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Annex A

TITLE 28. HEALTH AND SAFETY

PART I. GENERAL HEALTH

CHAPTER 9. MANAGED CARE ORGANIZATIONS

Subchapter A. (Reserved)

§ 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)

§ § 9.401--9.416. (Reserved).

Subchapter E. (Reserved)

§ § 9.501--9.519. (Reserved).

Subchapter F. GENERAL

Sec.

Applicability.
Definitions.
Technical advisories.
Plan reporting requirements.
Department investigations.
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) 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.

Active clinical practice--The practice of clinical medicine by a health care provider for an average of not less than 20 hours per week.

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 or basic health care services--*The health care services in § 9.651 (relating to HMO provision and coverage of basic health care services to enrollees).

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

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

*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 non-covered benefits), operations or management policies of a managed care plan, that 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.

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

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 such that a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in 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 services 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 or other individual who is entitled to receive health care services under a managed care plan. For purposes of the complaint and grievance processes, the term includes parents of a minor enrollee as well as designees or legal representatives who are entitled or authorized to act on behalf of the enrollee.

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 EQRO.

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

Gatekeeper--A primary care provider selected by an enrollee or appointed by a managed care plan, or the plan or an agent of the plan serving as the primary care provider, from whom an enrollee shall obtain covered health care services, a referral or approval for covered nonemergency health services as a precondition to receiving the highest level of coverage available under the managed care plan.

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 any 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 or health service--Any 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--

(i) A partnership, association, corporation or other legal entity which does the following:

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

(B) Employs or contracts with health care providers.

(C) Agrees under its arrangement with the plan to do the following:

(I) Provide or arrange for the provision of a defined set of health care services to enrollees covered under a plan contract principally through its participating providers.

(II) Assume under the arrangement with the plan some responsibility for conducting in conjunction with the plan and under compliance monitoring of the plan quality assurance, UR, credentialing, provider relations or related functions.

(ii) The IDS may also perform claims processing and other functions.

Inpatient services--Care, including professional services, at a licensed hospital, skilled nursing or rehabilitation facility, including preadmission testing, diagnostic testing related

to an inpatient stay, professional and nursing care, room and board, durable medical equipment, ancillary services, drugs administered during an inpatient stay, meals and special diets, use of operating room and use of intensive care and cardiac units.

Managed care plan or plan--

(i) A health care plan that does each of the following:

(A) Uses a gatekeeper to manage the utilization of health care services.

(B) Integrates 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) Provides 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 includes managed care plans that require the enrollee to obtain a referral from any primary care provider in its network as a condition to receiving the highest level of benefits for specialty care.

(v) 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 ambulatory 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, including professional services.

Outpatient setting--A physician's office, outpatient facility, patient's home, 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--A health care plan provided by a managed care plan that may require 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 and that may allow enrollees access to providers inside or outside the network without referral by a gatekeeper.

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 review and decisionmaking, performed by a UR entity or managed 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.

[Continued on next Web Page]

§ 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 the Department's interpretation of, and how

a plan may maintain compliance with, the HMO act, Article XXI and this chapter. Notice of the availability of a technical advisory will be published in the *Pennsylvania Bulletin*.

§ 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 data by product line--for example, commercial, Medicare and Medicaid and by county.

(2) Utilization statistics containing the following minimum data:

(i) The number of days of inpatient hospitalization on a quarterly, year-to-date and annualized basis.

(ii) The average number of physician visits per enrollee on a quarterly, year-to-date and annualized basis.

(3) The number, type, and disposition of all complaints and grievances filed with the plan or subcontractors.

(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. Reimbursement information submitted to the Department under this paragraph may not be disclosed or produced for inspection or copying to a person other than the Secretary or the Secretary's representatives, without the consent of the plan which provided the information, unless otherwise ordered by a court.

(9) A copy of the plan's written description of its quality assurance program, a copy of the quality assurance work plan, and 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 all contracted CREs that perform UR on behalf of the plan or a contracted IDS.

(b) *Quarterly reports.* Four times per year, a plan shall submit to the Department two copies of a brief quarterly report summarizing data specified in subsection (a)(2) and (6) and 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 plans as necessary to determine compliance with Act 68, the PPO Act, the HMO Act and this chapter

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

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

(d) The Department will have access to medical records of plan enrollees for the 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 plan 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.

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

(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 or arranging for 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 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, for a hearing of the matter to be held. Hearing procedures and appeals shall be conducted in accordance with 2 Pa.C.S. (relating to administrative law and procedure).

(d) For violations of the HMO Act, the PPO Act, Act 68 and this chapter, the Department may require a plan to develop and adhere to a plan of correction approved by the Department that the plan shall make available to enrollees upon written request. The Department will monitor compliance with the plan of correction. Failure to comply with the plan of correction may result in the Department's taking action under subsection (a) or (b), as appropriate.

(e) The Department's actions under subsection (a)(1) or (3) are subject to 2 Pa.C.S. Chapter 5, Subchapter A (relating to practice and procedure of Commonwealth agencies).

Subchapter G. HMOS

Sec.

GENERALLY

Applicability.

Prohibition against uncertified HMOs.

Preapplication development activities.

APPLICATION FOR CERTIFICATE OF AUTHORITY

Content of an application for an HMO certificate of authority.

HMO certificate of authority review by the Department.

Location of HMO activities, staff and materials.

Delegation of HMO operations.

Issuance of a certificate of authority to a foreign HMO.

OPERATIONAL STANDARDS

HMO provision and coverage of basic health services to enrollees.

HMO provision of other than basic health services to enrollees.

HMO provision of limited subnetworks to select enrollees.
HMO external quality assurance assessment.

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 choices that 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 issuance 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, UR, 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 standard IDS contract including a detailed description of the reimbursement methodologies and types of financial incentives that the HMO proposes to utilize. Reimbursement information submitted to the Department under this paragraph may not be disclosed or produced for inspection or copying to a person other than the Secretary or the Secretary's representatives, without the consent of the plan which provided the information, unless otherwise ordered by a court.

(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 consistent with the requirements of § 9.674 (relating to quality assurance standards).

(9) A detailed description of the applicant's proposed UR system consistent with the requirements of §§ 9.749--9.751 (relating to UR system description; UR system standards; and time frames for UR).

(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 job description for the medical director.

(17) A procedure for referral of enrollees to nonparticipating providers.

(18) A copy of the HMO'S proposed general subscriber literature including the member handbook.

(19) A copy of the HMO's most recent financial statement.

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

(21) 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 any 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 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 will visit and 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. 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 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 30 days, unless the Department determines for matters of patient safety the documents must be provided within 2-business days.

(2) The HMO shall identify a physician to serve as its medical director who is licensed in this Commonwealth and qualified to perform the duties of a medical director. The medical director shall be responsible for the following:

(i) Oversight of the UR and quality assurance activities regarding coverage and services provided to enrollees.

(ii) General coordination of the medical care of the HMO.

(iii) Appropriate professional staffing of the HMO's medical management operations.

(iv) Designing protocols for quality assurance.

(v) Implementation of quality assurance programs and continuing education requirements.

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

§ 9.634. Delegation of HMO operations.

(a) An HMO may contract with an 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 under section 1558(b) of the HMO Act and may 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).

§ 9.635. 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. A foreign HMO shall submit a letter to the Department and a copy of its approved application for licensure or certification on file with its state of domicile.

(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) and the following:

(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, this subchapter and Subchapters F and J (relating to general; and health care provider

contracts) insofar as they apply to HMOs, 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.

(e) If the Department and the Insurance Department arrive at reciprocal licensing agreements with other states, the requirements of this subchapter may be waived or modified.

(f) 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*.

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 services, except to the extent that a service is required to be covered by State or Federal law.

(c) An HMO shall provide or arrange for the provision of 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. See § 9.672 (relating to emergency services).

(2) Outpatient services.

(3) Inpatient services for general acute care hospitalization for a minimum of 90 days per contract or calendar year.

(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 in accordance with § 9.679 (relating to access requirements in service areas).

(2) The health care provider contracts it uses to contract with participating providers meet 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. HMO provision of limited subnetworks to select enrollees.

(a) An HMO that wants to offer benefit plans based on limited subnetworks, that is, networks which include only selected participating 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 and any current enrollees who would be affected by a change to a limited subnetwork benefit package of the economic penalties that apply when enrollees do not obtain health care services through the limited subnetwork. Disclosure of the limitations in the number of the HMO's participating providers must be consistent with the act and the requirements of 31 Pa. Code § 154.16 (relating to disclosure of information).

