Regulatory Analysis Form

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INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency

Department of Health

IRRC Number:

Bush

#2079

(2) I.D. Number (Governor's Office Use)

DOH Reg. No.10-160

(3) Short Title

Managed Care Organizations

(4) PA Code Cite

28 PA Code Ch. 9

(5) Agency Contacts & Telephone Numbers

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(6) Type of Rulemaking (Check One)

√ Proposed Rulemaking

___ Final Order Adopting Regulation

Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

√ No

___ Yes: By the Attorney General

___ Yes: By the Governor

Regulatory Analysis Form

(8) Briefly explain the regulation in clear and non-technical language.

The Department of Health (the Department) is proposing to amend Subchapter A of 28 Pa. Code Chapter 9 (relating to "Health Maintenance Organizations") by repealing the existing regulations at sections 9.1 to 9.97 (relating to managed care organizations), the statement of policy set out in sections 9.401 to 9.416 (relating to PHOs, POs and IDSs) and the statement of policy set out in sections 9.501 to 9.519 (relating to quality health care accountability and protection), and replacing them with the proposed regulations.

In the years since the HMO regulations were originally promulgated, there have been significant changes to the managed care industry. Mechanisms for the delivery of health care financing and health care services have evolved so that provisions intended to deal with HMOs no longer provide sufficient oversight and protection to enrollees.

Further, with the passage of the health care accountability and protection provisions of the act of June 17, 1998 (P.L. 464, No. 68) (40 P.S. §§991.2101-991.2193) (Article XXI), amending the Insurance Company Law of 1921 (P.L. 682, No. 284) (40 P.S. §361 et seq.), the Department became responsible for additional responsibilities, including creation of standards for provider credentialing, and certification of utilization review entities.

In proposing regulations, the Department is attempting to address the changes in the managed care industry, to include its statements of policy in regulation as necessary, and to implement the health care accountability and protection provisions of Article XXI.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The Department's authority to promulgate these proposed regulations is based upon three statutes: the Health Maintenance Organization Act (40 P.S. §1551 et seq.) (The HMO Act); the amendments to the Insurance Company Law of 1921 known as the P.O. Act, (40 P.S. §764a(e)); and Act 68.

The Department has authority to promulgate regulations relating to the certification and operations of HMOs pursuant to section 14 of the HMO Act. (40 P.S. §1564). Section 5.1(a) gives the Department the authority to determine what form the application will take and what information will be contained in a corporation's application for certification as an HMO. (40 P.S. §1555.1(a)). Section 5.1(b)(1)(ii) provides the Department with authority to determine whether an HMO has demonstrated potential ability to assure both availability and accessibility of adequate personnel and facilities in manner enhancing availability, accessibility and continuity of services. (40 P.S. §1555.1(b)(1)(i)). Section 5.1(b)(1)(ii) provides the Department with authority to determine whether an HMO has demonstrated it has arrangements for an ongoing quality of health care assurance program. (40 P.S. §1555.1(b)(1)(ii)). Section 5.1(b)(1)(iii) provides the Department with authority to determine whether an HMO has appropriate mechanisms to effectively provide or arrange for provision of basic health care services on a prepaid basis. (40 P.S. §1555.1(b)(1)(iii).

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(9) State the statutory authority for the regulation and any relevant state or federal court decisions. (Continued)

Section 8(a) allows the Secretary to require renegotiation of provider contracts when those contracts provide for excessive payments, fail to include reasonable incentives or contribute to escalation of costs of health care services to enrollees. (40 P.S. §1558(a)).

Section 8(a) also permits the Secretary to require renegotiation when he determines that the contracts are inconsistent with the purposes of the HMO Act. (Id.) Section 10(e) requires that an HMO establish and maintain a grievance resolution system satisfactory to the Secretary. (40 P.S. §1560(e)). Section 11(c) provides the Secretary and his agents with free access to all books, records, papers, and documents that relate to the non-financial business of the HMO. 40 P.S. §1561(c)). Finally, section 15 provides the Department with the authority to suspend or revoke an HMO's certificate of authority, or to fine the HMO for isolations of the HMO Act. (40 P.S. §1565).

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

Section 2102(g) of the Administrative Code of 1929 (71 P.S. §51, §532(g)) ("the Code"), provides the Department with general authority to promulgate its regulations.

The Department also has authority to review and approve grievance resolution systems and to require quality and utilization controls of certain preferred provider organizations ("PPOs") pursuant to the PPO Act. 40 P.S. §764a(e) requires that the Department of Insurance consult with the Department in determining whether arrangements and provisions for a PPO which assumes financial risk which may lead to under treatment or poor quality care are adequately addressed by quality and utilization controls as well as by formal grievance system. (40 P.S. §764a(e)).

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

The Department is required by Act 68 to promulgate regulations to carry out its responsibilities under Article XXI. (See 40 P.S. §991.2181(e)). The Department must also promulgate regulations to carry out its responsibilities under the HMO Act. (See 40 P.S. 1564).

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(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

In 1998, the General Assembly passed Act 68. That act requires the Department to enforce certain of its requirements, and mandates the promulgation of regulations for its implementation.

The Department's regulations governing health maintenance organization (HMOs), set out in 28 Pa. Code §§9.1 through 9.97, were adopted in 1983. The rapid growth in the industry of managed care and the changes in the entities which may deliver and finance health services in the managed care field, made the current regulations obsolete, and created a demand for a revision of these regulations. The need for revision was highlighted by the Department's review of these regulations pursuant to Executive Order 1996-1, which required each state agency under the Governor's jurisdiction to review its existing regulations.

The proposed regulations update the outdated HMO regulations, and facilitate the implementation of Article XXI as required by Act 68.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

The General Assembly has determined that HMOs should be regulated to ensure quality assurance, cost-effectiveness, and access to health care services. (See 40 P.S. §1552 (relating to the purpose of the HMO Act)). The General Assembly also determined that the issues of health care accountability and protection should be addressed. (See generally, 40 P.S. §991.2101 et seq.). The legislature authorized the Department to carry out responsibilities with regard to both these acts.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The proposed regulations would affect HMOs certified to do business in the Commonwealth, since the proposed regulations would clarify and simplify certain requirements for HMO certification. Managed care plans as defined by Act 68, including certified HMOs, would also benefit, in that the proposed regulations would create a level playing field with regard to certain consumer protection issues; for example, Act 68 requires that enrollees be permitted to request the assignment of a specialist as a primary care provider. The proposed regulations most directly benefit enrollees served by, and providers who participate in, these managed care plans, since Act 68 was intended to enhance consumer access to, and the availability of, health care services offered through covered managed care plans. The proposed regulations, in implementing the requirements of Article XXI, would also set standards for health care provider credentialing, provider participation in grievances, and integrated delivery systems, all of which have the effect of clarifying provider roles in the managed care system, and giving providers a voice in that system.

Regulatory Analysis Form

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

The proposed regulations place certain requirements on HMOs seeking certification to do business in the Commonwealth and not exempted by the HMO Act (See 40 P.S. §1566). For the most part, these requirements are clarifications of the Department's current regulations set out at 28 Pa. Code §9.1 et seq., however, the Department has added several additional requirements, relating, for example, to the composition of the HMO board. Such requirements may be viewed as adversely affecting HMOs, although the Department's intention is to ensure accessibility and availability of health care by ensuring the quality of the system providing the care.

The proposed regulations might also be said to adversely affect managed care plans as defined by Act 68, since the proposed regulations place new requirements on these entities to ensure their compliance with Article XXI. For example, depending upon how plans have structured complaint and grievance processes prior to the passage of Act 68, the complaint and grievance process mandated by Act 68 may increase cost. Among other things, the proposed regulations and Act 68 require a certain composition of review committees, which may add to the cost of the review. The additional disclosure requirements of the act may also have a fiscal impact upon managed care plans, including HMOs.

The proposed regulations also affect entities either conducting or wishing to conduct internal or external utilization reviews, since Act 68 requires these utilization review entities (except for licensed insurers and managed care entities with certificates of authority) to be certified by the Department.

Licensed insurers are also affected by sections 9.742 of the proposed regulations (relating to utilization review); Act 68 requires licensed insurers performing utilization review to comply with the terms of section 2152 (40 P.S. §991.2152) (relating to operational standards for certified utilization review entities). (See 40 P.S. §991.2151(e)). Such licensed insurers are not required to seek certification. (Id.)

The Act also imposes limitation on the length of time enrollees have to file appeals of complaints and grievances; prior to Act 68 there were no such limits.

Regulatory Analysis Form

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

Corporations wishing to receive certification to operate as HMOs would be required to comply with the proposed regulations, as would HMOs currently in existence, and not exempted by the exclusion provision of the HMO Act. (40 P.S. §1566).

Managed care plans as defined by Act 68 (including HMOs and gatekeeper PPOs) not exempted by the preemption provisions of Article XXI (40 P.S. §991.2193) would be required to comply with the proposed regulations.

Health care providers wishing to provide or providing services through a managed care arrangement would be required to comply with the proposed regulations.

Utilization review entities wishing to review health care services delivered or proposed to be delivered in the Commonwealth, or currently operating in the Commonwealth would be required to comply with the proposed regulations. Licensed insurers would be required to comply with the proposed regulations relating to utilization review, except for those provisions which would require certification as a review entity.

Enrollees of managed care plans covered by Act 68 would be required to comply with the proposed regulations.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

In drafting its proposed regulations, the Department has taken into account the recommendations of managed care work groups the Department convened in the summer of 1997 to review its regulations relating to health maintenance organizations. The work groups met from July of 1997 through December of that year, and included representatives from health plans, providers, purchasers, and consumers, as well as Department staff and staff from the Departments of Insurance, Public Welfare, Aging, Education and the Health Care Cost Containment Council.

The Department has also taken into account the comments it has received on draft proposed regulations from various groups of stakeholders, again including consumers, plans, and health care providers.

Regulatory Analysis Form

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

The proposed regulations relating to HMOs should not have a significant fiscal impact upon HMOs since comprehensive revision and updating of the HMO regulations should make compliance with those regulations easier. With respect to the requirements of Article XXI, however, which the Department proposes to implement through its proposed regulations, there may be some increased cost to managed care plans. For example, depending upon how plans have structured complaint and grievance processes prior to the passage of Act 68, the complaint and grievance process mandated by Act 68 may increase cost. Among other things, the proposed regulations and Act 68 require a certain composition of review committees, which may add to the cost of the review. The additional disclosure requirements of the act may also have a fiscal impact upon managed care plans, including HMOs.

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

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

Act 68 may also create an additional cost for utilization review entities (CREs). Pursuant to Act 68 , CREs are required to obtain certification from the Department in order to perform reviews health care services delivered or proposed to be delivered in the Commonwealth. Prior to the passage of Act 68, this requirement did not exist. CREs would be required to pay a fee to the Department along with the application, and would again have to pay a fee for recertification every three years.

The regulations concerning Act 68 will create additional costs to the regulated community. The disclosure requirements in the Act could exceed an estimated $3.00 per family contract, estimated at 2 million, for approximately $6 million in the first year of implementation. Obtaining the input from specialists of same or similar specialty, as Act 68 requires, and the grievance review process will also increase cost to managed care plans.

There is also cost to the health care provider community. Health care providers that initiate grievances could pay for the cots of the external grievance review if they are the non-prevailing party. Enrollees who file grievances could face a $25 filing fee for external grievance reviews.

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(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required. (Continued)

The managed care industry has estimated the impact of Act 68 to be approximately a 3% premium increase. Due to the requirements and implications not yet foreseen, it is not possible to calculate specific cost estimates. It is expected there will be no cost savings.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

The proposed regulations would not affect local governments.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including and legal, accounting, or consulting procedures which may be required.

The revisions to the current regulations at 28 Pa. Code Ch. 9 (relating to health maintenance organizations) would create no additional cost to the Commonwealth, since these revisions are intended to reflect the current operations of the Department. There is no fiscal impact even though there will be additional monitoring duties placed on the Department by Act 68. Those duties are reflected in provisions of the proposed regulations relating to health care accountability and access, complaints and grievances, provider contracts, accreditation of utilization review entities, and credentialing. The Department would, among other things, be required to review additional contracts and grievance and complaint procedures submitted by managed care plans, and requests for certification from utilization review entities. The Department would also coordinate the external review procedure set out in Act 68, which would require the Department to appoint and oversee the operations of the certified review entity conducting the review.

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(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	$	$	$	$	$	$
Regulated Community	$0	0	0	0	0	0
Local Government	$0	0	0	0	0	0
State Government	$0	0	0	0	0	0
Total Savings	$0	0	0	0	0	0
COSTS:						
Regulated Community	$6 million	$6million	$6million	$6million	$6million	$6million
Local Government	$ 0	0	0	0	0	0
State Government	$0	$0	$0	$0	$0	$0
Total Costs	$0	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community	$0	0	0	0	0	0
Local Government	$ 0	0	0	0	0	0
State Government	$0	0	0	0	0	0
Total Revenue Losses	$0	0	0	0	0	0

(20a) Explain how the cost estimates listed above were derived.

Cost: Regulated community costs based on disclosure requirements.
Approximately 2 million family contracts x $3 = $6 million.

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(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	95/96	96/97	97/98	98/99
Bureau of Managed Care	$659,403	$698,572	$1,134,102	$1,142,144

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs

Article XXI (relating to health care accountability and protection) reflects the legislature's emphasis on ensuring that managed care plans act responsibly, and that health care providers and enrollees are provided with essential information to make informed decisions. It is expected that these benefits outweigh the costs to the managed care plans.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Because Act 68 requires regulations to facilitate the implementation of Article XXI, and the HMO Act requires regulations for its implementation, no alternatives were considered.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

Because the Department currently has regulations addressing managed care organizations, the Department made the decision to facilitate the implementation of Article XXI through revision of the current regulations. In doing so, the Department is able to both address the issue of the outdated HMO regulations, and facilitate the implementation of Article XXI.

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

Because of various preemptive and exclusionary provisions in State and Federal law, entities governed by Federal regulation are not subject to State regulation.

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(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

No other state has issued as comprehensive a set of regulations on health care accountability and protection as the Departments of Health and Insurance of this Commonwealth. The regulations being proposed by the Department, however, are required by both the HMO Act and Act 68. Some states have issued provision dealing with specific issues addressed by the health care accountability and protection provisions of Act 68; for example, the state of New York recently enacted legislation addressing prompt payment of claims which is very aggressive in penalizing noncompliant plans. Approximately 28 states have passed external review legislation, each piece of legislation contains different requirements.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

These proposed regulations will not affect the Department's current regulations. Under both Act 68 and the HMO Act, both the Department and the Department of Insurance are required to promulgate regulations to facilitate implementation. The Department of Insurance has not altered its regulations regarding HMOs at 31 P.S. ch. 301. The Department's proposed regulations regarding Article XXI issues are intended to complement the regulations on the same topic being proposed by the Department of Insurance. The Department of Insurance's regulations were published as proposed on July 31, 1999 (29 Pa. Bull. 4064).

(27) Will any public hearings or information meetings be scheduled? Please provide the dates, times, and locations, if available.

The Department made draft regulations available in May of this year, and placed them on its website for greater public access. The Department intends to propose a 30-day public comment period on its proposed regulations once they are published in the Pennsylvania Bulletin.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

There would be changes in paperwork requirements associated with the proposed regulations. While the proposed regulations relating solely to HMOs would not alter paperwork requirements for those entities to obtain and maintain certificates of authority, there may be additional paperwork for managed care plans that are not HMOs, since they would be required for the first time to submit provider contracts and complaint and grievance procedures to the Department. HMOs are required by current regulations to make these submissions. Act 68 itself creates additional paperwork, since the plans must comply with the mandated complaint and grievance systems detailed in the act.

Depending upon how plans operated their grievance systems prior to Act 68, the act and the Department's proposed regulations could require additional paperwork of plans. Again, depending upon how managed care plans operated prior to Act 68, the act's requirement that certain disclosures be made to enrollees could result in an increase in paperwork.

Act 68 also creates additional paperwork for utilization review entities (CREs). Pursuant to the act, CREs are required to obtain certification from the Department in order to perform reviews health care services delivered or proposed to be delivered in the Commonwealth. Prior to the passage of Act 68, this requirement did not exist.

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

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(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

Section 2111(11) of Act 68 (40 P.S. §991.2121(11)) requires managed care plans to ensure that they have participating providers that are physically accessible to people with disabilities and can communicate with persons with sensory disabilities in accordance with Title III of the Americans with Disabilities Act of 1990 (42 U.S.C. §12181 et seq.) The proposed regulations would include a section reflecting this requirement. (See proposed section 9.680) (relating to access for persons with disabilities).

The proposed regulations would also reflect Act 68's requirement that plans disclose their procedures for addressing the needs of non-English speaking enrollees. (See proposed section 9.676 (relating to standards for statements of enrollee rights and responsibilities).

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The regulations would be effective upon publication in the Pennsylvania Bulletin as final rulemaking. Any entity requiring licensure or certification must obtain that licensure or certification prior to doing business in the Commonwealth.

(31) Provide the schedule for continual review of the regulation.

The Department will continually review and monitor the effectiveness of these proposed regulations.

