the conduct of grievance reviews. An applicant will not be certified as CRE unless the proposed fees for external reviews are determined to be reasonable by the Department.

(5) A certification that the following conditions apply:

(i) The CRE is willing and able to participate on a rotational basis in grievance reviews.

(ii) Internal and external grievances and expedited grievances will be reviewed and processed in accordance with Act 68 and Subchapter F (relating to complaints and grievances).

(b) The Department will add the name of each certified CRE to its rotational list of CREs certified to conduct external grievances.

§ 9.745. Responsible applicant.

(a) To be certified by the Department, an applicant for certification to perform UR seeking certification shall be a responsible person.

(1) To make this determination, the Department may review and verify the credentials of any officer, director or member of the management staff of the applicant.

(2) The Department may consider whether any of the officers, directors or management personnel have ever:

(i) Filed for bankruptcy.

(ii) Been convicted of a state or Federal offense related to health care.

(iii) Been listed by a state or Federal agency as debarred, excluded or otherwise ineligible for state or Federal program participation.

(iv) Been convicted of a criminal offense which would call in to question the individual's ability to operate a CRE.

(v) Have a history of malpractice or civil suits, penalties or judgments against them.

(b) To be determined a responsible person, an applicant shall demonstrate to the Department that it has the ability to perform URs and grievance reviews based on medical necessity and appropriateness, without bias.

§ 9.746. Fees for certification and recertification of CREs.

(a) A CRE applying for certification shall include a fee of $1,000 payable to the Commonwealth of Pennsylvania with its application. Applicants seeking certification for external grievance reviews shall include an additional $1,000. By _____ (*Editor's Note:* The blank refers to the effective date of adoption of this proposal.) each CRE that is already certified by the Department shall pay the fee to the Department.

(b) The fee for recertification is $500.

§ 9.747. Department review and approval of a certification request.

(a) The Department will review the application for certification as a CRE. If the Department finds deficiencies, it will notify the applicant, identifying the changes required to bring the applicant into compliance.

(b) The Department will have access to the applicant's books, records, staff, facilities and other information it finds necessary to determine an applicant's compliance with Act 68 and this subchapter. In lieu of a site visit and inspection, the Department may accept accreditation of the applicant by a Nationally recognized accrediting body whose standards meet or exceed the standards of Act 68 and this subchapter.

(c) If the applicant is not accredited by a Nationally recognized accrediting body whose standards are acceptable to the Department, the Department may provide the applicant with the option to undergo an onsite inspection

by a Nationally recognized accrediting body whose standards meet or exceed the standards of Act 68 and this subchapter. The cost of the inspection shall be borne by the applicant.

§ 9.748. Maintenance and renewal of CRE certification.

(a) *Maintenance.* To determine whether a CRE is complying with Act 68 and this subchapter, and maintaining its certification during the 3-year certification period, the Department may do one or more of the following:

(1) Perform periodic onsite inspections.

(2) Require proof of the CRE's continuing accreditation by a Nationally recognized accrediting body whose standards meet or exceed the standards of Act 68 and this subchapter.

(3) Require an onsite inspection as set forth in § 9.747 (relating to Department review and approval of a certification request).

(b) *Renewal.*

(1) A CRE shall submit an application for renewal of certification to the Department along with the appropriate renewal fee at least 60 days prior to the expiration of the 3-year certification period.

(2) The renewal application shall include the following:

(i) Evidence of the CRE's continued accreditation by a Nationally recognized accrediting body whose standards meet or exceed the standards of Act 68 and this subchapter.

(ii) A certification that the CRE has complied with and will continue to comply with Act 68 and this subchapter.

(iii) An updating of the CRE's originally filed list of conflicts of interest and CRE contracts with plans.

(iv) A reaffirmation of certifications included in the CRE's original application.

(3) The Department may perform an onsite inspection at the CRE before approving renewal of certification, or may require an onsite inspection set forth in § 9.747.

Subchapter L. CREDENTIALING

Sec.
9.761. Provider credentialing.

§ 9.761. Provider credentialing.

(a) A plan shall establish and maintain a health care provider credentialing system to evaluate and enroll qualified health care providers for the purpose of creating an adequate health care provider network. The credentialing system shall include policies and procedures for the following:

(1) Initial credentialing.

(2) Recredentialing at least every 2 years.

(3) Including in the initial credentialing and recredentialing process, a plan assessment of the participating health care providers' ability to provide urgent care appointments, routine appointments and routine physical examinations to enrolled patients, and their ability to enroll additional patients in the practice in accordance with standards adopted by the plan.

(4) Inclusion of enrollee satisfaction and quality assurance data in the recredentialing review.

(5) Restrictions or limitations.

(6) Termination of a health care provider's participation.

(7) In cases of denial or nonrenewals, notification to health care providers that includes a clear rationale for the decision.

(8) Evaluating credentials of health care providers who may be directly accessed for obstetrical and gynecological care.

(9) Evaluating credentials for specialists who are being requested to serve as primary care providers, including standing referral situations, to ensure that access to primary health care services remain available throughout the arrangement.

(b) The plan shall submit its credentialing plan to the Department prior to implementation. Changes to the credentialing plan shall also be submitted to the Department prior to implementation.

(c) A plan may meet the requirements of this section by establishing a credentialing system that meets or exceeds standards of a Nationally recognized accrediting body acceptable to the Department. The Department will publish a list of these bodies annually in the *Pennsylvania Bulletin.*

(d) A plan may not require full credentialing of nonparticipating health care providers providing health care services to new enrollees under the continuity of care provision. A plan may require verification of basic credentials such as licensure, malpractice insurance, hospital privileges and malpractice history as basic terms and conditions.

(e) Upon written request, a plan shall disclose relevant credentialing criteria and procedures to health care providers that apply to become participating providers or who are already participating.

(f) A plan shall comply with section 2121 of the act (40 P. S. § 991.2121).

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