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

(3) The limited subnetwork meets the minimum healthcare provider standards in § 9.679 (relating to access requirements in service areas) and 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 the limited participating subnetwork providers.

(5) The limited subnetwork meets the standards for adequate networks and accessibility in § 9.679.

§ 9.654. HMO external quality assurance assessment.

(a) Within 18 months after enrollment of the first enrollee, and every 3 years thereafter unless otherwise required by the Department, an HMO shall have an external quality assurance assessment conducted using an EQRO acceptable to the Department. Department personnel may participate in the external quality assurance assessment. The following also apply to external quality assurance assessments:

(1) The Department will perform a site visit of the HMO 12 months after the issuance of a certificate of authority whether or not the HMO has enrollees, to ensure that the HMO is complying with the requirements of the HMO Act, Act 68 and this chapter.

(2) If the HMO has no enrollees more than 18 months from the issuance of a certificate of authority the Department will perform a site visit to ensure that the HMO is in compliance with the HMO Act, Act 68 and this chapter.

(3) If, following the site visit in paragraph (2), the HMO has no enrollees for the next 6 months, the HMO may not begin to enroll members until the Department performs an additional site visit.

(b) Costs for the required external quality assurance assessment shall be paid by the HMO.

(c) An HMO may combine the external quality assurance assessment with an accreditation review offered by an EQRO acceptable to the Department, if the review adequately incorporates information required by the Department to determine the HMO's compliance with Act 68, the HMO Act and this chapter, and allows for Department staff to actively participate in the external quality assurance assessment.

(d) The external quality assurance assessment shall study the quality of care being provided to enrollees and the effectiveness of the quality assurance program established by the HMO under § 9.674 (relating to quality assurance standards) and shall assess the HMO's compliance with the HMO Act, Act 68 and this chapter.

(e) The EQRO shall issue a copy of its findings to the HMO's senior management, which shall provide a copy to the board of directors. It is the responsibility of the HMO to ensure

that a copy of all interim and final reports regarding the external quality assurance assessment are filed within 15 days with the Department, either directly by the HMO, or by the EQRO.

(f) The Department's requests for corrective action plans resulting from the external quality assurance assessment concerning deficiencies found requiring an HMO response, and the HMO's ensuing responses, including correspondence between the plan and the Department, plans of correction and follow-up documentation, will be made available to the public upon request as required under the Right to Know Law (65 P. S. § § 66.1--66.4). The remainder of the assessment containing proprietary information may not be disclosed or produced for inspection or copying to a person other than the Secretary or the Secretary's representatives, without the consent of the plan which provided the information, unless otherwise ordered by a court.

(g) The Department will publish annually in the *Pennsylvania Bulletin* a list of EQROS acceptable to it for the purpose of performing external quality assurance assessments.

Subchapter H. AVAILABILITY AND ACCESS

Sec.

Applicability.

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§ 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 prior to seeking emergency service.

(c) A plan shall 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 provided during the period of the emergency, shall include evaluation, testing, and if necessary, stabilization of the condition of the enrollee, 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) The emergency health care provider shall notify the enrollee's managed care plan of the provision of emergency services and the condition of the enrollee.

(g) If the enrollee is admitted to a hospital or other health care facility, the emergency health care provider shall notify the enrollee's managed care plan of the emergency

services delivered within 48 hours or on the next business day, whichever is later. An exception to this requirement will be made where the medical condition of the patient precludes the provider from accurately determining the identity of the enrollee's managed care plan within 48 hours of admission.

(h) If the enrollee is not admitted to a hospital or other health care facility, the claim for reimbursement for emergency services provided shall serve as notice to the enrollee's managed care plan of the emergency services provided by the emergency health care provider.

§ 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, a prospective enrollee, or health care provider may make a written or verbal 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. If the drug that is the subject of the inquiry is not on the plan's formulary, the plan's response shall include a listing of the drugs in the same class that are on the formulary or instruct the enrollee how to access the formulary.

(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. The following standards apply when an exception is sought:

(1) Exception requests are to be considered requests for prospective UR decisions and shall be processed within 2-business days.

(2) If the exception is granted, the plan shall provide coverage in the amount disclosed by the plan for the nonformulary alternative under section 2136(a)(1) of the act (40 P. S. § 991.2136(a)(1)).

(3) A letter denying the request shall include the basis and clinical rationale for the denial and instructions on how to file a complaint or a grievance.

(d) The plan shall distribute its policy and process to each participating health care provider who prescribes. A plan shall provide a description of the process to be used to obtain coverage of a drug that is an exception to the formulary to an enrollee or prospective enrollee upon request. If a drug, class of drugs or drugs used to treat a specific condition are specifically excluded from coverage in the enrollee contract, appeals for coverage of specific exclusions shall be considered complaints. If no specific exclusion exists, the appeal of a denial of a physician's request for an exception to the formulary based on medical necessity and appropriateness, shall be considered to be a grievance.

(e) A plan shall provide at least 30 days notice of formulary changes to health care providers, except when the change is due to approval or withdrawal of approval of the Food and Drug Administration of a drug.

§ 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 outlining its structure and content.

(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 health care providers 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 documenting studies undertaken, evaluation of results, subsequent actions recommended and implemented, and aggregate data annually to the plan's board of directors, and shall provide a copy of the report to the Department.

(c) In administering a quality assurance plan, the plan shall do the following:

(1) Include in its quality assurance plan regularly updated standards for the following:

(i) Health promotion.

(ii) Early detection and prevention of disease.

(iii) Injury prevention for all ages.

(iv) Systems to identify special chronic and acute care needs at the earliest possible time.

(v) Access to routine, urgent and emergent appointments that shall be approved by the plan's quality assurance committee. The plan shall conduct annual studies of access and availability, the results of which shall be incorporated into the report referenced in subsection (b)(10).

(2) Notify health care providers and enrollees of these standards.

(3) Involve health care providers and enrollees in the updating of its quality assurance plan.

§ 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 be responsible for assuring that the medical management contract meets the requirements of all applicable laws. The plan shall submit the medical management contract to the Department for review and approval. The Department will review a medical management contract within 45 days of receipt of the contract. If the Department does not approve or disapprove a contract within 45 days of receipt, the plan may use the contract and it shall be presumed to meet the requirements of all applicable laws. If, at any time, the Department finds that a contract is in violation of law, the plan shall correct the violation. Reimbursement information submitted to the Department under this paragraph may not be

disclosed or produced for inspection or copying to a person other than the Secretary or the Secretary's representatives without the consent of the plan which provided the information, unless otherwise ordered by a court.

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

(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 on at least a quarterly basis regarding the delegated activities concerning the arrangement or provision of health care services and the impact of the delegated activities on the quality and delivery of health care services to the plan's enrollees.

(3) Annual 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 will cooperate with and participate in quality assurance activities and studies undertaken by the plan that pertain to the enrollee

populations served by the contractor, including submitting written reports of activities and accomplishments on plan directed and any contractor initiated activities 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 § 9.654 (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. Enrollee rights.

(a) A plan shall have a written policy that shall state the plan's commitment to treating an enrollee in a manner that respects the enrollee's rights and shall include the plan's expectations of a member's responsibilities.

(b) An HMO shall offer to each enrollee, who becomes ineligible to continue as a part of a group subscriber agreement, a nongroup subscription agreement offering the same level of benefits as are available to a group subscriber.

(c) An HMO may not expel or refuse to reenroll an enrollee solely because of the enrollee's health care needs, nor refuse to enroll individual subscribers of a group on the basis of health status or health care needs of the individuals.

§ 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. The definition shall comply with the HMO Act, the PPO Act, Act 68 and this chapter.

§ 9.678. PCPs.

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

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

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

(2) Be available directly or through on-call arrangements with other qualified plan participating PCPs, 24 hours-per-day, 7 days-per-week for urgent and emergency care and to provide triage and appropriate treatment or referrals for treatment. A participating provider may arrange for on-call services with a nonparticipating provider if the plan approves the arrangement, agrees to provide the level-of-benefit for the service provided by the nonparticipating provider, and agrees to hold the enrollee harmless for any errors committed by the nonparticipating provider that would result in noncoverage of covered benefits or would mislead the enrollee into believing a noncovered service would be covered.

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

(4) Maintain hospital 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. The plan shall comply with § 9.683.