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INDEPENDENT REGULATORY REVIEW COMMISSION

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

#2079

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or independent Agencies.
BY _____ DEPUTY ATTORNEY GENERAL	DEPARTMENT OF HEALTH (AGENCY)	BY _____
DEC 06 1999 DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-160	11-12-99 DATE OF APPROVAL
	DATE OF ADOPTION: _____	(Deputy General Counsel) ~~(Chief Counsel, Independent Agency)~~ (Strike inapplicable title)
☐ Check if applicable. Copy not approved. Objections attached.	BY: Robert S. Zimmerman, Jr. TITLE: Secretary of Health	☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

[28 Pa. Code Chapter 9]

RELATING TO MANAGED CARE ORGANIZATIONS

CONTINUATION SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU
(Pursuant to Commonwealth Documents Law)

The Department of Health (Department) proposes to amend 28 Pa. Code Chapter 9 (relating to Managed Care Organizations) by repealing the existing regulations in Subchapter A (relating to health care organizations) §§9.1 - 9.97, the statement of policy in subchapter D (relating to PHOs, POs and IDSs) §§9.401 - 9.416, and the statement of policy in subchapter E (relating to quality health care accountability and protection) §§9.501 - 9.519. The Department proposes to replace these regulations and statements of policy with the proposed regulations in Annex A.

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PURPOSE OF THE REGULATIONS

The Department's regulations governing health maintenance organizations (HMOs) in 28 Pa. Code §§9.1 through 9.97, hereinafter referred to as the "HMO regulations" were adopted in 1983. The rapid growth in the industry of managed care and the changes in the entities that may deliver and finance health services in the managed care field have caused the Department to supplement those regulations over time through statements of policy. One such statement of policy addresses an HMO's ability to contract for certain services through an integrated delivery system. See 28 Pa. Code §§9.401- 9.416. Another provides guidelines for the implementation of §§2101-2193 (Article XXI) of the Insurance Company Law of 1921 (P.L. 682, No. 284) (40 P.S. §361 et seq.), amended by the act of June 17, 1998 (P.L. 464, No. 68) (40 P.S. §991.2001-991.2361) (Act 68). See 28 Pa. Code §§9.501-9.519.

In 1996, the Governor Ridge issued Executive Order 1996-1, which required all State agencies under the Governor's jurisdiction to review their existing regulations. In response to

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

In 1998, before revisions to the HMO regulations were completed, the General Assembly passed amendments to the Insurance Company Law of 1921. Act 68 set out specific requirements for managed care plans, which it specifically defined to include any health care plan using a gatekeeper to manage the utilization of health care services. See 40 P.S. §991.2102 (definition of "managed care plan"). In October of 1998, the Department issued a statement of policy providing interim guidance on implementation of §§2101-2193 of the Insurance Company Law of 1921 (Article XXI). The Department also stated that in 1999 it would adopt formal regulations facilitating the implementation of Article XXI. In May of 1999, the Department provided to stakeholders draft regulations combining revisions to the HMO regulations and new provisions facilitating the implementation of Article XXI, and received comments from those entities. The Department has also received input, comments,

and suggestions from stakeholders concerning their experiences during the implementation stage of Article XXI.

In drafting its proposed regulations, the Department has taken into account the recommendations of the managed care work groups as well as the comments received on the draft regulations from stakeholders. The Department's proposed regulations are intended to address both those areas which specifically impact HMOs, and those requirements which managed care plans (other than managed care plans subject to ERISA) must meet under Article XXI. These regulations do not apply to traditional indemnity products or preferred provider organizations without gatekeepers, except with respect to proposed section 6.72. Proposed section 742 reiterates the requirement of section 2151 of Article XXI (40 P.S. §991.2152 (relating to operational standards for utilization review)). Section 2151 requires licensed insurers and managed care plans with certificates of authority performing utilization review to comply with the operational standards for certified utilization review entities in section 2152, although it does not require them to be certified by the Department. See 40 P.S. §991.2151(e).

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

SUMMARY OF THE REGULATIONS

SUBCHAPTER A. GENERAL

Section 9.601. Applicability.

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

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

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

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

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

Section 9.602. Definitions.

The definition section would do two things: update and replace the current definitions relating to the HMO regulations in 28 Pa. Code §9.2; and add definitions relevant to the Department's responsibilities under Act 68.

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

The Department is also proposing to delete the definition of the term, "federally qualified health maintenance organization." Since Federal law no longer provides that a federally

qualified HMO may require an employer to offer it to employees, federally qualified HMOs are no longer the dominant market force, and need not be addressed specifically in the Department's regulations.

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

The Department's proposal to add a definition for "medical management" is also intended to address the actual manner of doing business in the managed care industry. Medical management is a comprehensive term incorporating the full range of utilization review, quality assurance, and disease and case management activities. These services have been

traditionally performed by HMOs, but with increasing frequency are being delegated by the HMO to IDSs and other entities, such as utilization review entities.

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

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

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

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

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

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

Section 9.603. Technical advisories.

This section would deal with new subject matter. It is intended to provide the Department with the flexibility to address the issues of a rapidly changing industry. A technical advisory

issued by the Department would be guidance from the Department on how to meet statutory and regulatory requirements, but would not in and of itself set legally binding standards.

Section 9.604. Plan reporting requirements.

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

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

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

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

Current section 9.91 requires the submission of copies of the HMO's quality assurance report and grievance resolution system. The Department is proposing to extend these requirements

to all managed care plans by virtue of Act 68 and the PPO Act. Section 5.1(b)(1)(ii) (40 P.S. §1555.1(b)(1)(ii)) of the HMO Act provides the Department with authority to determine whether an HMO has demonstrated it has arrangements for an ongoing quality of health care assurance program. Section 10(e) of the HMO Act (40 P.S. §1560(e)), requires that an HMO establish and maintain a grievance resolution system satisfactory to the Secretary. The PPO Act, (40 P.S. §764a(e)) provides the Department with the authority to review and approve grievance resolution systems and to require quality and utilization controls of certain preferred provider organizations (PPOs).

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

Section 9.605. Department Investigations.

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

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

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

Section 9.606. Penalties and sanctions.

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

Subchapter G. HMOs

This subchapter would be applicable to any corporation that proposes to undertake to establish, maintain and operate a health maintenance organization (HMO) within the

Commonwealth of Pennsylvania, with the exception of an HMO exempted under sections 16 and 17(b) of the HMO Act (40 P.S. §§1566 and 1567(b)).

The proposed regulations set out in this subchapter would be, for the most part, revisions of the regulations set out at 28 Pa. Code chapter 9, subchapter A (relating to health maintenance organizations) (HMO regulations). The Department proposes to delete several of the provisions altogether. Section 9.31 of the HMO regulations, refers to the certificate of need process. Chapter 701 of the Health Care Facilities Act (35 P.S. §448.701 et seq.) sunset in December of 1996, therefore, this provision is no longer relevant.

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

Several of the current regulations add nothing to the Department's regulatory scheme. Retaining similar provisions in the new regulations would be unnecessary. Section 9.54 (relating to standards regarding approval of certificate of authority) merely states that an HMO must meet the minimum operating standards in the regulations. Section 9.71 (relating

to operational standards), restates the HMO Act. The Department is proposing not to retain these provisions in the new regulations.

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

Section 9.622. Prohibition against uncertified HMOs.

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

Section 9.623. Pre-application development activities.

This section would revise and replace current section 9.32 of the HMO regulations (relating to pre-application development activities). The revisions would not be substantive except for language stating that a certificate of authority would not be issued until the HMO is able to demonstrate that it has an adequate provider network. The Department has been deeming applications complete even though the applicant has not provided all necessary relevant information relating to provider networks.

Application for Certificate of Authority

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

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

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

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

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

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

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

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

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

Section 9.633. HMO board requirements.

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

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

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

Section 9.635. Delegation of HMO operations.

This section would deal with new subject matter. Subsection (a) would address a growing industry trend of the managed care organization delegating certain functions to a contractor with expertise in performing the function. HMOs have never been prohibited from such

delegation. The Department asks for delegation information in current section 9.52(7) of the HMO regulations (relating to content of application for a certificate of authority).

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

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

To ensure that delegation occurs in a controlled manner that protects both the enrollee and the participating health care provider, the Department is proposing standards for delegation of this authority in proposed subchapter H (relating to access and availability), and would require an HMO to meet these standards before a delegation contract would be approved.

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

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

Operational Standards

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

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

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

Section 9.651 would contain a listing of basic health services that the HMO Act requires an HMO to provide. The Department is proposing to eliminate the definitional language in section 9.72, and to expand, update, and combine definitions where necessary. For example,

the Department proposes to include physician services in the definition for inpatient services. See proposed definition of "inpatient services" in proposed section 9.602 (relating to definition). The Department is also proposing to revise the definition of "emergency services" to reflect Act 68's definition of this term. See proposed definitions of "emergency care", "inpatient services", "outpatient services", and "preventive care services" in proposed section 9.602). Finally, the Department is proposing to insert the definitions, revised and updated, from current section 9.72 into proposed section 9.602.

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

Section 9.653. Use of copayments and coinsurances in HMOs.

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

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

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

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

Section 9.655. HMO external quality assurance assessment.

This section would replace and revise current section 9.93 of the HMO regulations (relating to external quality assurance assessment). In subsection (a), the Department is proposing to increase the time frame in which the quality assurance assessment would be required of the HMO from 1 year from the date the HMO receives its certificate of authority to 18 months

from that date. This change would be in accordance with standards of nationally recognized accrediting bodies. In subsection (e), the Department is also proposing to increase the time frame in which an HMO is required to submit a copy of the external quality assurance assessment report to it from 10 business days from the date of receipt by the HMO to 15 days from that date.

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

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

Subchapter H. Availability and Access

Section 9.671. Applicability.

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

Section 9.672. Emergency services.

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

Subsection (f) would be derived from current section 9.75(f) of the HMO regulations. Act 68 does not limit coverage for emergency services to participating plan providers. Subsection (f), therefore, would require the plan to pay for services provided by a nonparticipating

provider at the same rate as it pays to a participating provider, when the services are determined by the plan to be necessary based on the prudent layperson standard.

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

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

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

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

the formulary within 30 days of the receipt of the inquiry, and that the plan's response be in writing. This would aid the enrollee to prepare and timely file a grievance.

Section 9.674. Quality assurance standards.

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

Section 9.675. Delegation of medical management.

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

Subsection (b) would require any contractor performing utilization review, unless the contractor is a licensed insurer or a plan with a certificate of authority, to be certified in accordance with section 2151 of Article XXI (40 P.S. §991.2151).

Section 9.676. Standards for enrollee rights and responsibilities.

This section would replace and revise section 9.77 (relating to subscriber rights), and would extend the requirement that an HMO have standards for enrollee rights to all managed care plans. In fact, section 9.77 is a collection of personal rights provided enrollees by statutory and common law and regulation. This new section would require plans to develop procedures to implement enrollee rights and responsibilities. The Department is also

proposing that a plan address the disclosure requirements set out in section 2136 of Article XXI (40 P.S. §991.2136).

Section 9.677. Requirements of definitions of medical necessity.

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

Section 9.678. Primary care providers.

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

Subsections (c) and (d) would allow a plan to consider, as a primary care provider, both a physician in a non-primary care specialty and a certified registered nurse practitioner, if those individuals meet certain standards, including the plan's certification requirements.

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

Section 9.679. Access requirements in service areas.

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

miles in urban areas and 30 minutes or 30 miles in rural areas. These times and distances would reflect Federal Health Care Financing Administration (HCFA) requirements for access.

Section 9.680. Access for persons with disabilities.

This proposed section would be new, and would be taken directly from section 2111(11) of Article XXI (40 P.S. §991.2111(11)).

Section 9.681. Health care providers.

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

Section 9.682. Direct access for obstetrical and gynecological care.

This section would deal with new subject matter, and would be based on section 2111(7) of Article XXI (40 P.S. §991.2111(7)). Subsection (d) would implement the requirements of direct access for obstetrical and gynecological care by requiring the plan's quality assurance committee to approve the terms and conditions under which a directly accessed provider could provide services without prior plan approval. Given the difficulty of defining clinical terms such as, "routine gynecological care" adequately and exhaustively in regulation, the Department proposes to refer the matter to the plan's committee of experts, the quality assurance committee.

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

This section would deal with new subject matter, and would be based on section 2111(6) of Article XXI (40 P.S. §991.2111(6)). Section 2111(6) allows an enrollee with a life threatening, degenerative, or disabling disease or condition to request and receive an evaluation and, if the plan's established standards are met, receive either a standing referral to a specialist with clinical expertise in the area in question, or the designation of a specialist as the primary care provider. As in proposed section 9.682 (relating to direct access for obstetrical and gynecological care), subsection (b)(1) would require the plan to develop policies, procedures, and clinical criteria for conducting evaluations and submit them to its quality assurance committee. In this way, the Department would avoid attempting to regulate

clinical criteria, which could quickly become obsolete. The Department also proposes subsection (c) to require that the plan assess these standards annually to monitor the effectiveness of the polices and procedures, as well as the quality of the resultant services provided.

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

Section 9.684. Continuity of care.

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

Subsection (a)(3) and (4) would facilitate implementation of section 2117 by requiring the plan to notify the enrollees it is able to identify through available data and, in that notification,

provide the enrollee with written notice of how to exercise his option to continue care for a transitional period. These requirements would ensure that the enrollee is aware of the option as required by the act, and that the plan is aware of the enrollee's intention to exercise his option under the act.

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

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

the nonparticipating provider, until the plan notifies the enrollee that the nonparticipating provider would not agree to its terms.

Subchapter I. Complaints and Grievances

Section 9.701. Applicability.

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

Section 9.702. Complaints and grievances.

This section would deal with new subject matter. Subsection (a) would require a plan to provide copies of its complaint and grievance procedures to the Department for review prior to implementation. Subsection (b) would require the plan to correct noncompliant

procedures at the Department's direction. Because the plan is given the ability by Act 68 to classify a matter as either a complaint or grievance, the possibility exists that the plan could classify a matter in such a way as to confer an advantage on itself. Subsection (c) would permit either the Insurance Department or the Department to become involved at the classification stage to prevent this problem from arising.

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

Section 9.703. Health care provider initiated grievances.

This section would deal with new subject matter. Act 68 allows for provider initiated grievances with the written consent of the enrollee. 40 P.S. §991.2161(a). Subsection (b) would protect the enrollee from coercion by not allowing the provider to require consent as a condition of service. Subsection (c) would require that once a provider assumes responsibility for a grievance, the provider must continue to prosecute the grievance through the second level review. Subsection (h) would allow the enrollee to rescind his consent at any time. Through these subsections, the Department would attempt to protect the enrollee from the provider that initially is willing to grieve the matter, but makes a determination during the

process that the matter is no longer cost effective for it to pursue. The grievance issue, however, may still represent significant out-of-pocket expense to the enrollee. The Department is not proposing to allow the enrollee to begin the grievance at the initial review, however. Subsection (h) would allow an enrollee to take over the grievance at the point the provider chose to discontinue it. This provision would protect the interests of both parties, and would not be detrimental to the managed care plan.

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

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

Section 9.704. Internal complaint process.

This section would deal with new subject matter. Its requirements would be similar to those contained in section 2141 of Article XXI (40 P.S. §991.2141). To ensure the fundamental

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

Section 9.705. Appeal of a complaint decision.

This section would deal with new subject matter, and would include substantially the same information as contained in section 2142 of Article XXI (40 P.S. §991.2142). Subsection (b)

would require that an enrollee provide to it certain information along with the appeal, for example, the name of the plan and a description of the issue involved.

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

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

Section 9.706. Enrollee and provider grievance system.

This section would deal with new subject matter. Its requirements would be similar to those contained in section 2161 of Article XXI (40 P.S. §991.2161). To ensure the fundamental fairness of the process, subsection (c)(2)(ii) would impose similar requirements on the second level grievance review as it is proposing for the second level complaint review. Act 68 requires that the enrollee be afforded notice of the right to be present in the second level review committee meeting of both the complaint and the grievance process. Compare 40 P.S. §991.2141(c)(2) with 40 P.S. §991.2161(c)(2). Subsection (c)(2)(ii)(A), (B) and (C) would

require that the plan provide reasonable flexibility in terms of the enrollee's time and travel distance when scheduling the second level review, that it provide the enrollee the opportunity to communicate with the review committee if he cannot attend, and that it identify all persons present at the review for the enrollee. Subsection (c)(2)(iii) would require that the deliberations of the committee, including the enrollee's comments, either be transcribed verbatim or summarized, and forwarded to the certified utilization review entity as part of the grievance record.

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

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

Section 9.707. External grievance process.

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

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

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

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

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

Section 9.708. Grievance reviews by certified utilization review entities (CRE).

This section would deal with new subject matter. It would be base on the requirements for CRE review of an external grievance set out in section 2162(c)(2)-(5) of Article XXI (40 P.S. §991.2162(c)(2)-(5)). Subsections (a) and (b) would set out the time frame for the CRE decision, to whom the decision is to be sent, the basis and clinical rationale for the decision, and the standard of review. These two proposed subsections would be based upon language included in section 2162(c)(5) of Article XXI (40 P.S. §991.2162(c)(5)). Subsection (c), which would set out information that the CRE is required to consider, would be based upon section 2162(c)(2) and (3) of Article XXI (40 P.S. §991.2162(c)(2) and (3)). Subsection (d),

which would set requirements for who can make the decision on the CRE's behalf, is taken from section 2162(c)(4) of Article XXI (40 P.S. §991.2162(c)(4)).

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

Section 9.709. Expedited review.

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

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

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

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

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

Section 9.711. Alternative provider dispute resolution systems.

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

Subchapter J. Health Care Provider Contracts

Section 9.721. Applicability.