(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 PCP, if the CRNP meets the plan's credentialing criteria and practices in accordance with the Medical Practice Act (63 P. S. § § 422.1--422.45) and its applicable regulations, 49 Pa. Code Chapter 18, Subchapter C (relating to certified registered nurse practitioners), and the Nurse Practice Act (63 P. S. § § 211--225) and its applicable regulations, 49 Pa. Code Chapter 21, Subchapter C (relating to certified registered nurse practitioners).

(e) A plan shall include in its provider directory a clear and adequate notice of the possibility that the choice of a given provider as a PCP may result in access to a limited subnetwork based on the PCP's employment or other affiliation arrangements.

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

§ 9.679. Access requirements in service areas.

(a) A plan shall only provide coverage to enrollees who work or reside in a service area when the plan has been approved to operate in that service area 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 report to the Department any probable loss from the network of any general acute care hospital and any primary care provider, whether an individual practice or a group practice, with 2,000 or more assigned enrollees.

(d) Except as otherwise authorized in this section, a plan shall provide for at least 90% of its enrollees in each county in its service area, access to covered services that are within 20 miles or 30 minutes travel from an enrollee's residence or work in a county designated as a metropolitan statistical area (MSA) by the Federal Census Bureau, and

within 45 miles or 60 minutes travel from an enrollee's residence or work in any other county.

(e) A plan shall at all times assure enrollee access to primary care providers, speciality care providers and other health care facilities and services necessary to provide covered benefits. At a minimum, the following health care services must be available in accordance with the standards in subsection (d):

- (1) General acute inpatient hospital services.
- (2) Common laboratory and diagnostic services.
- (3) Primary care.
- (4) General surgery.
- (5) Orthopedic surgery.
- (6) Obstetrical and gynecological services.
- (7) Ophthalmology.
- (8) Allergy and immunology.
- (9) Anesthesiology.
- (10) Otolaryngology.
- (11) Physical medicine and rehabilitation.
- (12) Psychiatry and neurology.
- (13) Neurological surgery.
- (14) Urology.

(f) If a plan is unable to meet the travel standards in subsection (d), it shall inform the Department in writing and provide a written description of why it is unable to do so and its alternative arrangements to ensure access to health care providers of these services. The plan shall include in its description a specific explanation of exactly how it intends to provide access to health care services including:

(1) The use of participating or nonparticipating providers.

(2) Applicable payment arrangements.

(3) Measures to secure health care provider cooperation with plan policies and procedures concerning UR, case management, claims payment and access to medical information necessary to authorize payment of covered health care services.

(4) Travel arrangements, if any.

(g) A plan using a health care provider of services delivered in the home need not meet the requirements of subsection (d) or (f) as long as the services can be reliably provided in the enrollee's home regardless of distance between the home and the provider's location.

(h) For infrequently utilized health care services, such as transplants, a plan may provide access to nonparticipating health care providers or contract with health care providers outside of the approved service area.

(i) A plan offering coverage for nonbasic health care services, either as part of the basic benefit package or through supplemental coverage, such as prescription drugs, vision, dental, and durable medical equipment, shall ensure that its network of health care providers for these services meets the standards for frequently utilized services in subsections (d)--(g).

(j) If there is a therapeutic reason to arrange for services at a distance greater than the travel standards in subsections (d) and (f), whether for frequently or infrequently utilized health care services, the plan may make arrangements necessary to provide access to quality health care services.

(k) A plan shall cover services provided by a nonparticipating health care provider at no less than the in-network level of benefit when the plan has no available network provider. A plan is not required to have network providers available outside of the approved service area for the purposes of enrollees seeking basic health care services while outside of the service area. A plan is not required to pay a noncontracted provider at the same benefit level as a network provider for basic health care services sought by and provided an enrollee while outside the service area when in-network providers were available.

(l) A plan seeking to expand its service area beyond that which was initially approved shall file with the Department, for the Department's approval, a service area expansion request that meets the requirements of this section and includes:

(1) Projected enrollment for the first year of operation.

(2) A provider listing of contracted and credentialed health care providers.

(m) A plan shall provide the Department with a description of its provider network in a format specified by the Department, annually, and at other times at the Department's request to enable the Department to analyze network disruptions or investigate complaints.

§ 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 list by specialty of the name, address and telephone number of participating health care providers to which an enrollee may have access either directly or through a referral. The list may be a separate document, which may be a regional or county directory, and shall be updated at least annually. The plan shall satisfy the following in providing the list:

(1) If it provides a regional or county directory, the plan shall make enrollees aware that other regional directories or a full directory are available upon request.

(2) If it provides a list of participating providers for only a specific type of provider or service, the plan shall include in the list all participating providers authorized to provide those services. Information shall be provided as required under 31 Pa. Code § 154.16 (relating to information for enrollees).

(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 other providers with equivalent training and experience.

(c) A plan that has no participating health care providers within the approved service area 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 and ensuring 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.

(5) Routine appointments.

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§ 9.682. Direct access for obstetrical and gynecological care.

(a) A plan shall permit enrollees direct access to obstetrical and gynecological services for maternity and gynecological care, including medically necessary and appropriate follow-up care and referrals, for diagnostic testing related to maternity and gynecological care from participating health care providers without prior approval from a primary care provider. Time restrictions may not apply to the direct accessing of these services by enrollees.

(b) A plan may require a provider of obstetrical or gynecological services to obtain prior authorization for selected services, such as diagnostic testing for subspecialty care--for example, reproductive endocrinology, oncologic gynecology, and maternal and fetal medicine.

(c) 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 improvement or quality assurance committee.

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

(3) Include a treatment plan approved by the plan in consultation with the primary care provider, the enrollee and as appropriate, the specialist, 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 specialist as, a primary care provider will be made to participating health care providers when possible.

(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 or quality assurance committee on an annual basis.

§ 9.684. Continuity of care.

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

(1) Except as noted in subsections (i) and (j), an enrollee may continue an ongoing course of treatment, at the option of the enrollee, for up to 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 provider who is terminated 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 provider who is terminated is not a primary care provider, the plan shall notify all 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 notice of termination or pending termination 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 undergo full credentialing.

(g) A plan shall provide the nonparticipating or terminated 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) To be eligible for payment by a plan, a nonparticipating or terminated provider shall agree to the terms and conditions of the plan prior to providing service under the continuity of care provisions. If the health care provider does not agree to the terms and conditions of the plan prior to providing the service, the provider shall notify the enrollee of that fact.

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

(j) If the plan terminates a participating health care provider for cause, as described in section 2117(b) of the act (40 P. S. § 991.2117(b)) the plan will not be responsible for the health care services provided by the terminated provider to the enrollee following the date of termination.

§ 9.685. Standards for approval of point-of-service products.

(a) If a plan offers a point-of-service product, it shall submit a formal product filing for the POS product to the Department and the Insurance Department.

(b) A plan may offer POS options to groups and enrollees, if the plan:

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

(i) To ensure that self-referral activity is not occurring because of an access problem, a deliberate attempt to force an enrollee to bypass a primary care provider for nonmedical reasons or over restrictive or burdensome plan requirements.

(ii) To promptly investigate 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, inappropriate patient direction or burdensome plan requirements.

(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 I. COMPLAINTS AND GRIEVANCES

Sec.

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§ 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 procedure and a two-level grievance procedure which meets the requirements of sections 2141, 2142, 2161 and 2162 of the act (40 P. S. § § 991.2141, 991.2142, 991.2161 and 991.2162) and this subchapter.

(2) The plan may not incorporate administrative requirements, time frames or tactics to directly or indirectly discourage the enrollee or health care provider from, or disadvantage the enrollee or health care provider in utilizing the procedures. The following apply if the enrollee or health care provider believes the plan is violating this paragraph:

(i) An enrollee or a health care provider may contact the Department to complain that a plan's administrative procedures or time frames are being applied to discourage or disadvantage the enrollee or health care provider in utilizing the procedures.

(ii) The Department will investigate the allegations, and take action it deems necessary and appropriate under Act 68.

(iii) Referral of the allegations to the Department will not operate to delay the processing of the complaint or grievance review.

(3) At any time during the complaint or grievance process, an enrollee may choose to designate a representative to participate in the complaint or grievance process on the enrollee's behalf. The enrollee or the enrollee's representative shall notify the plan of the designation.

(4) The plan shall make a plan employee available to assist the enrollee or the enrollee's representative at no charge in preparing the complaint or grievance if a request for assistance is made by the enrollee or the representative at any time during the complaint

or grievance process. The plan employee made available by the plan may not have participated in any plan decision with regard to the complaint or grievance.

(5) As part of its complaint and grievance process, a plan shall have a toll-free telephone number for an enrollee to use to obtain information regarding the filing and status of a complaint or grievance. The plan shall make reasonable accommodations to enable enrollees with disabilities and non-English speaking enrollees to secure the information.

(6) A plan shall provide copies of its complaint and grievance procedures to the Department for review and approval under § 9.710 (relating to approval of plan enrollee complaint and enrollee and provider grievance systems). 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 with the act or this chapter.

(c) *Complaints versus grievances.*

(1) The plan may not classify the request for an internal review as either a complaint or a grievance with the intent to adversely affect or deny the enrollee's access to the procedure.

(2) If the plan has a question as to whether the request for an internal review is a complaint or a grievance, the plan shall consult with the Department or the Insurance Department as to the most appropriate classification. The decision shall be final and binding.

(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 a request for an internal review.

(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. If the Department determines that a complaint has been improperly classified as a grievance prior to the external review, the filing fee shall be refunded.

(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) If a plan establishes time frames for the filing of complaints and grievances, it shall allow an enrollee at least 45 days to file a complaint or grievance from the date of the occurrence of the issue being complained about, or the date of the enrollee's receipt of notice of the plan's decision.

(2) A health care provider seeking to file a grievance with enrollee consent under § 9.706 (relating to health care provider initiated grievances) shall have the same time frames in which to file as an enrollee.

§ 9.703. 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. The process shall address how an enrollee or the enrollee's representative may file complaints by which the enrollee or the enrollee's representative seek to have the plan review and change plan decisions regarding participating health care providers, or the health plan coverage, plan operations and management policies of the plan.

(b) A plan shall permit an enrollee or the enrollee's representative 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) Upon receipt of the complaint, the plan shall provide written confirmation of its receipt to the enrollee and the enrollee's representative, if the enrollee has designated one, including the following information:

(A) That the plan considers the matter to be a complaint, and that the enrollee or the enrollee's representative may question this classification by contacting the Department.

(B) That the enrollee may appoint a representative to act on the enrollee's behalf at any time during the process.

(C) That the enrollee or the enrollee's representative may review information related to the complaint upon request and submit additional material to be considered by the plan.

(D) That the enrollee or the enrollee's representative may request the aid of a plan employee who has not participated in previous decisions to deny coverage for the issue in dispute, at no charge, in preparing the enrollee's complaint.

(E) If the plan chooses to permit attendance at the first level review, that the enrollee and the enrollee's representative may attend the first level review.

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

(iii) A plan shall provide the enrollee and the enrollee's representative access to all information relating to the matter being complained of and shall permit an enrollee to provide written data or other material in support of the complaint. The plan may charge a reasonable fee for reproduction of documents.

(iv) The plan shall provide, at no charge, at the request of the enrollee or the enrollee's representative, a plan employee who has not participated in previous decisions to deny

coverage for the issue in dispute, to aid the enrollee or the enrollee's representative in preparing the enrollee's first level complaint.

(v) The plan shall complete its review and investigation of the complaint and shall arrive at its decision within 30 days of receipt of the complaint.

(vi) 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 to the enrollee and the enrollee's representative shall include the basis for the decision and the procedures to file a request for a second level review of the decision of the initial review committee including:

(A) A statement of the issue reviewed by the first level review committee.

(B) The specific reasons for the decision.

(C) References to the specific plan provisions on which the decision is based.

(D) If an internal rule, guideline, protocol, or other similar criterion was relied on in making the decision, either the specific rule, guideline, protocol or criterion, or instructions on how to obtain the internal rule, guideline, protocol or criterion.

(E) An explanation of how to request a second level review of the decision of the initial review committee.

(F) The time frames for requesting a second level review, if any. See § 9.702(d)(1) (relating to complaints and grievances).

(2) *Second level review.*

(i) Upon receipt of the request for the second level review, the plan shall send the enrollee and the enrollee's representative an explanation of the procedures to be followed during the second level review. This information shall include the following:

(A) A statement that, and an explanation of how, the enrollee or the enrollee's representative may request the aid of a plan employee at no charge, who has not participated in previous decisions to deny coverage for the issue in dispute, in preparing the enrollee's second level complaint.

(B) Notification that the enrollee and the enrollee's representative have the right to appear before the second level review committee and that the plan will provide the enrollee and the enrollee's representative with 15 days advance written notice of the time scheduled for that review.

(ii) 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 matter under review.

(A) At least one third of the second level review committee may not be employees of the plan or of a related subsidiary or affiliate.

(B) The members of the second level review committee shall have the duty to be impartial in the committee's review and decision.

(iii) The second level review shall satisfy the following:

(A) The enrollee or the enrollee's representative, or both, shall have the right to be present at the second level review.

(B) The plan shall notify the enrollee and the enrollee's representative at least 15 days in advance of the date scheduled for the second level review.

(C) The plan shall provide reasonable flexibility in terms of time and travel distance when scheduling a second level review to facilitate the attendance of the enrollee and the enrollee's representative. The plan shall make reasonable accommodation to facilitate the participation of the enrollee and the enrollee's representative by conference call or in person and shall take into account the enrollee's and the enrollee's representative's access to transportation and any disabilities that may impede or limit the enrollee's ability to travel.

(D) 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.

(E) Attendance at the second level review shall be limited to members of the review committee; the enrollee or the enrollee's representatives, including any legal representative or attendant necessary for the enrollee to participate in or understand the proceedings, or both; the enrollee's provider if the enrollee consents to the provider being present; 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.

(F) The plan shall provide, at no charge, at the request of the enrollee, or the enrollee's representative, a plan employee, who has not participated in previous decisions to deny coverage for the issue in dispute, to aid the enrollee or the enrollee's representative in preparing the enrollee's second level complaint.

(G) Committee proceedings at the second level review shall be informal and impartial to avoid intimidating the enrollee or the enrollee's representative.

(H) The committee may not discuss the case to be reviewed prior to the second level review meeting.

(I) A committee member who does not personally attend the review meeting may not vote on the case unless that person actively participates in the review meeting by telephone or videoconference, and has the opportunity to review any additional information introduced at the review meeting prior to the vote.

(J) The plan may provide an attorney to represent the interests of the committee and to ensure the fundamental fairness of the review and that all disputed issues are adequately addressed. In the scope of the attorney's representation of the committee, the attorney representing the committee may not argue the plan's position, or represent the plan or plan staff.

(K) The committee may question the enrollee, the enrollee's representative and plan staff representing the plan's position.

(L) The committee shall base its decision solely upon the materials and testimony presented at the review meeting.

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

(v) The plan shall complete the second level review and arrive at a decision within 45 days of the plan's receipt of the request of the enrollee or the enrollee's representative for a second level review.

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

(vii) The plan shall include in its notice to the enrollee the basis for the decision and the procedures to file an appeal to the Department or the Insurance Department, including the addresses and telephone numbers of both agencies which shall include the following information:

(A) A statement of the issue reviewed by the second level review committee.

(B) The specific reason or reasons for the decision.

(C) References to the specific plan provisions on which the decision is based.

(D) If an internal rule, guideline, protocol, or other similar criterion was relied on in making the decision, either the specific rule, guideline, protocol or criterion, or instructions on how to obtain the internal rule, guideline, protocol or criterion.

(E) An explanation of how to appeal to the Department or the Insurance Department, including the addresses and telephone numbers of both agencies and the time frames for appealing to the agencies included in § 9.704 (relating to appeal of a complaint decision) and 31 Pa. Code § 154.17 (relating to complaints).

(d) The Department of Health address for purposes of this section is: Bureau of Managed Care, Pennsylvania Department of Health, Post Office Box 90, Harrisburg, Pennsylvania 17108, (717) 787-5193. Toll free (888) 466-2787, fax number: (717) 705-0947, or the Pennsylvania AT&T relay service at (800) 654-5984. The Department may change this address upon prior notification in the *Pennsylvania Bulletin*.

§ 9.704. 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 with either the Department or the Insurance Department. The appeal shall be in writing unless the enrollee requests to file the appeal in an alternative format. The Department will make staff available to transcribe an oral appeal.

(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 identification number.

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

(5) The second level denial letter from the plan concerning the complaint.

(c) Upon the Department's request, the plan shall forward the complaint file, including relevant contract language and all material considered as part of the first two reviews, within 30 days of the Department's request.