This section would explain that subchapter J applies to contracts between plans and health care providers, between HMOs and IDSs, and between IDS and health care providers. The Department is proposing this subchapter, relating to health care provider contracts, under its authority to promulgate regulations relating to contractual relationships between the managed care plan and health care providers pursuant to Act 68, the HMO Act, and the PPO Act. Section 2111(1) of Article XXI (40 P.S. §991.2111(1)), requires a managed care plan to assure availability and access of adequate health care providers to enable enrollees to have access to quality and continuity of care. Section 8(a) of the HMO Act (40 P.S. §1558(a)) gives the Secretary the authority to require re-negotiation of provider contracts when they require excessive payments, fail to include reasonable incentives, or contribute to cost escalation.

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

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

Section 9.722. Plan and health care provider contracts.

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

Section 9.723. Integrated Delivery Systems (IDS)

Section 9.724. HMO-IDS provider contract.

Section 9.725. IDS provider contracts.

In 1996, the Department issued a policy statement addressing integrated delivery systems (IDS). This policy statement, entitled, "PHOs, POs, and IDSs – Statement of Policy," (sections 9.401-9.416), would be replaced by section 9.723 (relating to integrated delivery systems), section 9.724 (relating to HMO-IDS provider contract) and section 9.725 (relating

to IDS-provider contracts). The Department is proposing to combine certain provisions of that policy statement, and include those provisions in these sections as discussed below.

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

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

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

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

Subchapter K. Utilization Review Entities

Section 9.741. Applicability.

This section would explain that this subchapter applies to entities seeking certification to practice as utilization review entities in the Commonwealth. This section also applies to licensed insurers for a limited purpose. Sections 2151 and 2152 of Article XXI (40 P.S. §§991.2151 and 991.2152) give the Department the authority to set standards for and approve certification of utilization review entities.

Section 9.742. Certified utilization review entities (CRE.)

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

Section 9.743. Content of an application for certification as a utilization review entity.

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

This section would also require the applicant to describe how it would be able to meet the terms and conditions in section 2152 of Article XXI (40 P.S. §991.2152). For example,

subsection (c)(5)(i) – (iv) and (vi) would require the applicant to describe its ability to respond to telephone calls within the period of time set out in the act, its reviewer credentialing process, its ability to arrange for a wide range of health care providers to conduct the reviews, its procedures for ensuring confidentiality, and its capacity for maintaining written records for a three year period. Subsection (c)(5)(viii) and (ix) would also require the applicant to provide information relating to its experience, including the length of time it has operated in the Commonwealth, if applicable, and a list of three clients for whom the applicant has performed utilization review.

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

Further, section 2151(c) of Article XXI (40 P.S. §991.2151(c)), permits the Department to adopt the standards for certification of utilization review entities of a nationally recognized accrediting body to the extent the standards meet and exceed the standards set forth in Act 68. Subsection (c)(5)(vii) would require an entity seeking certification to provide evidence of this accreditation if the applicant has undergone such accreditation.

Section 9.744. CREs participating in internal and external grievance reviews. This section would deal with new subject matter. The Department is proposing to set additional requirements for a utilization review entity wishing to participate in external grievance reviews as contemplated by Act 68. See 40 P.S. §991.2162. Since this entity may

have to participate in expedited reviews, subsection (a)(4) would provide additional information relevant to its ability to conduct an external review.

Section 9.745. Responsible applicant.

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

Section 9.746. Fees for certification and re-certification of utilization review entities.

This section would deal with new subject matter. The Department has the authority to establish fees for certification and re-certification applications pursuant to section 2151(d) of Article XXI (40 P.S.§991.2151(d)). Subsection (a) would require a fee of $1000 for the initial application for an entity seeking to perform internal utilization reviews, and an additional $1000 for any entity seeking to perform external reviews as well. Subsection (b) would require a fee of $500 for any re-certification application. These fees would be commensurate with the amount of administrative time and resources required to review and verify the information in the application (including site visits) and to periodically monitor compliance with the standards.

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

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

Section 9.748. Maintenance and renewal of CRE certification.

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

Subsection (b) would require the CRE to submit a renewal application to the Department 60

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

Subchapter L. Credentialing.

Section 9.761. Provider credentialing.

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

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AFFECTED PARTIES

The proposed regulations would affect HMOs certified to do business in the Commonwealth; managed care plans as defined by Act 68; including certified HMOs, and enrollees served by and providers who participate in these managed care plans. The proposed regulations would also affect entities, which conduct or want to conduct internal or external utilization reviews, since Act 68 requires these utilization review entities to be certified by the Department. Licensed insurers would also be affected by proposed section 9.742 of the proposed regulations (relating to certified utilization review entities). Licensed insurers and managed care plans with certificates of authority performing utilization review are required to comply with the terms of section 2152 of Article XXI (40 P.S. §991.2152). See 40 P.S. §991.2151(e). Licensed insurers and managed care plans with certificates of authority are not required to seek certification.

COST AND PAPERWORK ESTIMATES

A. Cost

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

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

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

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

B. Paperwork

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

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

Act 68 also creates additional paperwork for utilization review entities (CREs). Pursuant to Act 68, CREs are required to obtain certification from the Department in order perform utilization reviews of health care services delivered or proposed to be delivered in the Commonwealth. Prior to the passage of Act 68, this requirement did not exist.

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

EFFECTIVE DATE/SUNSET DATE

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

STATUTORY AUTHORITY

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

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The Department has authority to promulgate regulations relating to the certification and operations of HMOs pursuant to section 14 of the HMO Act (40 P.S. §1564). Section 5.1(a) of the HMO Act (40 P.S. §1555.1(a)) provides the Department with the authority to determine what information to require in a corporation's application for certification as an HMO. Section 5.1(b)(1)(i) of the HMO Act (40 P.S. §1555.1(b)(l)(i)) provides the Department with authority to determine whether an HMO has demonstrated potential ability to assure both availability and accessibility of adequate personnel and facilities in manner enhancing availability, accessibility and continuity of services. Section 5.1(b)(1)(ii) of the HMO Act (40 P.S. §1555.1(b)(1)(ii)) provides the Department with authority to determine whether an HMO has demonstrated it has arrangements for an ongoing quality of health care assurance program. Section 5.1(b)(1)(iii) of the HMO Act (40 P.S. §1555.1(b)(1)(iii)) provides the Department with authority to determine whether an HMO has appropriate mechanisms to effectively provide or arrange for provision of basic health care services on a prepaid basis. Section 8(a) of the HMO Act (40 P.S. §1558(a)) allows the Secretary to require re-negotiation of provider contracts when those contracts provide fore excessive payments, fail to include reasonable incentives or contribute to escalation of costs of health care services to enrollees. Section 8(a) also permits the Secretary to require renegotiation when he determines that the contracts are inconsistent with the purposes of the HMO Act. Section 10(e) of the HMO Act (40 P.S. §1560(e)) requires that an HMO establish and maintain a grievance resolution system satisfactory to the Secretary. Section 11(c) of the HMO Act (40 P.S. §1561(c)) provides the Secretary and his agents with free access to all books, records,

papers, and documents that relate to the non-financial business of the HMO. Finally, section 15 of the HMO Act (40 P.S. §1565) provides the Department with the authority to suspend or revoke an HMO's certificate of authority, or to fine the HMO for violations of the HMO Act.

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

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

The Department also has authority to review and approve grievance resolution systems and to require quality and utilization controls of certain preferred provider organizations ("PPOs") pursuant to the PPO Act. Section 630 of the Insurance Company Law of 1921 (40 P.S. §764a(e)) requires that the Department of Insurance consult with the Department in determining whether arrangements and provisions for a PPO which assumes financial risk

which may lead to undertreatment or poor quality care are adequately addressed by quality and utilization controls as well as by a formal grievance system.

REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act (71 P.S. §§745.1-745.15), the Department submitted a copy of these proposed regulations on December 8, 1999, to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. In addition to submitting the proposed regulations, the Department has provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

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

CONTACT PERSON

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulations to Stacy Mitchell, Director, Bureau of Managed

CONTINUATION SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU
(Pursuant to Commonwealth Documents Law)

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

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ANNEX A

CHAPTER 9. MANAGED CARE ORGANIZATIONS

Subchap.

Subchapter A. [HEALTH MAINTENANCE ORGANIZATIONS] [GENERAL INFORMATION] Reserved.

§9.1. [Applicability] Reserved.

[This chapter is applicable to persons who propose to undertake to establish, maintain and operate a health maintenance organization within this Commonwealth, with the exception of health maintenance organization programs exempted under sections 16 and 17(b) of the act (40 P.S. §§ 1566 and 1567(b)).]

§9.2. [Definitions] Reserved.

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

Act - The Health Maintenance Organization Act (40 P.S. §§ 1551--1567).

Basic health services - Those health services, including as a minimum but not limited to emergency care, inpatient hospital and physician care, ambulatory physician care, and outpatient and preventive medical services; the term is elaborated on in §9.72 (relating to basic health services).

Certificate of authority - The document issued jointly by the Secretary and the Commissioner permitting a corporation to establish, maintain and operate a health maintenance organization.

Commissioner - The Insurance Commissioner of the Commonwealth.

Department - The Department of Health of the Commonwealth.

Federally qualified health maintenance organization - An entity which has been found by the Secretary of the United States Department of Health and Human Services to meet the requirements of section 1301 of the Public Health Service Act (42 U.S.C.A. §300e).

Group practice HMO - An HMO that contracts with a medical group, partnership, or corporation composed of health professionals licensed to practice medicine or osteopathy as well as other health professionals necessary for the provision of health services.

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

Individual practice association (IPA) HMO - An HMO that contracts for delivery of services with a partnership, corporation, or association whose major objective is to enter into contractual arrangements with health professionals for the delivery of such health services.

Primary care physician - A physician who supervises, coordinates, and provides initial and basic care to members; initiates their referral for specialist care; and maintains continuity of patient

care.

Secretary - The Secretary of Health of the Commonwealth.

Staff HMO - An HMO that delivers services through its own physicians who are paid employes (staff) of the HMO.

Subscriber - An individual who is contractually entitled to receive basic health services from a health maintenance organization.]

DEVELOPMENT OF A HEALTH MAINTENANCE ORGANIZATON

§9.31. [Certificate of Need requirements] Reserved.

[Corporations seeking to develop health maintenance organizations may be subject to the Health Care Facilities Act (35 P.S. §§ 448.101 -- 448.904) and Chapter 401 (relating to Certificate of Need Program). Applications for a Certificate of Authority under the act will be examined to ensure compliance with Certificate of Need requirements.]

§9.32. [Preapplication development activities] Reserved.

[Corporations in the process of developing a health maintenance organization are urged, but not required, to periodically inform the Department of their developmental activities and to make use of Department technical advice and assistance as authorized by section 2 of the act (40 P.S. § 1552).]

APPLICATION FOR A CERTIFICATE OF AUTHORITY

§9.51. [Prohibition against uncertified health maintenance organizations] Reserved.

[A corporation may not solicit enrollment of subscribers, enroll subscribers or deliver prepaid basic health care services by, through or in a health maintenance organization until it has reviewed a Certificate of Authority to operate and maintain the health maintenance organization from the Secretary and the Commissioner.]

§9.52. [Content of application for Certificate of Authority] Reserved.

[An application for a Certificate of Authority under the act shall be made to the Secretary and the Commissioner in writing. That part of the application directed to the Secretary shall contain the following information:

(1) A copy of the basic organizational document of the applicant organization, such as the articles of incorporation, and amendments thereto.

(2) A copy of the bylaws, rules and regulations or similar documents regulating the conduct of the internal affairs of the applicant corporation.

(3) A list of the names, addresses and official positions of the board of directors of the applicant corporation and of persons who are to be responsible for the conduct to the affairs of the applicant--including, but not limited to, the Executive Director or President, Medical Director, Director of Marketing and Director of Finance.

(4) A description of the service area of the proposed health maintenance organization-

including geographic boundaries, demographic data and identification of population groups which would be sources of prepayment.

(5) A copy of the applicant corporation's proposed contracts with subscribers and groups of subscribers, setting forth the corporation's contractual obligations to provide basic health services.

(6) A copy of the applicant corporation's contracts with physicians, groups of physicians organized on a group-practice or individual-practice basis, hospitals, skilled nursing facilities and other providers of health care services enabling it to provide basic health services to a voluntarily enrolled population.

(7) A copy of any contract with any individual, partnership, association or corporation for the performance on its behalf of necessary functions including, but not limited to, marketing, enrollments and administration and of any contract with an insurance company, hospital plan corporation or professional health service corporation for the provision of insurance or indemnity or reimbursement against the cost of health care services provided by the health maintenance organization.

(8) A detailed description of the applicant corporation's proposed grievance resolution system whereby the complaints of its subscribers may be acted upon promptly and satisfactorily.

(9) A detailed description of the applicant corporation's arrangements for an ongoing quality-of-health-care assurance program.

(10) A detailed description of the applicant corporation's potential ability to assure both the availability and accessibility of adequate personnel and facilities to serve

enrolled subscribers in a manner enhancing availability, accessibility and continuity of services, including information regarding proposed practice site locations and hours of operation.

(11) A detailed description of reasonable incentives for cost control within the structure and function of the proposed health maintenance organization.

(12) A brief description of Federal grant or loan funds received by the applicant corporation for the purposes of developing a Federally qualified health maintenance organization.

(13) A copy of the applicant corporation's most recent financial statement.

(14) A description of the applicant corporation's capability to collect and analyze necessary data relating to the utilization of health care services by enrolled subscribers.

(15) A copy of proposed general subscriber literature.

(16) A job description for the position of medical director.

(17) A procedure for referral of subscribers to nonparticipating specialists.

(18) Written procedures for payment of emergency services provided by other than a participating provider.

(19) A description of the manner in which subscribers will be selected to meet the statutory requirement that 1/3 of the board members be subscribers.

(20) A description of the system established to ensure that the records of the corporation pertaining to its operation of a health maintenance organization are identifiable and distinct from other activities that corporation may engage in.

(21) A copy of the written procedures regarding frequently utilized services required

by §9.75(e) (relating to assurance of access to care).

(22) Other information that the applicant corporation may wish to submit which reasonably relates to its capability of operating and maintaining a health maintenance organization.]

§9.53. [Review by the Department] Reserved.

[(a) Before the Department approves issuance of a certificate of authority, it will conduct a thorough assessment to ascertain whether the proposed health maintenance organization, the plan under which it proposes to operate, and the services which it proposes to provide are consistent with the purposes and provisions of the act and this chapter.

(b) Within 10 business days of receiving an application for a Certificate of Authority, the Department will determine whether the information submitted is complete. If the Department determines that the information is not complete and that additional information is required, it will send a request as soon as possible in writing to the applicant corporation stating specifically what information is needed. A copy of the request will be sent to the Commissioner.

(c) The application for a certificate of authority will not be considered complete until the additional information is received by the Department.

(d) The Department may visit or inspect the site or proposed site of the health maintenance organization's facilities to ascertain its capability to carry out its required functions.

(e) Upon receipt of an application for a Certificate of Authority, the Department will publish notification of receipt of the filing in the *Pennsylvania Bulletin* in order to provide an opportunity for public comment.

(f) The Department may hold a public hearing to obtain additional information about a proposed health maintenance organization. The Department, whenever possible and appropriate, will attempt to hold joint hearings with the Insurance Department.

(1) If the Department decides to hold a public hearing, notification in writing will be provided to the applicant corporation by certified mail at least 10 business days prior to the hearing.

(2) Notice of the hearing will also be published in the *Pennsylvania Bulletin* at least 10 days prior to the hearing.

(3) The hearing will be conducted as soon as possible, but no earlier than 10 business days after written notice has been provided to the applicant corporation.

(g) The Department will confer with and coordinate its investigation with the Commissioner.

(h) Within 90 days of receipt of a completed application for a Certificate of Authority, the Secretary and Commissioner will, jointly do either of the following:

(1) Approve the application and issue a Certificate of Authority.

(2) Disapprove the application, specifying in writing the reasons for the disapproval. A disapproval of an application may be appealed in accordance with 2 Pa. C.S. §§501 – 508 and 701 – 704 (relating to administrative agency law).]

§9.54. [Standards regarding approval of Certificate of Authority] Reserved.

[An application for a Certificate of Authority will be reviewed to ensure that the applicant corporation and proposed health maintenance organization are capable both initially and on an ongoing basis to meet the minimum operating standards found in §§9.71 – 9.77 (relating to

operational standards for a health maintenance organization).]

§9.55. [Alternative application format] Reserved.

[With prior permission of the Department an applicant corporation may submit, in lieu of the information and format required in § 9.52 (relating to content of application for Certificate of Authority), a copy of its Federal qualification application appropriately annotated and referenced to the submission requirements of the chapter.]

OPERATIONAL STANDARDS FOR A HEALTH MAINTENANCE ORGANIZATION

§9.71. [Operational standards] Reserved.

[A corporation receiving a Certificate of Authority to establish and operate a health maintenance organization under the act shall provide quality health care services in a cost-effective manner to voluntarily enrolled subscribers by meeting the minimum standards set forth in this subchapter.]

§9.72. [Basic health services] Reserved.

[(a) A health maintenance organization shall provide at least the following basic health services:

(1) *Emergency care.* Professional health services medically necessary immediately to preserve life or stabilize health, available on an inpatient or an outpatient basis 24 hours per day, 7 days per week.

(2) *Ambulatory physician care.* Medically necessary and preventive health services performed, prescribed or supervised by physicians for patients who are not confined to bed in an institution or at home. These services may be provided in a nonhospital based health care facility, at a hospital, or in a physician's office.