(d) The plan and the enrollee may provide additional information for review and consideration to the Department. Each shall provide to the other copies of additional documents provided to the Department.

(e) The Department and the Insurance Department will determine the appropriate agency for the review.

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

§ 9.705. Internal grievance process.

(a) A plan shall establish, operate and maintain an internal enrollee grievance process in compliance with sections 2161 and 2162 of the act (40 P. S. § § 991.2161 and 991.2162) and this subchapter, 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 the enrollee's representative, or a health care provider with written consent of the enrollee, may file a written grievance with the plan. The plan shall make staff available to record an oral grievance for an enrollee who is unable by reason of disability or language barrier to file a grievance in writing.

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

(1) *First level review.*

(i) Upon receipt of the grievance, the plan shall provide written confirmation of its receipt to the enrollee and the enrollee's representative, if the enrollee has designated one, and the health care provider if the health care provider filed the grievance with enrollee consent, and shall also provide the following information:

(A) That the plan considers the matter to be a grievance, and that the enrollee, the enrollee's representative, or health care provider may question this classification by contacting the Department.

(B) That the enrollee may appoint a representative to act on the enrollee's behalf at any time during the internal grievance process.

(C) That the enrollee, the enrollee's representative, or the health care provider that filed the grievance with enrollee consent may review information related to the grievance upon request and submit additional material to be considered by the plan.

(D) That the enrollee or the enrollee's representative may request the aid of a plan employee who has not participated in previous decisions to deny coverage for the issue in dispute, at no charge, in preparing the enrollee's first level grievance.

(E) If the plan chooses to permit attendance at the first level review, that the enrollee, the enrollee's representative, and the health care provider who filed the grievance, may attend the first level review.

(ii) 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.

(iii) The plan shall provide the enrollee, the enrollee's representative, or a health care provider that filed a grievance with enrollee consent, access to all information relating to the matter being grieved and shall permit the enrollee, the enrollee's representative, or the health care provider to provide written data or other material in support of the grievance. The plan may charge a reasonable fee for reproduction of documents. The enrollee, the enrollee's representative or the health care provider may specify the remedy or corrective action being sought.

(iv) The plan shall provide, at no charge, at the request of the enrollee or the enrollee's representative, a plan employee who has not participated in previous decisions to deny coverage for the issue in dispute, to aid the enrollee or the enrollee's representative in preparing the enrollee's grievance.

(v) The plan shall complete its review and investigation, and shall arrive at its decision, within 30 days of the receipt of the grievance.

(vi) The plan shall notify the enrollee, the enrollee's representative, and the health care provider if the health care provider filed a grievance with enrollee consent, of the decision of the internal review committee in writing, within 5 business days of the committee's decision. The notice to the enrollee, the enrollee's representative, and the health care provider, shall include the basis for the decision and the procedures for the enrollee or provider to file a request for a second level review of the decision of the initial review committee including:

(A) A statement of the issue reviewed by the first level review committee.

(B) The specific reasons for the decision.

(C) References to the specific plan provisions on which the decision is based.

(D) If an internal rule, guideline, protocol, or other similar criterion was relied on in making the decision, either the specific rule, guideline, protocol or criterion, or instructions on how to obtain the internal rule, guideline, protocol, or criterion.

(E) An explanation of the scientific or clinical judgment for the decision, applying the terms of the plan to the enrollee's medical circumstances.

(F) An explanation of how to file a request for a second level review of the decision of the initial review committee and the time frames for requesting a second level review, if any. See § 9.702(d)(1) (relating to complaints and grievances).

(2) *Second level review.*

(i) Upon receipt of the request for a second level review, the plan shall send the enrollee, the enrollee's representative, and the health care provider, if the health care provider filed the grievance with enrollee consent, an explanation of the procedures to be followed during the second level review. This information shall include the following:

(A) A statement that, and an explanation of how, the enrollee or the enrollee's representative may request the aid of a plan employee at no charge, who has not

participated in previous decisions to deny coverage for the issue in dispute, in preparing the enrollee's second level grievance.

(B) Notification that the enrollee and the enrollee's representative, and the health care provider, if the health care provider filed the grievance with enrollee consent, have the right to appear before the second level review committee and that the plan will provide the enrollee and the enrollee's representative, and the health care provider with 15 days advance written notice of the time scheduled for that review.

(ii) The second level review committee shall be made up of three 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 shall have the duty to be impartial in their review and decision.

(iii) The second level review shall satisfy the following:

(A) The enrollee, the enrollee's representative, and the health care provider, if the health care provider filed the grievance with enrollee consent, shall have the right to be present at the second level review, and to present a case.

(B) The plan shall notify the enrollee, the enrollee's representative, and the health care provider at least 15 days in advance of the date scheduled for the second level review.

(C) The plan shall provide reasonable flexibility in terms of time and travel distance when scheduling a second level review to facilitate the attendance of the enrollee, the enrollee's representative, and the health care provider. The plan shall make reasonable accommodation to facilitate the participation of the enrollee and the enrollee's representative, and the health care provider, if the provider has filed the grievance with enrollee consent, by conference call or in person and shall take into account the enrollee's and the enrollee's representative's access to transportation and any disabilities that may impede or limit the enrollee's ability to travel.

(D) If an enrollee or the enrollee's representative, or the health care provider if the health care provider filed the grievance with the enrollee's consent, cannot appear in

person at the second level review, the plan shall provide the enrollee and the enrollee's representative or the health care provider the opportunity to communicate with the review committee by telephone or other appropriate means.

(E) Attendance at the second level review shall be limited to members of the review committee; the enrollee, or the enrollee's representatives, including any legal representative or attendant necessary for the enrollee to participate in or understand the proceedings, or both; the health care provider if the health care provider filed the grievance with enrollee consent; applicable witnesses; and appropriate representatives of the plan. Persons attending and their respective roles at the review shall be identified for the enrollee and the enrollee's representative.

(F) The plan shall provide, at no charge, at the request of the enrollee or the enrollee's representative, a plan employee, who has not participated in previous decisions to deny coverage for the issue in dispute, to aid the enrollee or the enrollee's representative in preparing the enrollee's second level grievance.

(G) Committee proceedings at the second level review shall be informal and impartial to avoid intimidating the enrollee or the enrollee's representative.

(H) The committee may not discuss the case to be reviewed prior to the second level review meeting.

(I) A committee member who does not personally attend the review meeting may not vote on the case unless that person actively participates in the review meeting by telephone or videoconference, and has the opportunity to review any additional information introduced at the review meeting prior to the vote.

(J) The plan may provide an attorney to represent the interests of the committee and to ensure the fundamental fairness of the review and that all disputed issues are adequately addressed. In the scope of the attorney's representation of the committee, the attorney representing the committee may not argue the plan's position, or represent the plan or plan staff.

(K) The committee may question the enrollee and the enrollee's representative, the health care provider if the provider filed the grievance with enrollee consent, and plan staff representing the plan's position.

(L) The committee shall base its decision solely upon the materials and testimony presented at the review. The committee may not base its decision upon any document obtained on behalf of the plan which sets out medical policies, standards or opinions or specifies opinions supporting the decision of the plan unless the plan has made available for questioning by the review committee or the enrollee, in person or by telephone, an individual, of the plan's choice, who is familiar with the policies, standards or opinions set out in the document.

(iv) The proceedings of the second level review committee, including the enrollee's comments and the comments of the enrollee's representatives and the health care provider if the provider filed the grievance with enrollee consent shall be either transcribed verbatim, summarized, or recorded electronically, and maintained as a part of the grievance record to be forwarded upon a request for an external grievance review.

(v) The plan shall complete the second level grievance review and arrive at its decision within 45 days of receipt of the request for the review.

(vi) The plan shall notify the enrollee, the enrollee's representative, and 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.

(vii) The plan shall include the basis for the decision and the procedures for the enrollee and the enrollee's representative or the health care provider to file a request for an external grievance review in its response to the enrollee, the enrollee's representative or health care provider, if the health care provider filed the grievance with the enrollee's consent including the following:

(A) A statement of the issue reviewed by the second level review committee.

(B) The specific reasons for the decision.

(C) References to the specific plan provisions on which the decision is based.

(D) If an internal rule, guideline, protocol, or other similar criterion was relied on in making the decision, either the specific rule, guideline, protocol or criterion, or instructions on how to obtain the internal rule, guideline, protocol, or criterion.

(F) An explanation of the scientific or clinical judgment for the decision, applying the terms of the plan to the enrollee's medical circumstances.

(G) An explanation of how to request an external grievance review.