(3) *Inpatient hospital care.* Medically necessary hospital service affording inpatient treatment to subscribers in a general hospital for a minimum of 90 days per contract or calendar year. Hospital services include room and board; general nursing care; special diets when medically necessary; use of operating room and related facilities; use of intensive care unit and services; X-ray , laboratory and other diagnostic tests; drugs, medication, biologicals, anesthesia and oxygen services; special duty nursing when medically necessary; physician therapy, radiation therapy and inhalation therapy; administration of whole blood and blood plasma; and short-term rehabilitation services.

(4) *Inpatient physician care.* Generally accepted and medically necessary health services performed, prescribed or supervised by physicians within a hospital for registered bed patients, including diagnostic and therapeutic care.

(5) *Outpatient and preventive medical services.* Services, such as well baby care, immunizations and periodic physical examinations, provided with the goal of protection against and early detection and minimization of the ill effects and causes of disease or disability.

(b) A health maintenance organization shall provide basic health services to its subscribers as needed and without unreasonable limitations as to time and cost. Nominal copayments may be imposed upon basic health services, subject to the following conditions:

(1) To insure that copayments are not a barrier to the utilization of health services or membership in the organization, a health maintenance organization shall neither impose copayment charges that exceed 50% of the total cost of providing any single service to its subscribers nor 20% of the total cost of providing all basic health services.

(2) A copayment may not be imposed on a subscriber covered under his contract in a calendar year when the copayments made by the subscriber in the calendar year total 50% of the total annual premium cost which the subscriber would be required to pay if enrolled under an option with no copayments. The subscriber must demonstrate that copayments in that amount have been paid during the calendar year.

(c) Reasonable exclusions, such as are customarily found in group health insurance policies, will be permitted. Examples of reasonable exclusions are cosmetic surgery unless medically necessary, custodial or domiciliary care and durable medical equipment for home use.

(d) A health maintenance organization may provide in addition to basic health services, other health services such as cosmetic surgery, prescription drug coverage, dental coverage, mental health benefits and similar services which a voluntarily enrolled population may require to maintain physical and mental health.]

§9.73. [Subscriber grievance systems] Reserved.

[An health maintenance organization shall have a written grievance procedure for prompt and effective resolution of subscriber grievances. The grievance procedure shall include the following elements:

(1) There shall be an initial level of investigation and review of any grievance.

(i) The initial review shall be conducted by a committee consisting of one or more individuals who may be employes of the health maintenance organization.

(ii) The initial review shall provide the opportunity for the subscriber and another party of interest to present written data pertinent to the grievance.

(iii) The decision of the initial review committee shall be binding unless the subscriber appeals the decision.

(iv) The subscriber shall be notified in writing of his right to appeal the decision to a second level review committee.

(2) A subscriber shall have the right to appeal a decision of the initial review committee to a second level of review.

(i) The second level of review shall be conducted by a committee established by the board of directors of the health maintenance organization.

(ii) At least 1/3 of the members of the committee shall be subscribers of the health maintenance organization.

(iii) The decision of the second level review committee shall be binding unless the subscriber appeals the decision depending upon the nature of the grievance to the Secretary or the Commissioner.

(iv) The subscriber shall be notified in writing of his right to appeal a decision of the second level of review committee.

(v) The second level review committee shall have written procedures for investigating grievances, for conducting formal hearings and for utilizing informed consultants to resolve grievances.

(3) An oral complaint which cannot be resolved informally shall be presented in writing according to paragraphs (1) and (2) before it shall be considered a formal grievance.

(4) The health maintenance organization shall specify reasonable time limits for disposition of grievances at each level of review.

(5) The health maintenance organization shall include a description of the grievance system in subscriber contracts.

(6) The health maintenance organization shall have a separate and additional form notifying subscribers of the existence of and their rights within the grievance system. This form shall be distributed to subscribers at least annually. Publication of this information in a member newsletter published by the health maintenance organization shall be sufficient to meet this paragraph.

(7) At any stage of the grievance process, at the request of a subscriber, the health maintenance organization shall appoint a member of its staff who has no direct involvement in the case to represent the subscriber. A subscriber presenting a grievance shall be specifically notified of his right to have a staff member appointed to assist him.

(8) The health maintenance organization shall maintain records of grievances and shall include in its annual reports to the Department a description of the total number of grievances handled, a compilation of the causes underlying the grievances, and the resolution of the grievances. See § 9.91 (relating to annual reports).]

§9.74. [Quality assurance systems] Reserved.

[(a) A health maintenance organization shall have a written procedure to provide ongoing review, analysis, assessment and subsequent actions for improvement of the quality of health care services delivered to its subscribers. This procedure shall include at least the following elements:

(1) Medical records shall be maintained in a current, detailed and comprehensive manner which conforms with good professional medical practice, permits effective quality assurance review and facilitates continuity of care.

(2) A procedure shall be specified to assure that only those services which represent proper utilization of health care facilities and conform with contractual provisions are provided.

(b) review of the quality of care may not be limited to technical aspects of care alone but shall also include availability, accessibility and continuity of care provided to members.

(c) The results of quality assurance activities shall be made known to participating providers in a manner designed to facilitate improvement in the quality of service delivered, and which is approved by the Department.

(d) At least once a year, a report on quality assurance activities—including studies undertaken, results, subsequent actions and aggregate data on utilization and quality of services rendered to subscribers—shall be presented to the board of directors.

(e) Data on the utilization of health care services shall be collected and shall be analyzed periodically to identify for further indepth investigation potential over-utilization, under-utilization or misutilization of health care services by members or providers. Aggregate utilization data shall be reported quarterly to the Secretary. See § 9.92 (relating to quarterly

reports).]

§9.75. [Assurance of access to care] Reserved.

[(a) A health maintenance organization shall have and maintain adequate arrangements, such as written contracts, to provide the health service contracted for by its subscribers.

(b) A health maintenance organization shall have available sufficient personnel to meet the standards set forth in this chapter and its contractual obligations.

(c) A health maintenance organization shall make available to each subscriber a primary care physician to supervise and coordinate the health care of the subscriber.

(1) Referrals for specialty care, except in emergency situations, shall be approved by the subscriber's primary care physician.

(2) A subscriber who is dissatisfied with his primary care physician shall be allowed to select another; however, the health maintenance organization may impose a reasonable waiting period to accomplish this transfer.

(d) A health maintenance organization shall provide covered basic health services which require the services of a specialist.

(1) In those specialties which are generally available and frequently utilized in the geographic area served by the health maintenance organization, services of qualified specialty practitioners shall be provided through effective arrangements between the health maintenance organization and the practitioner, assuring subscriber access to medically necessary specialty care. Letters signed by practitioners indicating their intent to participate in the health maintenance organization are an example of such

arrangements.

(2) Medically necessary specialty services other than those described in paragraph (1) shall be provided by participating or nonparticipating specialists.

(3) A health maintenance organization shall provide for coordination and continuity of care for subscribers referred to nonparticipating specialists.

(4) When a subscriber is referred by a health maintenance organization or by a health maintenance organization physician to a nonparticipating specialist, the subscriber shall incur no financial liability above that which he would have incurred had he been referred to a participating specialist.

(e) A health maintenance organization shall have written procedures governing the availability of frequently utilized services contracted for by subscribers, including at least 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 illness.

(5) Treatment of chronic illnesses.

(f) A health maintenance organization shall have a written procedure for payment of emergency health services provided outside of its service area.]

§ 9.76. [Professional staffing of health maintenance organizations] Reserved.

[(a) *Professional staff standards.*

(1) A health maintenance organization shall have at least the equivalent of one full-time primary care physician per 1600 members.

(2) To qualify as a primary care physician, a physician must meet one of the following conditions:

(i) He performs the functions of a primary care physician as defined in §9.2 (relating to definitions) at least 50% of the time in which he engages in the practice of medicine.

(ii) He has limited his practice of medicine for at least 2 years prior to association with the health maintenance organization to general practice, internal medicine, pediatrics or family medicine.

(3) As an overall ratio for all physicians serving health maintenance organization subscribers, the health maintenance organization shall have at least the equivalent of one full-time physician per 1200 members.

(4) To meet physician-subscriber ratios, a health maintenance organization may use licensed and certified physician-extenders such as nurse practitioners, nurse midwives and physician assistants.

(i) A health maintenance organization shall include in its application a summary of the qualifications and experience of each physician-extender.

(ii) For the purposes of this subsection, a physician-extender shall be counted as ½ of a physician.

(iii) There may not, at any time, be more than two physician-extenders per primary care physician.

(5) An individual practice association health maintenance organization shall submit to the Department evidence of other standards or mechanisms which it applies to assure patient access to physicians as necessary to meet the intent of the standards in this subsection.

(6) Each physician must be licensed to practice medicine in this Commonwealth.

(7) Each physician must have staff privileges in at least one hospital utilized by the health maintenance organization within its service area.

(b) *Medical director standards.*

(1) A health maintenance organization shall identify a physician who shall serve as its medical director.

(2) The medical director shall be responsible, at least, for the following:

(i) General coordination of the medical care of the health maintenance organization on behalf of the health maintenance organization.

(ii) Appropriate professional staffing of the health maintenance organization.

(iii) Design of protocols for quality assurance.

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

(3) The time spent by the medical director in performing medical director functions may not be counted in the physician-subscriber ratio required by subsection (a).]

§ 9.77. [Subscriber rights] Reserved.

[(a) A health maintenance organization shall develop and adhere to written procedures for informing subscribers of at least the following subscriber rights:

(1) A subscriber has the right to timely and effective redress of grievances through a system established under § 9.73 (relating to subscriber grievance systems).

(2) A subscriber has the right to have health maintenance organization literature and materials for his use written in a manner which truthfully and accurately provides relevant information so that it is easily understood by a person of average intelligence.

(3) A subscriber has the right to obtain from his physician, unless it is not medically advisable, complete, current information concerning his diagnosis, treatment and prognosis in terms that he can reasonably be expected to understand.

(4) A subscriber has the right to be given the name, professional status and function of any personnel providing health services to him.

(5) A subscriber has the right to give his informed consent before the start of any procedure or treatment.

(6) A subscriber has the right to be advised if a health care facility or any of the providers participating in his care propose to engage in or perform human experimentation or research affecting his care or treatment. A subscriber or legally responsible party on his behalf may, at any time, refuse to participate in or to continue in any experimentation or research program to which he has previously given informed consent.

(7) A subscriber has the right to refuse drugs, treatment or other procedures offered to him by the health maintenance organization or its providers to the extent permitted by law

and to be informed by a physician of the medial consequences of the subscriber's refusal of any drugs, treatment or procedures.

(8) A subscriber has the right to have records pertaining to his medical care treated as confidential unless disclosure is necessary to interpret the application of his contract to his care or unless disclosure is otherwise provided for by law.

(9) A subscriber has the right to information contained in his medical records unless access is specifically restricted by the attending physician for medical reasons.

(10) When emergency services are necessary, a subscriber has the right to obtain those services without unnecessary delay.

(11) A subscriber has the right to be informed of these rights listed in this subsection.

(b) A health maintenance organization shall offer to each subscriber who becomes ineligible to continue as part of a group subscriber agreement a non-group subscription agreement offering the same level of benefits as are available to a group subscriber. A reasonable premium differential may be charged to a nongroup subscriber in consideration of the somewhat higher administrative expenses involved in direct payment of premiums.

(c) A health maintenance organization may not expel or refuse to reenroll a member solely because of his health care needs nor refuse to enroll individual subscribers of a group on the basis of the health status or health care needs of the individuals.]

CONTINUING SUPERVISION OF OPERATIONAL HEALTH MAINTENANCE ORGANIZATIONS

§ 9.91. [Annual reports] Reserved.

[(a) A corporation which has received a Certificate of Authority to operate a health maintenance organization from the Secretary and the Commissioner shall submit to the Department before March 1 of each year a detailed report of its activities during the preceding calendar year. The report shall include at least the following:

(1) A copy of the annual financial report submitted to the Com-missioner.

(2) A copy of the quality assurance report submitted to the board of directors according to § 9.74(d) (relating to quality assurance systems).

(3) A description of the grievance resolution system established according to § 9.73 (relating to subscriber grievance systems), including a summary of total number of grievances handled, a compilation of causes underlying the grievances and the resolution of grievances.

(4) A statement of the number of physicians leaving the health maintenance organization and the number of physicians replacing them.

(5) A summary of enrollment and disenrollment rates during the year.

(b) Federally qualified health maintenance organizations may submit copies of reports submitted to Federal authorities which contain substantially the information required by subsection (a).]

§ 9.92. [Quarterly reports] <u>Reserved</u>.

[(a) A health maintenance organization shall submit to the Department four times per year a detailed report concerning utilization of the health care services it provides.

(1) The report for the first quarter, January 1 to March 31, shall be submitted no later

than May 15.

(2) The report for the second quarter, April 1 to June 30, shall be submitted no later than August 15.

(3) The report for the third quarter, July 1 to September 30, shall be submitted no later than November 15.

(4) The report for the last quarter, October 1 to December 31, shall be submitted concurrently with the annual report required in § 9.91 (relating to annual reports.)

(b) Each report shall include utilization statistics on both a quarterly and year-to-date basis and shall contain the following minimum data:

(1) The hospitalization experience of the plan in terms of the number of days of inpatient hospitalization experienced per 1,000 subscribers on a quarterly, year-to-date and annualized basis.

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

(c) Federally-qualified health maintenance organizations may submit copies of reports submitted to Federal authorities which contain substantially the same information required by this subsection.]

§ 9.93. [External quality assurance assessment] Reserved.

[(a) Within 1 year of receipt of its certificate of authority and every 3 years thereafter, or when the Department may direct for cause, each health maintenance organization shall have an external quality assurance assessment performed.

(b) The assessment shall study the quality of care being provided to plan subscribers and the effectiveness of the quality assurance program established according to § 9.74 (relating to quality assurance systems).

(c) (1) The assessment shall be conducted by an expert experience d in health maintenance organization review activities.

(2) The expert shall be hired by the health maintenance organization and not involved in the operation or direction of the health maintenance organization nor in the delivery of health care services to its subscribers.

(3) The expert must be an individual or organization with recognized experience in the appraisal of medical practice and quality assurance, in a health maintenance organization setting.

(4) The expert shall be approved by the Department.

(5) The expert shall review, at least, a statistically significant sample of medical records.

(6) The expert shall issue a written report of his findings to the board of directors.

(d) A copy of the expert's report shall be submitted to the Department within 10 business days of its receipt by the health maintenance organization.]

§ 9.94. [Departmental investigation] Reserved.

[(a) The Department may investigate further any information contained in reports submitted according to §§ 9.91 and 9.92 (relating to annual reports; and quarterly reports).

(b) Investigation may include onsite inspection of the health maintenance organization's

facilities and records of the health maintenance organization.

(c) The Secretary or his agents shall have free access to all the books, records, papers and documents that relate to the business of the health maintenance organization, other than financial business.

(d) The Department shall have access to medical records of health maintenance organization subscribers for the sole purpose of determining the quality of care rendered by the health maintenance organization.]

§ 9.95. [Federally-qualified health maintenance organizations] Reserved.

[(a) In applying this chapter to Federally-qualified health maintenance organizations, the Department may take into account the fact and extent of compliance with Federal standards.

(b) Where there is a conflict or potential conflict between this chapter and Federal regulations applicable to Federally-qualified health maintenance organizations, the Department will coordinate directly with the appropriate Federal authority in order to attempt to remove or resolve the conflict.]

§ 9.96. [Board composition] Reserved.

[(a) *Establishment.* A corporation receiving a Certificate of Authority to establish, operate and maintain a health maintenance organization under the act shall, within 1 year of the date of receipt of such Certificate of Authority, establish and maintain a board of directors, at least 1/3 of whom are subscribers of the health maintenance organization. The subscriber board membership selection process shall be structured so as to prevent undue influence in the selection process by

nonsubscriber members of the board and to obtain diverse representation of broad segments of subscribers covered under health maintenance organizations contracts issued by the corporation.

(b) *Conflict of interest.*

(1) A member of the board shall execute a conflict of interest statement.

(2) A member of the board of directors may not engage in the following forms of self-dealing:

(i) The sale, exchange or leasing of property, goods or services between the health maintenance organization and a member, his employer of an organization substantially controlled by him in a manner less favorable to the health maintenance organization than the manner in which such property, goods or services is made available to the general public.

(ii) The furnishing of goods, services or facilities by a health maintenance organization to a member unless the furnishing is made on a basis no more favorable to the member than the basis on which the goods, services or facilities are made available to the general public or employes of the health maintenance organization.

(iii) A transfer of the income or assets of the health maintenance organization to use by or for the benefit of a member except by purchase for fair market value. Excluded from this subparagraph are cash dividends, stock dividends, stock distribution and stock splits.]

§ 9.97. [Exceptions] Reserved.

[(a) The Department may, for justifiable reasons and only in cases where the health, safety and welfare of a citizen would not be impaired, grant exceptions to and departures from this chapter when the policy objectives and intentions of this chapter are otherwise substantially met.

(b) A request for exceptions to this chapter shall be made in writing to the Department. A request, whether approved or not, will be retained on file by the Department. An approved request shall be retained on file by the corporation during the period the exception remains in effect.

(c) An exception granted under this chapter may be revoked by the Department at its discretion for good cause whenever the policy objectives and intentions for granting the exception will no longer be furthered.

(d) The Department will give written notice by certified mail, return receipt requested, revoking an exception and will state the reason for its action and a specific date upon which the exception will be terminated.

(1) The Department will provide for a reasonable time between the date of written notice or revocation and the date of termination of an exception for the health maintenance organization from compliance with the applicable regulations.

(2) Failure of the health maintenance organization to comply by the specified date may result in action to revoke the previously approved certificate of authority.