(H) The time frames for the enrollee and the enrollee's representative, or the health care provider to file a request for an external grievance review. See § 9.707(b)(1) (relating to external grievance process).

(3) *Same or similar specialty.*

(i) Both the initial and second level grievance review 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 review meeting and discussion by written report, telephone or videoconference. A licensed physician or approved licensed psychologist who does not personally attend the review meeting may not vote on the grievance, unless that person actively participates in the review meeting by telephone or videoconference and has the opportunity to review any additional information introduced at the review meeting prior to the vote. A licensed physician or approved licensed psychologist not voting on the grievance shall provide input by written report as stated in subparagraph (iii).

(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, the

enrollee's representative, and the health care provider, if the health care provider filed the grievance with the enrollee's consent, of that fact in advance of the review and of the right of the enrollee and the enrollee's representative, and the health care provider, if the health care provider filed the grievance with the enrollee's consent, to request a copy of the written report of the licensed physician or approved licensed psychologist. The plan shall provide the enrollee and the enrollee's representative, and the health care provider who filed the grievance with enrollee consent, 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.

(iv) The plan shall include in the report in subparagraphs (ii) and (iii) the credentials of the licensed physician or approved licensed psychologist reviewing the case. If the licensed physician or approved licensed psychologist is included in the review in subparagraph (ii), a copy of the credentials of the physician or approved licensed psychologist shall be provided to the enrollee, the enrollee's representative and to the health care provider, if the health care provider filed the grievance.

(v) For purposes of this section, if a specialist who is a physician or psychologist is requesting the health care service in dispute, the reviewing physician or psychologist must be a specialist in the same or similar specialty.

§ 9.706. Health care provider initiated grievances.

(a) A health care provider may, with the written consent of an enrollee that meets the requirements of subsection (g), file a written grievance with a plan.

(b) A health care provider may obtain written consent from an enrollee or the enrollee's legal representative to pursue a grievance in lieu of the enrollee at the time of treatment. A health care provider may not require an enrollee or the enrollee's legal representative to sign a 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 bill the enrollee or the enrollee's legal representative for services provided that are the subject of the grievance until the external grievance review has been completed or the enrollee or the enrollee's legal representative rescinds consent for the health care provider to pursue the grievance. If the health care provider chooses never to bill the enrollee or the enrollee's legal representative for the services provided that are the subject of the grievance, the health care provider may drop the grievance with notice to the enrollee and the enrollee's legal representative in accordance with subsection (g).

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

(e) The consent of an enrollee or the enrollee's legal representative to a health care provider to pursue a grievance shall be in writing, shall be automatically rescinded upon the failure of the health care provider to file or pursue a grievance under this subchapter and shall include each of the following elements:

(1) The name and address of the enrollee and of the policy holder, if they are different, the enrollee's date of birth and the enrollee's identification number.

(2) If the enrollee is a minor, or is legally incompetent, the name, address and relationship to the enrollee of the person who signs the consent for the enrollee.

(3) The name, address and plan identification number of the health care provider to whom the enrollee is providing the consent.

(4) The name and address of the plan to which the grievance will be submitted.

(5) An explanation of the specific service for which coverage was provided or denied to the enrollee to which this consent will apply.

(6) The following statements:

(i) The enrollee or the enrollee's representative may not submit a grievance concerning the services listed in this consent form unless the enrollee or the enrollee's legal representative rescinds consent in writing. The enrollee or the enrollee's legal representative has the right to rescind a consent at any time during the grievance process.

(ii) The consent of the enrollee or the enrollee's legal representative shall be automatically rescinded if the provider fails to file a grievance, or fails to continue to prosecute the grievance through the second level review process.

(iii) The enrollee or the enrollee's legal representative, if the enrollee is a minor or is legally incompetent, has read, or has been read this consent form, and has had it explained to his satisfaction. The enrollee or the enrollee's legal representative understands the information in the enrollee's consent form.

(7) The dated signature of the enrollee, or the enrollee's legal representative, and the dated signature of a witness.

(f) 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 continue with the grievance instead of the enrollee. The legal representative of the enrollee may exercise the rights conferred upon the enrollee by this subsection.

(g) The provider, having obtained consent from the enrollee or the enrollee's legal representative to file a grievance, shall have 10 days from receipt of the standard written UR denial and any decision letter from a first, second or external review upholding the plan's decision to notify the enrollee or the enrollee's legal representative of its intention not to pursue a grievance.

[Continued on next Web Page]

§ 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 request an external review of a 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, the enrollee's representative or the health care provider who filed the grievance shall have 15 days from receipt of the second level grievance review decision to file a request for an external review with the plan. If the request for an external grievance is being filed by a health care provider, the health care provider shall provide the name of the enrollee involved and a copy of the enrollee's written consent for the health care provider to file the grievance.

(2) Within 5 business days of receiving the external grievance from the enrollee or a health care provider filing a grievance with enrollee consent, the plan shall notify the Department, the enrollee and the health care provider if the health care provider has filed the grievance with enrollee consent, 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 notification and the request for assignment of a CRE, and the information in paragraph (5), 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 such reviews.

(5) The plan's request to the Department for assignment of a CRE shall include the following:

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

(ii) If the request for an external grievance is being filed by a health care provider, identifying information for that provider, and a copy of the enrollee's written consent to the health care provider to file the grievance.

(iii) The name of the plan.

(iv) The enrollee's plan identification number.

(v) The enrollee's appeal from the second level grievance review decision.

(vi) A copy of the decision of the second level review committee.

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

(viii) Other reasonably necessary supporting documentation, which may include UR criteria, technology assessments, care notes, information submitted by clinicians regarding the enrollee's health status as it relates to the matter being reviewed, opinions from specialists in a same or similar specialty or peer reviewers and information submitted by the enrollee, the enrollee's representative and the treating health care providers.

(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 request for an external grievance review, the plan shall forward to the CRE assigned to perform the external grievance review 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, the enrollee's representative, or the health care provider if the health care provider filed the grievance with consent, with the list of documents being forwarded to the CRE for the external review.

(8) The enrollee, the enrollee's representative, or the health care provider if the health care provider filed the grievance with enrollee consent, within 15 days of receipt of notice that the request for an external grievance review was filed with the plan, may supply additional information to the CRE for consideration in the external review but shall simultaneously provide copies of the information to the plan so that the plan has an opportunity to consider the additional information.

(c) Within 2-business days of receiving a request for an external grievance review, the Department will assign a CRE from its list of approved CREs on a rotation basis and will provide notice of the CRE assignment to the plan, the enrollee and the enrollee's representative, the health care provider, if the grievance was filed with enrollee consent, and the CRE.

(d) The Department will make available additional information from the CRE's accreditation application to the plan, the enrollee and the enrollee's representative, or the health care provider that filed a grievance with enrollee consent upon request. The Department will include in the notice issued under subsection (c), instructions on how to contact the Department for this information.

(e) If the Department fails to select a CRE within 2 business days of receipt of a request for an external grievance review, the plan may designate a CRE to conduct a review from the list of CREs approved by the Department. The plan may not select a CRE that has a current contract or is negotiating a contract with the plan or its affiliates to perform UR, or is otherwise affiliated with the plan or its affiliates to conduct the external grievance review.

(f) Each party has 7 business days from the date on the notice of assignment of the CRE to object orally or in writing to the Department about the CRE assigned whether the CRE has been assigned by the Department, or designated by the plan under subsection (e) based on conflict of interest. For purposes of this section, conflict of interest shall mean that the CRE has or is proposing to enter into a contract with the plan or an affiliate of the plan to perform UR, or is otherwise affiliated with the plan or its affiliates. The objecting party may request the assignment of another CRE.

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

(h) If either party objects to the second CRE assigned, the 60-day time period allowed for the CRE's review under § 9.708(a) (relating to external grievance reviews by CREs) will be calculated from the date on which the CRE is accepted by both parties.

(i) The Department will assign a uniform tracking number, which shall be utilized by the plan, CRE, enrollee and the enrollee's representative, and health care provider who filed the grievance with enrollee consent to communicate with or report data to the Department.

(j) 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.

(k) If the CRE's decision in an external grievance review filed by a health care provider is against the health care provider in full, the health care provider shall pay the fees and costs associated with the external grievance. Regardless of the identity of the grievant, if the CRE's decision is against the plan in full or in part, the plan shall pay the fees and costs associated with the external grievance review. If the enrollee or the enrollee's representative files an external grievance, and the plan prevails, the plan shall pay the fees and costs. For purposes of this section, fees and costs do not include attorney's fees.

§ 9.708. External grievance reviews by CREs.

(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. The decision shall be sent to the enrollee and the enrollee's representative, the health care provider, if the health care provider filed the grievance with enrollee consent, the plan, and the Department. The decision shall include the credentials of the individual reviewer, a list of the information considered in reaching the decision, the basis and clinical rationale for the decision, a brief statement of the decision, and the statement that the enrollee, and the enrollee's representative, or the health care provider have 60 days from receipt of the decision to appeal to a court of competent jurisdiction.

(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 in § 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 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, the prudent layperson standard and the enrollee's certificate of coverage.

§ 9.709. Expedited review.

(a) A plan shall make an expedited review procedure available to enrollees 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.

(b) An enrollee may request from the plan an expedited review at any stage of the plan's review process 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.

(c) In order to obtain an expedited review, an enrollee shall provide the plan with a certification, in writing, from the enrollee's physician that 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. The certification shall include a clinical rationale and facts to support the physician's opinion. The plan shall accept the physician's certification, and provide an expedited review.

(d) 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 the following:

(1) The time frames.

(2) The requirements of § 9.705(c)(2)(iii)(b), (c) and (i) (relating to internal grievance process). If the plan cannot accommodate the enrollee as to time and distance, or have the committee physically present at the review, the plan shall hold the hearing telephonically and ensure that all information presented at the hearing is read into the record.

(3) The requirements of § 9.705(c)(3)(iii) with respect to providing the report 7 days prior to the review. The plan shall provide a copy of the report to the enrollee prior to the hearing if possible. If not, the plan may read the report into the record at the hearing, and shall provide the enrollee with a copy of the report at that time.

(4) 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 the requirements of this section.

(e) A plan shall conduct an expedited internal review and issue its decision within 48 hours of receipt of the enrollee's request for an expedited review accompanied by a physician's statement in accordance with subsection (c).

(f) 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.

(g) 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.

(h) Within 24 hours of receipt of the enrollee request for an expedited external review, 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.

(i) The Department will assign a CRE within 1 business day of receiving the request for an expedited review.

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

(k) In all cases, the plan shall transfer a copy of the case file to the CRE for receipt on the next business day and the CRE shall have 2 business days to issue a decision.

§ 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 meet the requirements of Act 68 and this chapter.

(b) If changes are made by the plan that have the potential to impact the complaint or grievance process or the outcome of cases, the plan shall submit a copy of the proposed changes to the Department for prior review 60 days before the plan intends to implement the changes.

(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. Informal dispute resolution systems and alternative dispute resolution systems.

(a) *Informal dispute resolution systems.*

(1) A plan and a health care provider may agree to an informal 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.

(2) Procedural errors and administrative denials in which the enrollee is held financially 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 informal dispute resolution systems.

(3) The informal dispute resolution system agreed upon by the plan and its providers shall be included in the health care provider contract with the plan, and shall be enforceable.

(b) *Alternative dispute resolution systems.*

(1) To be acceptable to the Department, an alternative dispute resolution system shall:

(i) Be impartial.

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

(iii) Provide for final review and determination.

(2) An alternative dispute resolution system agreed upon by a plan and its participating providers shall be included in the health care provider contracts and shall be final and binding on both the plan and the health care provider.

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

Subchapter J. HEALTH CARE PROVIDER CONTRACTS

Sec.

Applicability.

Plan and health care provider contracts.

IDS.

Plan-IDS contracts.

IDS-provider contracts.

§ 9.721. Applicability.

This subchapter shall apply to provider contracts between plans subject to Act 68 and health care providers; plans 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, including any document incorporated by reference into that contract, to the Department for review and approval. The plan shall be responsible for assuring that the provider contract meets the requirements of all applicable laws. The Department will review a provider contract within 45 days of receipt of the contract. If the Department does not approve or disapprove the contract within 45 days of receipt, the plan may use the contract and it

shall be presumed to meet the requirements of all applicable laws. If, at any time, the Department finds that a contract is in violation of law, the plan shall correct the violation.

(b) The plan shall submit any material change or amendment to a standard health care provider contract, including a material change or amendment to any document incorporated by reference into the contract, to the Department 10 days before implementation of the change or amendment except for changes required by law or regulation.

(c) To be approved by the Department, a standard 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 sections 2113, 2121 and 2171 of the act (40 P. S. § § 991.2113, 991.2121 and 991.2171).

(d) To be approved by the Department, a standard 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 standard 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) If the provider contract is a contract that affects plan enrollees, language to the following effect:

"In no event including, but not limited to, non-payment 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 all 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 employees 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.

(6) Language concerning prompt payment of claims consistent with the requirements of section 2166 of the act (40 P. S. § 991.2166) and 31 Pa. Code § 154.18 (relating to prompt payment of claims).

(7) Language requiring that if the plan and the health care provider agree to include a termination without cause provision in the contract, neither party shall be permitted to terminate the contract without cause upon less than 60 days prior written notice.

(8) Language requiring the plan to give at least 30 days prior written notice of any changes to contracts, policies or procedures affecting health care providers or the provision or payment of health care services to enrollees, unless the change is required by law or regulation.

(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) Standard IDS contracts between the IDS and the plan 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) A plan and an IDS entering into an arrangement under this subchapter shall notify the Department in writing in advance of any action which could result in the IDS's participating providers being unavailable to provide covered services to enrollees.

§ 9.724. Plan-IDS contracts.

(a) A plan may contract with an IDS for the provision of care by IDS participating health care providers to plan enrollees. The contract between the plan and the IDS shall be in compliance with the requirements of this subchapter.

(b) The plan shall provide a copy of the IDS contract to the Department for review and approval. An IDS contract not based on an approved standard contract shall be submitted to the Department for review and approval. An IDS contract shall be reviewed by the Department in accordance with § 9.722(a) (relating to plan and health care provider contracts). If the IDS contract is based on a standard form contract, the plan shall provide the Department with notice of the contract, including the name, address and description of the IDS, before the effective date of the contract.

(c) The plan shall submit the IDS's standard provider contract to the Department for review and approval before the effective date of the IDS contract. If an IDS's providers have executed plan-provider contracts instead of IDS-provider contracts, the plan shall provide the Department with written notice of those contracts before the effective date of the IDS contract.

(d) For the Department to approve a contract between the plan and the IDS, the contract must meet the following standards:

(1) An IDS, assuming financial risk from a plan, is not required to obtain its own license to assume the risk, provided that the ultimate responsibility for benefits and services to enrollees, as set forth in the enrollee contract, remains the responsibility of the plan.

(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 plan 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 plan 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 plan'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 plan.

(5) The IDS shall acknowledge and agree that the plan 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 plan is directly accountable to the Department for compliance with the standards and for provision of quality, cost-effective care to plan enrollees. Nothing in the plan-IDS contract may limit the plan'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 plan 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 plan-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 plan functions to the IDS shall be subject to performance monitoring by the plan and Department, and is subject to independent validation by the plan, the Department, or an independent quality review organization or CRE approved by the Department.

(8) The IDS shall agree to collect and provide the plan 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 K (relating to CREs) and sections 2151 and 2152 of the act (40 P. S. § § 991.2151 and 2152).

(11) The 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 plan enrollees for covered services (other than authorized copayments, coinsurance, or deductibles) under any circumstances including insolvency of the plan or the IDS.

(12) The 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 plan enrollees if the IDS contractual agreement is in any way jeopardized, suspended, terminated or unexpectedly not renewed. In the event of termination, the plan shall ensure continuity of care for those affected enrollees, under Act 68 and § 9.684 (relating to continuity of care).

(13) If the plan and IDS agree to include a termination without cause provision in the contract between the plan and the IDS, neither party shall be permitted to terminate the contract without cause upon less than 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 IDS contract, the health care provider contracts between the IDS and its participating health care providers shall be submitted by the plan for review and approval to the Department. For this purpose, the IDS shall provide the plan with a copy of these contracts. To secure Department approval of a contract between the plan 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 contained in the IDS-provider contract limits the following:

(i) The authority of the plan to ensure the health care provider's participation in and compliance with the plan'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 plan's system and procedures or the extent to which the plan adequately monitors any function delegated to the IDS, or to require the plan to take prompt corrective action regarding quality of care or consumer grievances and complaints.