(3) The Department's denial or revocation of an exception is a final agency action and shall be appealable in accordance with 2 Pa. C.S. §§ 701--704 (relating to judicial review of Commonwealth agency action).]

* * *

Subchapter D. [PHOs, POs AND IDSs—STATEMENT OF POLICY] Reserved.

§ 9.401. [Applicability and purpose] Reserved.

[(a) This subchapter provides information to HMOs, providers, POs and IDSs concerning how the Department proposes to exercise its authority under the HMO Act and related acts to review, approve and monitor the establishment of provider contracts between HMOs and IDSs. The information will enable delivery systems and HMOs to negotiate to establish provider contracts in a manner likely to be found acceptable by the Department. This subchapter expresses the present intentions of the Department with respect to review and approval of provider contracts between and among HMOs, IDSs and providers participating in the systems.

(b) This subchapter should be reviewed by persons who undertake to establish, operate and maintain an IDS whose primary purpose is to contract with one or more HMOs for the provision of health care services to HMO members. These persons should also consult the Insurance Department's statement of policy on this subject at 31 Pa. Code Chapter 301, Subchapter I (relating to contractual arrangements between HMOs and IDSs--statement of policy).]

§ 9.402. [Definitions] Reserved.

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

Contract – An arrangement between an HMO and a provider, organization or group of providers under which the providers:

(i) Agree to provide or arrange to provide a defined set of health care services to HMO members.

(ii) May agree to assume responsibility for conduct of the quality assurance, utilization review, credentialling, provider relations or claims management or related functions.

(iii) Is reimbursed either directly on a fee-for-service basis or through a financial risk arrangement.

Department – The Department of Health of the Commonwealth.

HMO – Health Maintenance Organization – An organized system which 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--1567).

IDS – Integrated Delivery System – A partnership, association, corporation or other legal entity which enters into contractual arrangements with an HMO; employs or has contracts with providers (participating providers) and agrees under its arrangements with an HMO, to provide or arrange for the provision of a defined set of health care services to HMO members covered under an HMO benefits contract principally through its participating providers, assumes under the arrangements some responsibility for conduct, in conjunction with the HMO and under compliance monitoring of the HMO, of quality assurance, utilization review, credentialling, provider relations or related functions, may perform claims processing and other functions, and which assumes to some extent, through capitation reimbursement or other risk-sharing arrangements, the financial risk for provision of the services to HMO members.

LS-IDS-Limited service integrated delivery system – An IDS which contracts with an HMO for a limited or restricted range of health care services, including pharmacy, dental, cardiology,

radiology or behavioral health, even though the limited or restricted services may include inpatient, outpatient, diagnostic testing, treatment and facility charge coverage for limited services being provided.

PHO – Physician-hospital organization – An IDS jointly owned and controlled by a hospital and a physician.

PO – Physician organization – An IDS primarily owned and controlled by physicians, including a model whereby physicians are the primary shareholders of the IDS. A PO may assume financial risk and contractual responsibility from an HMO to provide hospital and other nonphysician services by contracting with hospitals and other providers which may not be members of the PO, or it may assume financial risk only for the professional component of an HMO benefit package and share in surplus or deficits relating to targeted hospitals and other health services utilization. POs also may contract with other physician POs or multispecialty practices and need not have provider contracts with nonphysician providers in order to share risk with an HMO by assuming liability for part or all of a budget shortfall.

Physician-hospital-community organization – An IDS typically not-for-profit, governed by a board that includes physicians, hospital representatives and community members, including, consumers, business representatives and government representatives that may engage in community health assessment or other community benefit activities beyond contracting to provide health services.

Provider – Any "health care facility" or "health care provider" as those terms are defined under section 802(a) of the Health Care Facilities Act (35 P.S. § 448.802); a mental health facility licensed by the Department of Public Welfare; or an individual licensed by the Commonwealth

to practice any profession involved in the healing arts. The term includes hospitals, mental health treatment facilities, drug and alcohol treatment facilities, physicians, dentists, podiatrists, psychologists, nurses, physician assistants, certified registered nurse practitioners, physical therapists, chiropractors, optometrists and pharmacists.

S-PHO – Super physician-hospital organization – A partnership, association, corporation or other legal entity created by two or more PHOs for the purpose of entering into provider contracts with HMOs collectively on behalf of the participating PHOs and of the providers participating in each of the participating PHOs.

S-PO—Super-physician organization – A partnership, association, corporation or other legal entity created by two or more POs for the purpose of entering into provider contracts with HMOs collectively on behalf of the participating POs and of the providers participating in each of the participating POs.]

§ 9.403. [Licensure requirements] Reserved.

[An HMO may contract with one or more IDSs under contractual arrangements which have been reviewed and approved by the Department and which meet the following standards:

(1) The HMO may contract with an IDS for the provision of care by IDS participating providers to HMO members. Any contract between an HMO and an IDS shall be incorporated by reference in all contracts between the IDS and providers with which the IDS contracts to provide services to HMO members, and shall be provided by the IDS to each of its participating providers upon request. Both the contract between the HMO and the IDS and the contract between the IDS and participating providers, shall include

consumer hold-harmless language acceptable to the Department.

(2) An HMO may contract with an IDS for the performance of quality assurance, utilization review and credentialling of those providers who will provide services to the HMO's members, so long as the utilization management, quality assurance and credentialling standards are submitted by the HMO and approved in advance by the Department and the implementation is subject to periodic review and compliance verification by the HMO, the Department and other external agencies. The standards shall be considered those of the HMO.

(3) An HMO may delegate primary care "gatekeeping" functions to an IDS, and an IDS may delegate the functions to its providers. The IDS may utilize primary care physician "gatekeepers' if the HMO has an acceptable plan of quality of care oversight to ensure that the IDS and its participating providers do not provide inadequate or poor quality care arising out of its reimbursement incentives.

(4) An HMO and IDS may utilize capitation and other financial reimbursement arrangements agreed to in the contracts between the HMO and IDS and between the IDS and its participating providers, as incentives for appropriate and cost-effective utilization of services.

(5) The IDS may arrange for its providers to assume financial risk from an HMO in the form of a fixed capitation fee, which does not vary by actual utilization of services, or percentage of premium arrangement without first receiving a separate license as an insurance company, risk-assuming PPO which is not licensed insurer, HMO or otherwise. An IDS, likewise, may arrange for its providers to participate only in bonus payment

systems based on favorable utilization or to limit provider risk to an amount withheld form provider reimbursement and distributed back to providers only if utilization or budget targets are met.]

§ 9.404. [Financial protection of HMO members served through IDSs] Reserved.

[To maximize protection of those HMO members who may be served through IDS and IDS participating providers from the adverse impact of an IDS's inability to pay its participating providers or the providers balance billing members for HMO covered services, the Department will not approve a provider contract between an HMO and IDS unless:

(1) The HMO-IDS contract and IDS participating provider contracts contain member financial hold harmless provisions acceptable to the Department which would prevent the IDS and IDS participating providers from billing HMO members for covered services (other than for authorized copayments, coinsurance or deductibles) under any circumstances, including the insolvency of the HMO or the IDS. (See § 9.407(a)(1) (relating to minimum compliance provisions which should be contained in an IDS-participating provider or compliance amendment) as well as the Insurance Department's statement of policy regarding HMO-IDS contracts at 31 Pa. Code § 301.311(c) (relating to annual and quarterly filings)).

(2) Provision of HMO covered services to HMO members are not delayed, reduced, denied or otherwise hindered because of the financial or contractual relationship between the HMO and IDS, and the HMO-IDS contract protects the HMO's members from being billed by providers, whether or not participating , by the IDS.

(3) The HMO-IDS contract contains a provision requiring the IDS and its participating providers to comply with data reporting requirements, including encounter, utilization and reimbursement methodology required by the Department. The Department's purpose in reviewing provider reimbursement methodology is to identify reimbursement methods which may lead to inadequate or poor quality care and to ensure that the HMO and IDS have adequate systems to monitor quality of care and prevent undertreatment and that reimbursement methodologies are not so inadequate so as to result in undertreatment or poor quality care. The Department reserves the right to require submission of actual rates of payment in those instances in which the information is necessary in its judgment, to diagnose and correct quality of care problems relating to reimbursement incentives or inadequate reimbursement levels or to investigate consumer or provider grievances alleging quality of care deficiencies arising out of reimbursement methods or levels of payment.]

§ 9.405. [Review and approval of HMO-IDS provider contracts] Reserved.

[For an HMO-IDS provider contract to be found acceptable and approved by the Department and not required to be renegotiated under section 8(a) of the HMO Act (40 P.S. § 1558(a)) the contract shall contain the following or substantially similar provisions:

(1) The IDS acknowledges and agrees that only those IDS participating providers who meet the HMO's credentialling and provider contracting standards may participate in the HMO and provide services to HMO members, and that the ultimate authority to accept IDS providers for participation or to terminate participation is retained by the HMO.

(2) The IDS acknowledges and agrees that the HMO is required to establish, operate and maintain a health service delivery system, quality assurance system, provider credentialling system, member grievance system and other systems meeting Department standards, and is directly accountable to the Department for compliance with the standards and for the provision of high-quality, cost-effective care to HMO members. Nothing in the HMO-IDS agreement be construed to in any way limit the HMO's authority or responsibility to meet standards or to take prompt corrective action to address a quality of care problem, resolve a member grievance or to comply with a regulatory requirement of the Department.

(3) The IDS agrees to provide the HMO and Department with access to medical and other records concerning the provision of services to HMO members by and through the IDS and its participating providers.

(4) The IDS agrees to collect and provide the HMO with utilization, financial and other data for the purposes of comparative performance analysis of HMO and IDS effectiveness.

(5) The IDS agrees that any delegation of authority or responsibility for provider credentialling and relations, quality assessment, utilization review and other functions by the HMO to IDS shall be subject to performance monitoring by the HMO and Department and is subject to independent validation by the HMO, the Department or an independent quality review/assessment organization approved by the Department.]

§ 9.406. [Review and approval of IDS-participating provider contracts] Reserved.

[(a) *Review of contract by Department.* In addition to the HMO-IDS contract, the provider contracts between the IDS and its participating providers which enable the IDS to provide care to HMO members shall be submitted for review and approval of the Department.

(b) *Methods of contracting.*

(1) Several methods of IDS-participating provider contracting are acceptable to the Department as follows:

(i) Each IDS-participating provider may enter into the HMO's standard provider agreement approved by the Department, which shall include an amendment or rider which reflects any special terms or conditions relating to the HMO-IDS agreement. The standard provider agreement with the amendment or rider should be signed by the HMO, the participating provider and the IDS. The amendment or rider should be filed by the HMO for review and approval of the Department.

(ii) The IDS may utilize a contract between itself and its participating providers, if the IDS-participating provider contract incorporates by reference the agreements between the IDS and each HMO with which it contracts, which HMO-IDS agreements shall be provided, upon request, prior to the effective date, to each IDS participating provider. The financial amounts in the HMO-IDS agreements may be redacted from the copies of the agreements the IDS shall provide to its participating providers. Unique terms or conditions relating to each HMO-IDS arrangement may be reflected in an amendment or rider to the IDS-participating provider contract. The IDS-participating provider contract, any

amendment to the contract and a list of providers who have entered into the contract shall be filed by the HMO for review and approval of the Department.

(2) Whichever compliance method is utilized, the compliance provisions specified in § 9.407 (relating to minimum compliance provisions which should be contained in an IDS-participating provider or compliance amendment) should be included.

(c) *Signatures required.* The HMO-IDS-participating provider contract or compliance amendment shall contain three signatures representing the HMO, IDS and participating provider. If the standard IDS-participating provider contract grants signature authority to the IDS to enter into provider contracts on behalf of participating providers, it will not be necessary for each participating provider to sign the amendment or rider.]

§ 9.407. [Minimum compliance provisions which should be contained in an IDS-participating provider or compliance amendment] Reserved.

[For the Department to accept and approve a participating provider contract between an IDS and a participating provider applicable to provision of services to HMO members and not require renegotiation of the contract under section 8(a) of the HMO Act (40 P.S. § 1558(a)), each IDS-participating provider contract or compliance amendment shall contain provisions substantially similar to the following:

(1) Provider agrees that in no event, including, but not limited to, nonpayment by the HMO or IDS, the insolvency of HMO or IDS, or breach of this agreement, shall provider bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against member/enrollee or persons other than HMO or IDS

acting on their behalf for services listed in this agreement. This provision shall not prohibit collection of supplemental charges or copayments on HMO's behalf made in accordance with terms of the contract between HMO and member/enrollee.

Provider further agrees that (1) the hold harmless provision shall survive the termination of the (applicable provider contract) regardless of the cause giving rise to termination and shall be construed to be for the benefit of the HMO member/enrollee and that (2) this hold harmless provision supersedes any oral or written contrary agreement now existing or hereafter entered into between provider and member/enrollee or persons acting on their behalf.

No modification, addition or deletion to the provisions of this section shall become effective without the specific prior written approval of the Department of Health.

(2) Provider acknowledges and agrees that nothing in the agreement shall be construed to limit: (a) the authority of the HMO to ensure provider participation in and compliance with HMO's quality assurance, utilization management, member grievance and other systems and procedures; (b) the Department of Health's authority to monitor the effectiveness of HMO's systems and procedures or the extent to which the HMO adequately monitors any function delegated to IDS, or to require the HMO to take prompt corrective action regarding quality of care or consumer grievances and complaints; (c) HMO's authority to sanction or terminate a provider found to be providing inadequate or poor quality care or failing to comply with HMO systems, standards or procedures as agreed to by the IDS. Provider agrees to participate in and abide by the decisions of the

HMO's quality assurance, utilization management and member grievance systems.

(3) Provider agrees to cooperate with and provide HMO, the Department of Health, and any external quality review organization approved by the Department of Health, with access to member medical records for the purposes of quality assessment and quality improvement or investigation of member complaints or grievances. Provider further agrees to provide such information, including but not limited to encounter, utilization, referral and other data, that the IDS may require to be submitted to it for compliance with its own data reporting requirements or as required by the Department of Health.

(4) Provider acknowledges and agrees that in order to participate in the HMO he, she or it must meet the minimum credentialling standards established by the HMO as approved by the Department of Health and that the HMO retains sole authority to accept, reject or terminate an IDS provider who fails to meet such standards on a continuing basis.

(5) Provider acknowledges and agrees that any delegation by HMO to IDS under the HMO-IDS contract for performance of quality assurance, utilization management credentialling, provider relations and other medical management systems, shall be subject to the HMO's oversight and monitoring of IDS performance. Provider further acknowledges and agrees that HMO, upon failure of IDS to properly implement and administer such systems or to take prompt corrective action after identifying quality, member satisfaction or other problems, may terminate its contract with IDS and that, as a result of such termination, provider's participation in the HMO may also be terminated.

(6) Provider acknowledges and agrees that, if in the judgment of HMO, the IDS

provide has failed to cooperate with HMO in the provision of cost-effective, quality services to HMO members, or has failed to cooperate with and abide by the provisions of the HMO's quality assurance, utilization management or member grievance systems, or is found to be harming HMO patients, the HMO may terminate provider's participation in HMO.]

§ 9.408. [Delegation of medical management authority by an HMO to an IDS] Reserved.

[(a) For the Department to approve a provider contract between an HMO and an IDS, under which the HMO will delegate responsibility to the IDS for performance of provider credentialling, quality assurance, utilization management or other essential HMO functions, the HMO should submit with the request for review and approval, an IDS "monitoring plan," which should include, at the minimum, each of the following:

(1) A clear definition of the quality assurance, utilization management and credentialling standards to be utilized and applied by the IDS to HMO members.

(2) A description of how the HMO will monitor the effectiveness of any quality assurance activities delegated to the IDS, including at least the following:

(i) Periodic reporting by the IDS quality assurance committee to the HMO.

(ii) Review and approval by the HMO of the IDS quality assurance committee's annual work plans and objectives.

(iii) Integration into the ISD's quality assurance system of the standards

approved by the Department and the Department's periodically required external quality reviews by approved external quality review organizations.

(iv) A plan for random sample re-review and validation of the results of quality assurance studies, credentialling, utilization management decisions, and similar activities undertaken by the IDS on behalf of the HMO.

(v) HMO input into design of methodology of focused medical record reviews undertaken by the IDS to measure and improve quality of care being provided to HMO members by IDS participating providers.

(vi) A description of the relationship between respective authorities of the HMO's medical director and quality assurance/utilization review staff and the IDS's medical director and quality assurance/utilization review staff.

(b) Alternatively, in recognition of the managed care industry's wide acceptance of the National standards developed by the National Committee for Quality Assurance (NCQA) in conjunction with its voluntary accreditation program, in lieu of submission of the monitoring plan specified in subsection (a), the filing HMO need only certify in its submission letter its covenant to comply with NCQA managed care organization contractor delegation standards.

(c) The effectiveness of an HMO's monitoring of the quality of care and other performance of an IDS, including, if applicable, compliance with NCQA contractor delegation standards, and of the IDS's actual provision of quality health care to HMO members shall be periodically reviewed by the Department through required submission and review of written reports, IDS quality assurance work plans submitted to the HMO, onsite visits to and inspections of the HMO and IDS, periodic external quality assessment of the HMO, and, if applicable, periodic external

quality assessment of the IDS.

(d) If the Department determines, through periodic review, external quality assessment by an approved external quality review organization, or otherwise that an HMO is deficient in its monitoring of delegated responsibilities to an IDS, the Department may require the HMO to file, receive approval of and implement an appropriate "corrective action plan."]

§9.409. [Delegation of member grievance system responsibility to an IDS] Reserved.

[(a) An HMO may not delegate responsibility for HMO member grievance system operation or resolution to an IDS contractor. The HMO shall apply its Department-approved grievance system uniformly to all members, including those members being served through an IDS contractor.

(b) One or more representatives of the IDS with no prior involvement in the grievance under consideration, may serve as members of the first or second level grievance review committees established by the HMO to hear the grievances of members served by the IDS. (See § 9.73 (relating to subscriber grievance system).)]

§9.410. [Contents of an HMO filing for review and approval of an IDS provider contract] Reserved.

[(a) An HMO requesting approval of a standard generic form IDS contract to be utilized in contracting with one or more IDSs shall submit a filing to the Department requesting approval and containing the following elements:

(1) A cover letter including:

(i) Indication, by page and section number reference, where in the HMO-IDS generic contract and in the IDS-participating provider contract, the requested compliance provisions of §§ 9.405 and 9.407 (relating to review and approval of HMO-IDS provider contracts; and minimum compliance provisions which should be contained in an IDS-participating provider or compliance amendment) are found.

(ii) A certification that the HMO will monitor delegation of medical management responsibilities to the IDS by complying with National Committee for Quality Assurance (NCQA) delegation standards or has included a "monitoring plan" as described in § 9.408 (relating to delegation of medical management authority by an HMO to an IDS).

(iii) A brief description of the reimbursement methodologies to be utilized by the HMO in reimbursing the IDS, and the reimbursement methodologies to be utilized by the IDS, in turn, to reimburse its participating provider.

(2) A copy of the proposed standard generic provider contract between the HMO and IDS, containing the provisions requested in § 9.405.

(3) A copy of the standard generic form of all provider contracts, including, compliance amendments/riders between the IDS and its participating providers, containing the provisions requested in § 9.407.

(4) A copy of the HMO's medical management delegation monitoring plan, in accordance with § 9.408, if the HMO is unwilling or unable to commit to utilization of NCQA delegation standards.

(b) In those cases in which the HMO is contracting with an IDS utilizing its own participating provider contracts rather than generic IDS-participating provider contracts developed by the HMO, the HMO shall include copies of the specified IDS's generic provider contracts in the filing, identify by name, address and telephone number the IDS, and include a list of the IDS's participating providers.

(c) In those cases in which the HMO is utilizing individually negotiated and unique HMO-IDS contracts rather than a generic form contract, these IDS-specific contracts shall be submitted and the cover letter shall identify by name, address and telephone number the IDS and include a list of the IDS's participating providers. If so filled, these case-specific HMO-IDS contracts may delete confidential payment rates otherwise included therein.

(d) In those cases in which the HMO enters into a standard form generic HMO-IDS contract, utilizing a previously filed and approved contract form, the HMO need only file with the Department a brief "Notice and Certification" notifying the Department that the HMO has entered into a contract with a particular IDS, identifying the IDS by name, address, telephone number and contact person, including a list of IDS participating providers, and certifying that it has used whatever generic contract that has been previously approved. If the HMO-IDS contract is generic, but the HMO-IDS participating provider contracts are not, the "Notice and Certification" letter also should include generic copies of the IDS-participating provider contracts and an identification, by page and section number, of the compliance provisions specified in § 9.407.

(e) A filing will be deemed "approved" by the Department if it is not specifically disapproved within 45 days of its receipt by the Department.]

§9.411. [Special products filings] Reserved.

[(a) If the HMO intends to market a special product at a special premium to HMO members willing to limit their utilization to a particular IDS's participating provider network, the HMO shall make an appropriate filing for prior review and approval of the Department. The filing shall address the capacity of the Ids participating provider network to provide adequate, accessible and available health care to members enrolling in the special product.

(b) If, as a result of an IDS contract, the HMO intends to expand its service area, it shall submit an appropriate service area expansion request.]

§9.412. [Super-PHOs] Reserved.

[(a). An HMO seeking review and approval of provider contracts with a super-PHO shall submit each layer of provider contracts between each level of subcontracting providers and HMO and ensure that all provider contracts meet the standards in this subchapter.

(b) HMOs seeking review and approval of provider contracts with super-PHOs should carefully explain in their application any intended delegation of quality assurance, utilization management, provider credentialling and related functions through the various layers of the super-PHO.]

§9.413. [Provider-patient complaint systems] Reserved.

[HMOs are encouraged to create a fundamentally fair provider grievance system, whereby a provider dissatisfied with a precertification or utilization management decision of an HMO, or

who desires to advocate for approval of a particular treatment, treatment plan or referral on behalf of a patient may do so without fear of reprisal from the HMO.]

§9.414. [External quality review of an IDS] Reserved.

[An IDS which voluntarily undergoes an external quality review by an external quality review organization approved by the Department, may receive consideration of the review in fulfilling its quality assurance oversight obligations and the obligations of one or more HMOs with which it may contract, if the following apply:

(1) The arrangement prior to implementation by one or more of its contracting HMOs and the Department.

(2) The results of the external quality review are shared with the HMO and the Department.

(3) Actual conduct of the external review, including scheduling thereof, is coordinated with the Department.

(4) Department staff have the opportunity to participate in the external quality review of the IDS.]

§9.415. [HMO-IDS filing requirement] Reserved.

[HMO-IDS contracts in force on April 6, 1996, should be filed with the Department, but all reimbursement levels or rates of payment may be deleted as being confidential.]

§9.416. [IDS contracts with political subdivisions] Reserved.

[IDS contracts with political subdivisions shall contain the provisions outlined in this subchapter unless the IDS is licensed as an HMO or risk-assuming preferred provider organization.]

Subchapter E. [QUALITY HEALTH CARE ACCOUNTABILITY AND PROTECTION-STATEMENT OF POLICY] Reserved.

§9.501. [Applicability and purpose] Reserved.

[(a) This subchapter establishes the guidelines which the Department will utilize to determine managed care plan and utilization review entity compliance with the act. It sets forth the Department's expectations regarding act implementation until formal regulations are adopted. This subchapter applies to each health plan meeting the definition of "managed care plan" contained in the act.

(b) This subchapter is effective January 1, 1999, and applies and provides compliance guidance to assist managed care plans, licensed insurers and utilization review entities subject to the act.

(c) The terms and conditions of group and individual contract renewals and new business written by managed care plans on or after January 1, 1999, shall conform to the act.]

§9.502. [Definitions] Reserved.

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

Act – Article XXI of The Insurance Company Law of 1921 (40 P.S. §§991.2101—991.2193) as added by Act No. 68 of 1998 regarding quality health care accountability and protection.

Department – The Department of Health of the Commonwealth.

Gatekeeper – A primary care provider selected by an enrollee at the time of enrollment or appointed by a health plan from whom an enrollee shall obtain covered health care services or a referral or approval for covered, nonemergency health services as a condition for the payment of the highest level of benefits/services available under the plan.

Managed care plan –

(i) A health care plan that:

(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 in the plan 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 Insurance Company Law of 1921 (40 P. S. § 764a).

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

(C) The Fraternal Benefit Societies Code (40 P.S. §§ 1141-101—1141-905).

(D) 40 Pa. C. S. Chapter 61 (relating to hospital plan corporations).

(E) 40 Pa. C. S. Chapter 63 (relating to professional health services plan corporations.

(iii) The term includes an entity, including a municipality, whether licensed or

unlicensed, that contracts with or functions as a managed care plan to provide health care services to enrollees.

(iv) The term does not include an indemnity arrangement which is primarily fee for service or an ancillary health care plan, including those which provide coverage exclusively for dental or vision services, or benefits supplementing benefits payable under the Federal Medicare or Civilian Health And Medical Program of the Uniformed Services (CHAMPUS).

(v) The term does not include "passive gatekeeper" preferred provider organizations (PPOs). A passive gatekeeper includes plans in which enrollees are not required to preselect a particular primary care physician, but require, as a condition for receipt of a higher level of benefits or reimbursement level, or both, that an enrollee receive care from or a referral from a participating preferred primary care physician. See 31 Pa. Code § 152.102 (relating to definitions).]

§9.503. [Enrollee complaint system] Reserved.

[(a) The act gives the Department and the Insurance Department shared oversight over the enrollee complaint process.

(b) A complaint is a dispute or objection regarding a participating health care provider, coverage, including contract exclusions and noncovered benefits as well as the operations or management policies of a managed care plan. Examples of issues constituting complaints which will be handled by the Department, include:

(1) Quality of care or quality of service issues.

(2) Denial of payment for treatment by a nonparticipating provider for failure to obtain a necessary referral or to utilize a participating provider when the enrollee alleges that the reason for seeking the care was inadequate care by the managed care plan, primary care provider or participating providers.

(c) The following applies to filing of complaints.

(1) An enrollee may file a written or oral complaint with the plan's internal complaint system as well as written data or other information in support of the complaint.

(2) An enrollee should indicate the remedy or corrective action being sought.

(3) Second level review.

(i) It is recommended that the one-third membership of a plan's internal second level review committee who are not plan employes include actual enrollees, or representatives of plan enrollees, such as employe benefits administrators, collective bargaining agents, consumer advocates or similar individuals.

(ii) The deliberations of the plan's second level review committee, including the enrollee's comments and written submissions, should be transcribed or summarized and maintained as part of the complaint record.

(iii) Attendance at the second level review hearing should be limited to members of the review committee, the enrollee or enrollee's representative, the enrollee's provider or applicable witnesses, and appropriate plan representatives. All persons attending and their respective roles at the hearing should be identified for the enrollee.

(iv) The second level review should provide reasonable flexibility in terms of time and travel distance when scheduling a hearing to facilitate the enrollee's attendance. If an enrollee cannot appear in person at the informal hearing, the enrollee should be provided the opportunity to communicate with the review committee by telephone or other appropriate means.

(v) The notice of the second level review decision shall include the basis for the decision and the procedure for appealing the decision to the Department or the Insurance Department, including the address and phone numbers of the Departments. The decision of the second level review committee should be binding on the plan unless appealed by the enrollee.

(d) The following applies to Department review of a complaint:

(1) An enrollee appeal of a decision by a managed care plan's second level review committee may be directed to either the Department or the Insurance Department. Appeals directed to the Department should include, at a minimum, the enrollee's name, address and telephone number, identification of the managed care plan, the enrollee's plan ID number and a brief description of the issue being appealed, and should be sent to:

Bureau of Managed Care
Department of Health
Attention: Complaint Appeals
P.O. Box 90
Harrisburg, Pennsylvania 17108-0080

(2) Upon receipt of the appeal, the Department will verify that the appeal was submitted within 15 days from the enrollees' receipt of the notice of the decision by the

managed care plan's second level review committee. The Department will review the complaint to ensure that it involves a matter appropriate for review by the Department. If the Department believes that the appeal more appropriately relates to issues and matters under the jurisdiction of the Insurance Department—for example, an issue involving interpretation of a coordination of benefits provision, the Department will notify the enrollee in writing of its finding and promptly transmit the appeal to the Insurance Department for consideration.

(3) Upon receipt of the appeal, the Department will request the complete complaint case file, including, but not limited to, records from the initial and second level review, including hearing transcript or summary, medical records, if appropriate, and other case materials be forwarded within 15 business days to the Department. The Department may request additional information from the managed care plan, enrollee or participating providers involved in the complaint. The enrollee, managed care plan or provider may submit additional materials relating to the appeal.

(4) The enrollee may be represented by an attorney or other individual before the Department. The Department will make the decision based on the written record.

(5) The Department may take any of the following actions:

(i) Request, for specified reasons, that the managed care plan's second level review reconsider the complaint.

(ii) Request an independent review by a consulting provider or certified utilization review entity, if the complaint involves the exercise of clinical judgement.

(iii) Issue a recommendation to the managed care plan and enrollee regarding the complaint.

(6) If the plan determines that additional information from the enrollee or the provider justifies reconsideration and resolution of a complaint, the resolution shall terminate a review by the Department.

(7) If the Department determines that the complaint reflects a violation of the act by the managed care plan, it may proceed with an enforcement action authorized by the act.]

§9.504. [Enrollee and provider grievance system] Reserved.

[(a) The act sets forth a procedure to deal with grievances by enrollees and health care providers.

(b) A grievance is a request by an enrollee or a health care provider, with the written consent of the enrollee, to have a managed care plan or utilization review entity review the denial of a health care service based on medical necessity and appropriateness. This includes cases in which the managed care plan: disapproves full or partial payment for a requested health service; approves the provision of a requested health care service for a lessor scope or duration than requested; or disapproved payment of the provision of a requested service but approves payment for the provision of an alternative health care service.

(1) If it is unclear to the enrollee or health care provider whether the issue in dispute is a complaint or a grievance, it is recommended that the plan classify the issue in dispute as a complaint or grievance.

(2) The primary test of determining whether a dispute is a complaint or a grievance is

whether medical necessity is the primary issue in dispute. For a denial to be a grievance, the requested service or treatment shall clearly be covered under the contract and must be denied because of the managed care plan's determination that the service or treatment is not medically necessary in accordance with the definition of medical necessity found in the enrollee's contract. Examples of issues considered to be grievances, include:

(i) Denial of an emergency claim on the basis that the condition did not meet the definition of an emergency.

(ii) Denial of a request by an enrollee for a referral to a nonparticipating provider with special skills, knowledge, experience or reputation regarding the performance of a needed procedure or treatment, on the basis that the procedure or treatment can be rendered appropriately by a participating provider.

(iii) Denial of a request for an organ transplant on the basis that the existence of complicating medical factors and the patient's condition make a transplant inappropriate.

(iv) Denial of a prescription drug on the basis that the drug is not part of the managed care plan's approved formulary.

(v) Denial of a request for treatment at or by a nonparticipating provider on the basis that a participating provider is available to provide the treatment or service.

(vi) Discharge from a facility on the basis that the continued stay is no longer medically necessary.

(vii) Refusal to continue to pay for skilled nursing facility care on the basis that

continued care is not medically necessary at the skilled nursing care level, but rather is custodial in nature.

(viii) Denial of a referral to a specialist.

(c) The following applies to second level review of grievances:

(1) The deliberations of the plan's second level grievance review committee, including the enrollee's or provider's comments and written submissions, should be transcribed or summarized and maintained as a part of grievance record.

(2) The second level review should provide reasonable flexibility in terms of time and travel distance when scheduling a hearing to facilitate the enrollee's or provider's attendance. If the enrollee or the provider cannot appear in person, the enrollee or provider should be given the opportunity to communicate with the review committee by telephone or other means.

(3) The written notice of a decision by the second level grievance review committee denying a health care service should include the basis and clinical rationale for the decision and the procedure for filing an external grievance.

(d) The following applies to external grievances:

(1) The managed care plan shall acknowledge receipt of an external grievance in writing to the enrollee or the health care provider, the utilization review entity that conducted the internal grievance review and the Department.

(2) In addition to the information required under section 2162 of the act (40 P.S. § 991.2162), the plan shall submit its contractual definition of "medical necessity" and any clinical criteria utilized by the plan in making its initial decision.

(3) To avoid duplication of grievances and related expenses, the provider filing a grievance with the written consent of the enrollee should be the primary provider (that is, the provider who manages the treatment and orders care) of the disputed services to the enrollee. If the external grievance is ultimately decided in favor of the enrollee or provider, all related disputed claims arising form that incident or service should be paid by the managed care plan. For example, if the enrollee grants written consent to a hospital to appeal a denial of services on the basis that a true emergency did not exist, separate grievance appeals need not be filed by related providers of emergency care which are covered services and which are medically necessary and appropriate, such as the ambulance company who transported the enrollee, the independent physician group which employs the ER physician, the independent radiology and laboratory medicine physicians providing the professional component of interpreting test results, and the like.

(e) The following applies to the processing of a grievance appeal by the Department:

(1) Requests for assignment of a certified utilization review entity to conduct an external grievance should be addressed to:

Bureau of Managed Care
Department of Health
Attention: Grievance Appeals
P.O. Box 90
Harrisburg, Pennsylvania 17108-0080

(2) The request should include the following basic information:

(i) An identification of the managed care plan, the enrollee/patient and the health care provider.

(ii) Whether the external grievance is being filed by the enrollee or a health

care provider with written consent of the enrollee.

(iii) The plan ID (including group number and enrollee ID number).

(iv) The date of receipt of the external grievance by the managed care plan from the enrollee or health care provider.

(v) A brief (few line) description of the medical necessity/claim denial being appealed.

(vi) The filing fee, if any, the enrollee has been charged by the managed care plan.

(3) Upon receipt of an external grievance, the Department will assign on a rotational basis utilization review entity to conduct the review within 2 business days of receiving the request. The Department may notify the managed care plan of the selection of the utilization review entity selected by means of telephone or facsimile machine, with written follow-up notification. Upon receipt of notification from the Department, the managed care plan should notify the enrollee or health care provider and utilization review entity which conducted the internal grievance review. The Department may assign the external grievance a uniform tracking number, which should be utilized by the plan, external utilization review entity, enrollee and provider to communicate with or report to the Department.

(4) If the Department fails to select a utilization review entity within 2 business days of receipt of the external grievance, the managed care plan may designate a certified utilization review entity to conduct the review. No certified utilization review entity affiliated, directly or indirectly, with the plan my be selected to review the external

grievance.

(5) Upon notification of the utilization review entity selected to conduct the external grievance, the managed care plan, utilization review entity, provider or enrollee should have 2 business days to object to the assignment of the utilization review entity on the basis that the entity has a conflict of interest, for example, that the review entity is a subsidiary or affiliate of the managed care plan. The Department will review the objection within 5 business days and either uphold the assignment of the utilization review entity, or assign the review to the next utilization review entity on the rational schedule.