(iii) The plan's authority to sanction or terminate a health care provider found to be providing inadequate or poor quality care or failing to comply with plan 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 plan to the IDS for performance of quality assurance, utilization management,

credentialing, provider relations and other medical management systems shall be subject to the plan's oversight and monitoring of IDS performance.

(3) An IDS health care provider shall acknowledge and agree that the plan, 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 the IDS, and that as a result of the termination, the health care provider's participation in the plan 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 plan enrollees for covered services (other than authorized co-payments, coinsurance, or deductibles) under any circumstances including insolvency of the plan or the IDS.

Subchapter K. CREs

CERTIFICATION

Sec.

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CERTIFICATION

§ 9.741. Applicability.

(a) Sections 9.742--9.748 of this subchapter set standards for the certification of CREs and the maintenance of that certification.

(b) Sections 9.749--9.751 set operational standards for entities performing UR.

§ 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.

§ 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 application shall contain the following:

(1) The name, address and telephone number of the applicant 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 all 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, if any, 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 time frames for prospective, concurrent and retrospective UR in section 2152 of the act (40 P. S. § 991.2152).

(c) The applicant shall certify that decisions resulting in a denial shall be made by:

(1) A licensed physician.

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

(d) Compensation from a plan to a CRE, employee, 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. See section 2152(b) of the act (40 P. S. § 991.2152(B)).

(e) The Department may request additional information from the applicant necessary to review the application for compliance with Act 68 and this chapter.

§ 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 known 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 an expedited 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. To be certified, an applicant shall demonstrate it has a contracted and credentialed network of providers, which shall include, at a minimum, all general specialities represented by the American Board Of Medical Specialities (ABMS),

the subspecialties of oncology and physician reviewers specializing in transplantation. An applicant shall also provide a description of its ability to obtain within 24 hours the services of a qualified peer reviewer from any speciality or subspecialty required for an external grievance review.

(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 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) Fee schedule for the conduct of grievance reviews. An applicant will not be certified as a 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 I (relating to complaints and grievances).

(b) The Department will add the name of each 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 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) Been involved in a bankruptcy proceeding as an officer, director or senior manager of a corporation.

(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) Had 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) An entity applying for certification shall include a fee of \$1,000 payable to the Commonwealth of Pennsylvania with its application. Applicants seeking certification to perform external grievance reviews shall include an additional \$1,000.

(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 any 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.* A CRE shall continue to comply with the requirements of Act 68 and this subchapter to maintain its certification. To determine whether a CRE is complying with Act 68 and this subchapter, and is qualified to maintain 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.

(c) The Department will have access to the books, records, staff, facilities and other information, including UR decisions, it finds necessary to determine whether a CRE is qualified to maintain its certification in accordance with Act 68 and this chapter.

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OPERATIONAL STANDARDS

§ 9.751. UR system description.

(a) An entity performing UR shall have a written UR system description which shall include the following:

(1) The scope of the program.

(2) The process used in making decisions.

(3) The resources used in making decisions.

(4) The requirements of this section and of § § 9.752 and 9.753 (relating to UR system standards; and time frames for UR).

(b) The entity shall evaluate its UR system annually. The evaluation shall include a report to the board of directors or the quality assurance or quality improvement committee, and shall address the following:

(1) The appropriateness of clinical criteria.

(2) The consistency of decisionmaking through the conduct of reliability studies of staff application of utilization criteria.

(3) Staff resources and training.

(4) The timeliness of decisions.

(c) The UR system shall include a policy and procedure to enable a health care provider to verify that an individual requesting information for UR purposes is a legitimate representative of the entity.

(d) The entity shall ensure that it has sufficient staff, resources and program oversight to ensure adherence to this subchapter, and to section 2152 of the act (40 P. S. § 991.2152).

(e) The entity shall make this description available to the Department for review every 3 years or upon request for the conduct of any investigation necessary to determine compliance of the entity with Act 68 and applicable sections of this chapter.

§ 9.752. UR system standards.

(a) An entity performing UR shall include a physician in any UR program.

(b) An entity performing UR shall develop clinical criteria to be used in making review decisions as follows:

(1) The clinical criteria shall be developed with input from health care providers in active clinical practice.

(2) The clinical criteria shall be reviewed regularly by the entity performing UR and shall be modified to reflect current medical standards.

(3) The entity shall make its UR criteria available upon the written request of any health care provider.

(c) A UR decision denying or approving payment of a service shall be based on the medical necessity and appropriateness of the requested service, the enrollee's individual circumstances, and the applicable contract language concerning benefits and exclusions. UR criteria may not be the sole basis for the decision.

(d) A UR decision denying payment based on medical necessity and appropriateness shall be made by a licensed physician. An approved licensed psychologist may perform UR for a behavioral health care service within the psychologist's scope of practice if the psychologist's clinical experience provides sufficient expertise to review that specific behavioral health care service, and the following standards are satisfied:

(1) An approved licensed psychologist may not review the denial of payment for a health care service involving inpatient care or a prescription drug.

(2) The use of a licensed psychologist to perform UR must be approved by the Department as part of the certification process for CREs.

(e) An entity performing UR shall notify the health care provider within 48 hours of the request for service of additional facts, documents or information required to complete the UR.

(f) If a UR decision includes a denial, it shall include the contractual basis and clinical reasons for the denial. If a UR decision is a denial, or approves anything less than what

was requested, it shall include language informing the enrollee of how to appeal the decision, including location to which the appeal must be sent and time frames.

(g) Copies of written decisions of internal grievance reviews conducted by CREs shall be sent to the plan at the same time the letter is sent to the enrollee, the enrollee's representative, and to the health care provider if the provider filed the grievance with the consent of the enrollee.

§ 9.753. Time frames for UR.

(a) A concurrent UR decision shall be communicated to the plan, the enrollee and the health care provider within 1-business day of the receipt of all supporting information reasonably necessary to complete the review. The plan shall give the enrollee and the health care provider written or electronic confirmation of the decision within 1-business day of communicating the decision.

(b) A prospective UR decision shall be communicated to the plan, enrollee and health care provider within 2-business days of the receipt of all supporting information reasonably necessary to complete the review. The plan shall give the enrollee and the health care provider written or electronic confirmation of the decision within 2-business days of communicating the decision.

(c) A retrospective UR decision shall be communicated to the plan, the enrollee and the health care provider within 30 days of the receipt of all supporting information reasonably necessary to complete the review. The plan shall give the enrollee and the health care provider written or electronic confirmation of its decision within 15-business days of communicating the decision.

(d) A grievance review decision shall comply with the requirements and time frames set out in §§ 9.705 and 9.707 (relating to internal grievance process; and external grievance process).

Subchapter L. CREDENTIALING

Sec.

Provider credentialing.
Credentialing standards.
Nonphysician providers at facility, agency or organizations.

§ 9.761. Provider credentialing.

(a) A plan shall establish, maintain and adhere to 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 3 years.

(3) Including in the initial credentialing and recredentialing process, a plan assessment of the participating health care providers' ability to provide urgent care and routine care, 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.

(10) Enrollee access to only those participating providers who have been properly credentialed.

(b) The plan shall submit its credentialing plan to the Department for approval. Changes to the credentialing plan shall also be submitted to the Department for approval before 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 submit a report to the Department regarding its credentialing process every 2 years. The report shall include the following:

- (1) The number of applications made to the plan.
- (2) The number of applications approved by the plan.
- (3) The number of applications rejected by the plan.
- (4) The number of providers terminated for reasons of quality.

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

§ 9.762. Credentialing standards.

(a) At a minimum, for PCPS and specialists, a plan shall verify the following credentialing elements:

- (1) Current licensure.
- (2) Education and training.
- (3) Board certification status.
- (4) Drug enforcement administration certification status.
- (5) Current and adequate malpractice coverage.
- (6) Malpractice claims history.
- (7) Work history.
- (8) Hospital privileges if the provider provides services at hospitals.
- (9) Any other information the Department may require.

(b) A plan shall verify, at a minimum, for non-PCPS and nonspecialists, current licensure and malpractice coverage, to the extent licensure and coverage is required by State or Federal law.

§ 9.763. Nonphysician providers at facility, agency or organizations.

A plan is not required to credential a nonphysician provider who practices as an employee or independent contractor of a plan-contracted facility, agency or organization if the plan verifies that the facility, agency or organization conducts credentialing that meets the standards of § 9.762 (relating to credentialing standards).

[Pa.B. Doc. No. 01-1032. Filed for public inspection June 8, 2001, 9:00 a.m.]

[31 Pa.B. 3175]