(6) A managed care plan should provide to the Department the name, title and phone number of a primary and alternative external grievance coordinator with whom the Department can communicate regarding the assignment of utilization review entities to undertake grievance reviews.

(7) If additional information provided by the enrollee or provider during the external grievance results in a reconsideration of the plan'[s denial on the basis of medical necessity, and the plan grants coverage, the external grievance shall be terminated upon notification to the utilization review entity.

(f) The following applies to the utilization review entity processing of a grievance review:

(1) The utilization review entity shall certify that the external grievance decision was made by one or more physicians or approved licensed psychologists, as specified in the act, and shall indicated whether the health care service denied by the internal grievance process is medically necessary and appropriate under the terms of the plan.

(2) In reviewing a grievance relating to emergency services, the utilization review entity should utilize the emergency services standards of the act and the definitions of medical necessity and emergency in the enrollee's current certificate of coverage.]

§9.505. [Reporting provisions for complaint and grievance systems] Reserved.

[(a) A managed care plan should maintain records of first and second level complaint and grievance decisions, including expedited reviews. A managed care plan should include in its quarterly and annual reports to the Department data regarding complaints and grievances during that reporting period. A managed care plan should periodically analyze, and make available to the Department, issues involved in complaints and grievances to identify potential areas for improvement or increased disclosure. Data which plans should submit to the Department in routine reports include:

(1) The total number of formal complaints filed, decided and pending, in the reporting period.

(2) The total number of complaints at the first internal committee review:

(i) Settled in favor of the plan.

(ii) Settled in favor of the enrollee.

(3) The total number of complaints at the second level internal review:

(i) Settled in favor of the plan.

(ii) Settled in favor of the enrollee.

(4) The total number of complaints appealed to the Commonwealth: (if known, to the Department; if known, to the Insurance Department).

(5) The total number of formal grievances filed, decided and pending, in the reporting period.

(6) The total number of grievances at the first internal review level:

(i) Settled in favor of the plan.

(ii) Settled in favor of the enrollee.

(iii) Settled in favor of the provider.

(7) The total number of grievances at the second level internal review:

(i) Settled in favor of the plan.

(ii) Settled in favor of the enrollee.

(iii) Settled in favor of the provider.

(8) The total number of internal expedited reviews conducted:

(i) Settled in favor of the plan.

(ii) Settled in favor of the enrollee.

(iii) Settled in favor of the provider.

(b) Reports should be filed with the Department as follows:

(1) *Quarterly reports.* 45 days after the last day of the quarter (such as, the report for the 1st quarter covering January, February and March should be filed no later than May 15th).

(2) *Annual reports.* No later than April 1st of the calendar year following the calendar year being reported.]

§9.506. [Alternative dispute resolution systems for external grievance] Reserved.

[(a) A managed care plan may submit for Department review and approval a system for dispute resolution as an alternative to the external grievance to be included in contracts between the plan and its participating providers. The alternative may apply only to grievances filed by providers and may include a provision that a decision from the alternative dispute resolution system shall be final and binding on both the managed care plan and provider.

(b) A proposed alternative dispute resolution system shall be impartial and include specific time limitations to initiate appeals, receive written information, conduct hearings and render decisions.]

§9.507. [Department review of complaint and grievance systems] Reserved.

[A managed care plan should file with the Department and maintain an updated detailed written description of its enrollee complaint and enrollee and provider grievance systems.]

§9.508. [Transition between former grievance system and new complaint and grievance systems] Reserved.

[(a) Prior to January 1, 1999, health maintenance organizations and gatekeeper preferred provider organizations (including "point-of-service" plans) were required to establish, operate and maintain a consumer grievance system complying with Department requirements in § 9.73 (relating to subscriber grievance systems), and various technical advisories and guidelines. To assure an orderly transition to the new systems, group and individual contract renewals and new business written by managed care plans on or after January 1, 1999, shall conform to the act, and the following:

1) Any enrollee complaint or grievance filed prior to the first renewal date of the enrollee's managed care plan contract on or after January 1, 1999, should be processed under the enrollee grievance system contained in the enrollee's contract.

(2) Any complaint or grievance filed by an enrollee, or a provider with the written consent of the enrollee, on or after the first renewal date of the enrollee's managed care plan contract in 1999 should be processed in accordance with the complaint and grievance systems established under the act.

(b) A managed care plan may voluntarily comply with the complaint and grievance procedures under the act for all complaints and grievances filed on or after January 1, 1999, if authorized by the enrollee contract.]

§9.509. [Application of enrollee complaint and enrollee and provider grievance systems to self-funded plans and nonmanaged care plans] Reserved.

[(a) The Department encourages managed care plans that administer, through their provider network and gatekeepers, the managed care programs of self-funded insurers under the Federal Employee Retirement Income Security Act (ERISA) to voluntarily extend the new complaint and grievance systems to self-funded enrollees.

(i) The self-funded group may elect to treat any grievance appeal decision rendered by a utilization review entity as: binding, unless appealed to a court of competent jurisdiction; or as advisory.

(ii) An appeal from the plan's second level complaint review or second level grievance review may be to the self-funded group itself.

(b) Some health care plans/insurers, particularly those associated or affiliated with health maintenance organizations and gatekeeper PPOs, voluntarily extended the Department's consumer grievance system to enrollees in health benefits plans without gatekeepers. Effective January 1, 1999, these grievance systems shall be amended to remove right of appeal to the Department, insofar as the appeal is inconsistent with the act.

(c) It is the Department's expectation that a managed care plan will apply its Department approved quality improvement system to all enrollees, including those enrolled in a self-funded employe benefit plan administered by the managed care plan, to protect enrollees from the risk of inadequate or poor quality care arising out the use of gatekeepers, financial incentives and limited provider networks.]

§9.510. [Fees for initial certification and renewal of utilization review entities] Reserved.

[Fees will be established in regulation for certification and renewal of utilization review entities.]

§9.511. [Content of an application for certification as a utilization review entity] Reserved.

[(a) A utilization review entity seeking certification, including an integrated delivery system as defined in § 9.402 (relating to definitions) performing utilization review under a delegation agreement from a managed care plan, shall submit two copies of an application to the

Department at the following address:

Bureau of Managed Care
Pennsylvania Department of Health
Attention: Utilization Review Certification
P.O. Box 90
Harrisburg, Pennsylvania 17108-0090

(b) A utilization review entity operating in this Commonwealth on or before January 1, 1999, shall comply with the act effective January 1, 1999, but need not file an application for certification until January 1, 2000. To avoid backlogs and time delays which might arise if all entities waited until January 1, 2000, to file, entities are encouraged to apply for certification as early in 1999 as possible. A utilization review entity will not be place on the Department's list of certified utilization review entities for external grievances unless the entity is certified. Entities desiring to be placed on the rotational list to hear external grievances should file their applications as soon as possible after adoption of this subchapter. A new utilization review entity not operating in this Commonwealth on or before January 1, 1999, may not operate until it receives a certification from the Department.

(c) The application shall contain the following:

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

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

(3) The name, title, address and telephone number of a primary contact responsible for answering any Department questions regarding the application.

(4) Information relating to its organization, structure and function, including:

(i) The location of the principal office handling utilization review in this Commonwealth.

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

(iii) If the applicant is publicly held, the name of each owner of more than 5% of the shares of the corporation.

(iv) A chart showing the internal organization of the applicant's management and administrative staff (which the applicant may designate as "confidential and proprietary" and not subject to public disclosure).

(v) 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 relationships between the applicant and affiliates (which applicant may designate as "confidential and proprietary" and not subject to public disclosure).

(vi) Biographical information about officers, directors and executives (which the applicant may designate as "confidential and proprietary" and not subject to public disclosure).

(5) A listing of each managed care plan in this Commonwealth for which the entity currently conducts utilization review.

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

(7) A description of the:

(i) Provision of toll-free telephone access.

(ii) Maintenance of a telephone answering service or recording system during nonbusiness hours.

(iii) Ability to respond to each telephone call received as required by the act.

(8) A description of procedures for protecting the confidentiality of medical records and certification that it will comply with the confidentiality provisions of the act and all other applicable State and Federal laws.

(9) A description of its procedures to ensure that a health care provider is able to verify that an individual requesting information on behalf of the managed care plan is a legitimate representative of the utilization review entity/plan.

(10) A description of its ability, including staffing and resources, to meet the time frames for decisions specified in the act.

(11) A certification that utilization review decisions resulting in a denial shall be made by a licensed physician or approved licensed psychologist, and that any utilization conducted not resulting in a denial shall be made by personnel having current licenses in good standing or other credentials, without restrictions, from the appropriate agency.

(12) A description of its ability to notify the health care provider of additional facts or documents required to complete the utilization review within 48 hours of receipt of the request for review.

(13) A description of its ability to maintain a written record of utilization review decisions adverse to enrollees for at least 3 years, including a detailed justification and all

required notifications to the health care provider and enrollee.

(14) A certification that compensation from a managed care plan to a utilization review entity, employe, consultant or other person performing utilization review on its behalf does not contain incentives, direct or indirect, to approve or deny payment for the delivery of any health care service.

(15) An indication that it is willing and able to participate on a rotational basis in an external grievance.

(16) A certification that all external grievances will be reviewed in accordance with the act.

(17) If the utilization review entity proposes to utilize licensed psychologists to perform utilization reviews for behavioral health care services within the psychologists' scope of practice, a request for approval to do so. The request shall include a description of the credentialing criteria and process the entity shall utilize to ensure that behavioral health service reviewed by the psychologist falls within the psychologist's scope of practice; the psychologist's clinical experience is sufficient to review specific behavioral health services; and any other standards the entity has adopted for approval of a licensed psychologist. The request shall also certify that licensed psychologists will not review the denial of payment for a health care service involving inpatient care or a prescription drug.

(18) Evidence of any approval, certification or accreditation received by a Nationally recognized accrediting body in the area of utilization review.

(19) A description of its ability to maintain records regarding grievances that result in a decision adverse to the enrollee for at least 3 years and to provide records and other data

to the Department upon request.

(20) Its agreement to provide information to the Department upon request regarding fees charged to perform utilization reviews to allow the Department to respond to a complaint by a managed care plan, enrollee or provider that the fees of a particular certified utilization review are excessive. This information shall be proprietary and confidential.

(21) If the plan is currently operating in this Commonwealth, a disclosure of how long it has been operating, and a list of three clients for which it has conducted utilization review in this Commonwealth, including the name, address, position and telephone number of contact persons for each client. The Department may contact these references for an assessment of the applicant's past performance, particularly its ability to meet the review times for prospective, concurrent and retrospective utilization review under the act.

(22) If the entity desires to be placed on the rotational list to receive and decide external grievances a description of its ability to:

(i) Receive and decide any and all external grievances.

(ii) Receive and decide only behavioral health grievances (mental health and drug and alcohol related medical necessity issues).

(23) If the entity desires to be placed on the rotational list to decide external grievances, a description of its ability and agreement to maintain the information obtained in the review of the grievances, including outcomes, in a manner that is confidential and unavailable to affiliated entities or persons who may be direct of indirect competitors to

the managed care plan being reviewed.]

§9.512. [Department review and approval of a certification request] Reserved.

[(a) The Department will review the application for certification as a utilization review entity. If the Department finds that the application meets the requirements of the act, it will approve it. If the Department finds deficiencies, it will notify the applicant identifying the changes required to bring the application into compliance. If the Department takes no action within 45 days of receiving the certification application, or a requested revision, the application shall be deemed to have been approved.

(b) Upon certification, the Department will add the name of the utilization review entity to its rotational list of entities to conduct external grievances, if requested by the entity.

(c) The Department may utilize site visits or a Nationally recognized accrediting body acceptable to the Department to determine an applicant's ability to comply with the act.

(d) The Department may utilize the following to verify a certificate utilization review entity's continuing compliance with the act:

(1) Periodic onsite reviews by the Department.

(2) Accreditation by a Nationally recognized accrediting body acceptable to the Department.

(3) If the entity is not accredited by a Nationally recognized accrediting body acceptable to the Department, an onsite inspection by an accreditation body acceptable to the Department, reimbursed directly by the entity.

(e) The initial certification is valid for 3 years, unless certification is rescinded or restricted

prior to that date for cause by the Department. Verification of compliance with the act is required to receive certification renewal.]

§9.513. [Nationally recognized accrediting bodies] Reserved.

[(a) The Department will identify and maintain a list of Nationally recognized accrediting bodies whose standards meet or exceed the requirements of the act regarding utilization review. The list will be public information.

(b) A utilization review entity or managed care plan seeking to demonstrate compliance with the act may submit documentation of its accreditation by a Nationally recognized accrediting body for consideration by the Department as evidence of compliance with the act.

(c) The Department may recognize the standards of a Nationally recognized accrediting body whose standards partially meet the requirements of the act to certify a utilization review entity. The Department will require the utilization review entity or managed care plan to submit evidence of compliance with the act not met by the standards of the accrediting body. The Department may permit an accrediting body qualified under subsection (d) to verify compliance with the act not met by the standards of an accrediting body at the expense of the entity seeking certification. An accrediting body performing a verification of compliance under this subsection shall submit a report certifying compliance with the act.

(d) The Department may qualify an accrediting body that has standards that meet or exceed the act to assist the Department to enforce the act with regard to entities performing utilization review for managed care plans, to include compliance monitoring and certification renewal, at the entity's expense.

(e) A utilization review entity that is not accredited by a Nationally recognized accrediting

body shall verify compliance with the act through an audit performed by a qualified accrediting body at the entity's expense or through an onsite verification by the Department. For a utilization review entity that maintains its records and other information at a location outside of this Commonwealth, a qualified accrediting body shall be utilized for certification and renewal verifications.]

§9.514. [Managed care plan and licensed insurer compliance with utilization review requirements] Reserved.

[(a) Managed care plan compliance with the utilization review requirements of the act will be verified by the Department during the course of its routine compliance monitoring of plans, including, but not limited to, external quality reviews required 1 year after licensure and every 3 years thereafter.

(b) Licensed insurers performing utilization review services for or on behalf of managed care plans within this Commonwealth shall file with the Department evidence of compliance with the standards and procedures in section 2152 of the act (40 P.S. § 991.2152), at the same time as the annual statement filing with the Insurance Department, beginning with the annual statement for Fiscal Year 1999.]

§9.515. [Continuity of care and expanded care provisions] Reserved.

[(a) A managed care plan shall adopt and maintain procedures by which an enrollee with a life-threatening, degenerative or disabling disease or condition shall be permitted to receive either a standing referral to a specialist with clinical expertise in treating the disease or condition,

or designation of a specialist to assume responsibility to provide and coordinate the enrollee's primary and specialty care, subject to the plan's utilization management requirements and plan criteria. The managed care plan should make a decision regarding the referral within 30 days of the receipt of the enrollee's request. An enrollee may appeal the decision through the enrollee complaint process.

(b) Whenever the plan is required to pay for care provided to enrollees by a nonparticipating provider under section 2117 of the act (40 P.S. § 991.2117), the plan may require a nonparticipating health care provider to:

(1) Accept the plan's payment as payment in full for covered services, less any permitted deductibles or copayments.

(2) Require that all referrals for specialty care, diagnostic testing and related services be made to participating providers.

(3) Require that all nonemergency inpatient care be provided at a participating hospital or facility.

(4) Require that the provider provide copies of the patient's medical records to the plan or the enrollee's participating primary care physician, or both.

(5) Require that plan procedure requiring precertification or prior approval of specified nonemergency services or procedure be met.

(c) The plan should provide affected enrollees and affected nonparticipating providers with written disclosure of the requirements which shall be met for the plan to be responsible for payment for services rendered by the provider.]

§9.516. [Confidentiality] Reserved.

[A managed care plan and a certified utilization review entity should adopt and maintain procedures to ensure that all identifiable information regarding enrollee health, diagnosis and treatment is adequately protected and remains confidential in compliance with the act and other applicable Federal and State laws and professional ethical standards. A copy of the procedures shall be filed with the Department within 30 days of adoption.]

§9.517. [Provider credentialing] Reserved.

[(a) A managed care plan should file a copy of its written credentialing process in the form of a separate and distinct document (even though it may be incorporated into a larger quality improvement plan) with the Department for approval. The process should include written criteria and procedures including:

(1) Qualifications which a provider shall meet to be accepted as a participating provider.

(2) Information which a provider shall provide as a part of the application process to demonstrate compliance with required qualifications.

(3) Requirements that a provider shall meet to be credentialed such as staff privileges at a participating hospital, board certification, or onsite review of office or medical records by the plan.

(4) Restrictions which a plan may place on the provider's status as a participating provider.

(5) Periodic recredentialing requirements.

(6) Termination procedures including any internal appeal procedures available to participating providers.

(7) Credentialing decisions to be made by a committee composed of practicing providers.

(b) A managed care plan may submit evidence of accreditation by the National Committee for Quality Assurance (NCQA) or other Nationally recognized accrediting body acceptable to the Department as evidence of compliance with this act.

(c) A managed care plan may refuse to accept applications for participation and credentialing if the plan believes it has sufficient providers of a given specialty in a given geographic area, provided that the refusal is done in a nondiscriminatory manner.]

§9.518. [Accessibility and availability] Reserved.

[The Department has, as a matter of practice, reviewed each applicant managed care plan's initial service area, and my expansions thereof, to ensure that the plan has adequate numbers of providers, distributed by specialty and geography, to provide covered health care services to enrollees in an accessible and available manner. The Department has utilized the informal standard for accessibility/availability that hospitalization services and primary care and frequently utilized specialty services be available within 20 miles/20 minutes in urban areas, and 30 miles/30 minutes in rural areas. The Department intends to continue to review initial and service area expansions, and to formalize the process and standards through adoption of regulations.]

§9.519. [Access for special needs populations] Reserved.

[A plan shall file with the Department its policies, plans and procedures for meeting the act's requirement to ensure that there are participating health care providers that are physically accessible to people with disabilities and can communicate with individuals with sensory disabilities in accordance with Title III of the Americans with Disabilities Act of 1990 (42 U.S.C.A. §§ 12181—12189), and a description of how the plan addresses the needs of non-English-speaking enrollees.]

Subchapter F. GENERAL

§9.601. Applicability.

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

(b) An entity, including an integrated delivery system, subcontracting with a managed care plan to provide services to enrollees shall meet the requirements of Article XXI of Act 68, and subchapters H (relating to availability and access), I (relating to complaints and grievances), J (relating to health care provider contracts), K (relating to utilization review entities) and L (relating to credentialing) for services provided to those enrollees.

(c) Section 9.742 (relating to certified utilization review entities) applies to licensed insurers and managed care plans with certificates of authority.

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

§9.602. Definitions.

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

Act 68 - The act of June 17, 1998 (P.L. 464, No. 68) (40 P.S. §§991.2001 - 991.2361) amending the Insurance Company Law of 1921 (P.L. 682, No. 284) (40. P.S. §361 et seq.)

Ancillary service plan - Any individual or group health insurance plan, subscriber contract, or certificate, that provides exclusive coverage for dental services or vision services. The term also includes Medicare Supplement Policies subject to §1882 of the Social Security Act (40 Stat. 620, 42 U.S.C. §1395SS) and the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) supplement.

Ancillary services – Any 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 Insurance Company Law of 1921 (relating to health care accountability and protection).

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

Certificate of authority - The document issued jointly by the Secretary and the Commissioner that permits a corporation to establish, maintain and operate a health maintenance organization.

Commissioner - The Insurance Commissioner of the Commonwealth.

Complaint - 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, which has not been resolved by the managed care plan and has been filed with the plan or the Department or the Insurance Department of the Commonwealth. The term does not include a grievance.

Department - The Department of Health of the Commonwealth.

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

Emergency service - Any 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:

(1) 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;

(2) Serious impairment to bodily functions; or

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

Transportation and related emergency care provided by a licensed ambulance service shall constitute an emergency service if the condition is as described above.

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

External quality assurance assessment – A review of an HMO's on-going quality assurance program and operations conducted by a non-plan reviewer such as a Department-approved external quality review organization.

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

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

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

Gatekeeper PPO - A preferred provider organization 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 - A request by an enrollee, or a health care provider with the written consent of the enrollee, to have a managed care plan or utilization review entity 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:

(1) disapproves full or partial payment for a requested health service;

(2) approves the provision of a requested health care service for a lesser scope or duration than requested; or

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

The term does not include a complaint.

HMO Act - The Health Maintenance Organization Act (P.L. 1701, No. 364) (40 P.S. §§ 1551-1567).

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 - 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.

Health maintenance organization -HMO - 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.

Inpatient services - Care at a licensed hospital, skilled nursing, or rehabilitation facility, including pre-admission testing, diagnostic testing performed during an inpatient stay, nursing

care, room and board, durable medical equipment, ancillary services, inpatient drugs, meals and special diets, use of operating room and related facilities, use of intensive care and cardiac units and related services.

Integrated delivery system - IDS - A partnership, association, corporation or other legal entity which does each of the following: enters into a contractual arrangement with a plan; employs or contracts with health care providers; agrees under its arrangement with the plan to provide or arrange for the provision of covered health care services to enrollees; or assumes under the arrangement with the plan full or partial responsibility for conducting any or all of the following activities: quality assurance, utilization review, credentialing, provider relations or enrollee services.

Licensed insurer – An individual, corporation, association, partnership, reciprocal exchange, inter-insurer, Lloyds insurer and other legal entity engaged in the business of insurance; fraternal benefit societies as defined in the Fraternal Benefits Societies Code (40 P.S. §§ 1142-101—1142-701), and preferred provider organizations as defined in §630 of The Insurance Company Law of 1921 (40 P. S. §764a).

Managed care plan - plan - A health care plan that uses a gatekeeper to manage the utilization of health care services; 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; and provides financial incentives for enrollees to use the participating health care providers in accordance with procedures established by the plan. A managed care plan includes health care

arranged through an entity operating under any of the following:

(1) Section 630 of the act of May 17, 1921, known as the Insurance Company Law of 1921 (P.L. 682, No. 284) (40 P.S. §764a).

(2) The act of December 29, 1972 (P.L. 1701, No. 364) (40 P.S. §1551 et seq.), known as the "Health Maintenance Organization Act."

(3) The act of December 14, 1992 (P.L. 835, No. 134) (40 P.S. §1141-101 et seq.), known as the "Fraternal Benefit Society Code."

(4) Chapter 61 of the act of May 17, 1921, known as the Insurance Company Law of 1921 (P.L. 682, No. 284) (40 Pa. C.S. §§6102-6127) (relating to hospital plan corporations).

(5) Chapter 63 of the act of May 17, 1921, known as the Insurance Company Law of 1921 (P.L. 682, No. 284) (40 Pa. C.S. §§6301-6334) (relating to professional health services plan corporations).

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. 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 utilization review, 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 – All outpatient medical and surgical, emergency room and ancillary services including, but not limited to, 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.

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

Point-of-service plan – POS plan - A health care plan which requires an enrollee to select and utilize a gatekeeper in order to obtain the highest level of benefits with the least amount of out-pocket expense for the enrollee. A POS plan may be provided by an HMO or by a gatekeeper PPO.

Primary care provider - PCP - 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.

Preventive health care services - Services provided by the plan in order to provide for the prevention, early detection, and minimization of the ill effects and causes of disease or disability. Such 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.

Utilization review -UR - A system of prospective, concurrent or retrospective utilization review, performed by a utilization review entity or health care plan, of the medical necessity and appropriateness of health care services prescribed, provided or proposed to be provided to an enrollee. The term does not include any of the following:

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

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

Utilization review entity - CRE - Any entity certified under this chapter to perform utilization review on behalf of a plan.

§9.603. Technical advisories.

The Department may issue technical advisories to assist plans in complying with the HMO Act, Article XXI, and this chapter. Such technical advisories do not have the force of law or

regulation, but shall provide guidance on how a plan may maintain compliance with the HMO Act, Article XXI and this chapter.

§9.604. Plan reporting requirements.

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

(1) Enrollment and disenrollment data by product line (e.g., commercial, Medicare, Medicaid) and by county.

(2) Health care services utilization data.

(3) Data relating to complaints and grievances.

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

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

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

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

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

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

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

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

(b) *Quarterly reports.* -- Four times per year, a plan shall submit to the Department two copies of a brief quarterly report summarizing key utilization, enrollment, and complaint and grievance system data. Each quarterly report shall be filed with the Department no later than 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 any information contained in annual, quarterly or special reports, enrollee complaints relating to quality of care or service, or the deficiencies identified in the course of external quality reviews.

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

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

(d) The Department shall have access to medical records of HMO enrollees for the sole purpose of determining the quality of care, investigating complaints or grievances, enforcement,

or other activities relating to ensuring compliance with Article XXI, this Chapter, or any other law of the Commonwealth.

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

§9.606. Penalties and sanctions.

(a) For violations of Article XXI and these regulations, the Department may take any or all of the following actions:

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

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

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

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

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

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

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

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

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

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

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

Subchapter G. HMOS

APPLICATION FOR CERTIFICATE OF AUTHORITY

OPERATIONAL STANDARDS

§9.621. Applicability.

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

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

§9.622. Prohibition against uncertified HMOs.

(a) A corporation may not, within this Commonwealth, solicit enrollment of members, enroll

members, or deliver prepaid basic health services, by or through an HMO, unless it has received a certificate of authority from the Secretary and Commissioner to operate and maintain the HMO.

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

§9.623. Pre-application development activities.

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

APPLICATION FOR CERTIFICATE OF AUTHORITY

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

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

(1) Organizational information including a copy of the applicant's articles of incorporation, bylaws that include a description of the manner by which subscribers will be selected and appointed to the board of directors, an organization chart, and clear disclosure of

the relationship between the applicant and any affiliated entities owned or controlled by the applicant or which directly or indirectly own or control the applicant.

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

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

(4) A copy of each proposed standard form health care services provider contract and each IDS contract including a detailed description of the types of financial incentives that the HMO may utilize.

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

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

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

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

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

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

(11) A detailed description of the applicant's proposed provider credentialing system, and standards for on-going re-credentialing activities incorporating quality assurance, utilization review 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 utilization review functions to a subcontractor, evidence of such subcontractor's certification as a utilization review entity pursuant to subchapter K (relating to utilization review entities) if such certification is required.

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

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

reimbursement against the cost of health care services provided by the HMO.

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

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

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

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

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

(b) Upon receipt of a complete application for a certificate of authority the Department will publish notification of receipt in the *Pennsylvania Bulletin*. The Department will accept public comments, suggestions or objections to the application for a period of 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 in order to demonstrate compliance with the HMO Act or this chapter. A copy of any requests for information sent to the applicant will be sent to the Commissioner.

(d) The Department will review the completed application for compliance with the HMO Act

and this chapter. The application shall not be considered complete until all required information is provided to the Department in writing, including evidence of a contracted and credentialed provider network of sufficient capacity to serve the proposed number of enrollees.

(e) The Department may visit or inspect the site or proposed site of the applicant's facilities or facilities of the applicant's contractors and its provider network, in order 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 do either of the following:

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

(2) Disapprove the application and specify in writing the reasons for the disapproval. A disapproval of an application may be appealed in accordance with Title 2 of Pennsylvania Consolidated Statutes (relating to administrative law and procedure).

§9.633. HMO board requirements.

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

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

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

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

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

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

(1) The HMO shall make available for review at a location within in the Commonwealth, by the Department or an agent of the Department, the books and records of the corporation, and such 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 the Commonwealth but must be made available within the Commonwealth within 48 hours.

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

(3) The HMO's Quality Assurance/Improvement Committee shall include Pennsylvania licensed health care providers.

§9.635. Delegation of HMO operations.

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

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

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

(a) A foreign HMO may be authorized by issuance of a certificate of authority to operate or to do business in the 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 all

requirements for HMOs organized within and certified by the Commonwealth.

(b) A foreign HMO shall submit a completed Commonwealth application for a certificate of authority in accordance with §9.631 (relating to content of an application for an HMO certificate of authority) and §9.632 (relating to HMO certificate of authority review by the Department). 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. 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. The foreign HMO shall otherwise affirm that such information submitted to the Department remains current and accurate at the time of submission.

(c) The Department may waive or modify its requirements under the HMO Act and this chapter following a written request from the foreign HMO for such 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 on-going reporting and operational requirements, including external quality assurance assessments.

OPERATIONAL STANDARDS

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

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

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

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

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

(2) Outpatient services.

(3) Inpatient services.

(4) Preventive services.

(d) An HMO shall provide such 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 non-basic health services to enrollees.

(2) The health care provider contracts it uses to contract with participating providers shall 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. Use of co-payments and co-insurances in HMOs.

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

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

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

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

the following requirements:

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

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

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

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

§9.655. HMO external quality assurance assessment.

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

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

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

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

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

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

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

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

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

(i) periodically informing an enrollee's primary care provider of enrollee self-referred services; and

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

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

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

in any given specialty.

Subchapter H. AVAILABILITY AND ACCESS

§9.671. Applicability.

(a) 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 §2102 of Article XXI (40 P.S. §991.2102) in administering benefits, adjudicating claims, and processing complaints and grievances.

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

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

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

(e) A plan shall not require an enrollee to utilize any particular emergency transportation services organization or a participating emergency transportation services organization for emergency care.

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

standard.

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

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

(b) An enrollee or a prospective enrollee may make a written inquiry to a plan asking whether a specific drug is on the plan's formulary. The plan shall respond in writing to such a request no later than 30 days from the date of its receipt of the request.

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

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

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

§9.674. Quality assurance standards.

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

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

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

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

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

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

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

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

(7) The plan's review of quality shall include consideration of clinical aspects of care,

access, availability, and continuity of care.

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

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

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

§9.675. Delegation of medical management.

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

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

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

(1) Reimbursement methods being used to reimburse the contractor which shall comply with the requirements of §2152(b) of Article XXI (relating to operational standards for certified utilization review entities 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, utilization review, or related medical management activities.

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

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

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

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

(e) With respect to medical management arrangements involving an HMO, the medical management contract shall include a statement by the contractor agreeing to submit itself to review as a part of the HMO's external quality assurance assessment. See §9.655 (relating to HMO external quality assurance assessment). A contractor may receive a separate review of its operations by an external quality review organization approved by the Department. The Department will consider the results of such review in its overall assessment provided the review satisfies the requirements of §9.674 (relating to quality assurance standards).

§9.676. Standards for enrollee rights and responsibilities.

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

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

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

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

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

§9.677. Requirements of definitions of medical necessity.

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

§9.678. Primary care providers.

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

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

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

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

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

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

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

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

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

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

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

§9.679. Access requirements in service areas.

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

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

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

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

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

§9.680. Access for persons with disabilities.

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

(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 (42 U.S.C. §§12181 et seq.).

§9.681. Health care providers.

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

(b) A plan shall include a clear disclaimer in the provider directories it provides to enrollees that the plan cannot guarantee continued access during the term of the enrollee's enrollment to any particular health care provider, and that in the event a participating health care provider used by the enrollee ceases participation, the plan will provide access to alternative providers with equivalent training and experience.

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

as if a network provider had been available.

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

(1) Well-patient examinations and immunizations.

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

(3) Treatment of acute emergencies.

(4) Treatment of acute minor illnesses.

§9.682. Direct access for obstetrical and gynecological care.

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

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

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

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

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

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

(b) The plan's procedures shall:

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

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

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

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

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

(6) Ensure the plan issues a written decision regarding the request for a standing referral or designation of a specialist as a primary care provider within a reasonable period of time taking into account the nature of the enrollee's condition, but no later than 45 days after the plan's receipt of the request.

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

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

§9.684. Continuity of care.

(a) *Provider terminations initiated by the plan.*

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

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

(3) If the terminating provider is not a primary care provider, the plan shall notify 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 non-participating provider shall notify the plan of the enrollee's request to continue an on-going course of treatment for the transitional period.

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

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

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

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

(g) A plan shall provide the non-participating 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 non-participating health care provider.

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

date.

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

(j) Nothing in this section shall require a plan to provide health care services that are not covered under the terms and conditions of the plan.

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

Subchapter I. COMPLAINTS AND GRIEVANCES

§9.711. Alternative provider dispute resolution systems.

§9.701. Applicability.

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

§9.702. Complaints and grievances.

(a) *General*

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

(2) The plan shall incorporate neither administrative requirements, time frames, nor tactics to directly or indirectly discourage the enrollee from, or disadvantage the enrollee in, utilizing the procedures.

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

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

(c) *Complaints versus grievances.*

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

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

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

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

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

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

(d) *Time frames.*

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

(2) If a plan establishes a time limit for an enrollee to file the initial complaint or

grievance, the plan shall allow the enrollee at least 30 calendar days to file the complaint or grievance from the date of the occurrence of the issue being complained about.

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

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

§9.703. Health care provider initiated grievances.

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

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

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

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

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

(f) A health care provider, seeking to obtain written consent from an enrollee to file a

grievance on behalf of the enrollee, shall clearly disclose to the enrollee in writing that such consent precludes the enrollee from filing a grievance on the same issue unless the enrollee, during the course of the grievance, rescinds in writing the previous written consent.

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

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

§9.704. Internal complaint process.

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

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

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

(1) *First level review.*

(i) The first level complaint review shall be performed by an initial review

committee which shall include one or more employees. The members of the committee shall not have been involved in a prior decision to deny the enrollee's complaint.

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

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

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

(2) *Second level review.*

(i) The second level complaint review shall be performed by a second level review committee made up of 3 or more individuals who did not participate in the first level review. At least one third of the second level review committee shall not be employees of the plan. The members of the second level review committee shall have the duty to be unbiased in their review and decision.

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

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

enrollee's attendance.

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

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

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

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

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

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

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

(d) The Department of Health address for purposes of this section is:

Bureau of Managed Care

Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108
(717) 787-5193

The Department may change this address upon prior notification in the *Pennsylvania Bulletin.*

§9.705. Appeal of a complaint decision.

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

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

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

(2) Identification of the plan.

(3) The enrollee's plan ID number.

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

(5) Any correspondence from the plan concerning the complaint.

(c) Upon receipt of the appeal, the Department will verify with the plan that the appeal was submitted within 15 days of the enrollee's receipt of the notice of the decision by the second level review committee.

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

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

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

(g) The Department may decide to hold an administrative hearing on the appeal. The

hearing shall be conducted in accordance with the procedures in 1 Pa. Code Part II (relating to administrative practices and procedures).

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

§9.706. Enrollee and provider grievance system.

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

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

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

(1) *First level review.*

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

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

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

(iv) The plan shall notify the enrollee or the health care provider of the

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

(2) *Second level review.*

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

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

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

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

(C) Attendance at the second level review shall be limited members of the review committee; the enrollee, or the enrollee's representatives, or both; the health care provider; any applicable witnesses; and appropriate representatives of the plan. All persons attending and

their respective roles at the review shall be identified for the record.

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

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

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

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

(3) *Same or similar specialty.*

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

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

(iii) If the licensed physician or approved licensed psychologist, in the same or

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

§9.707. External grievance process.

(a) The plan shall establish and maintain an external grievance process by which an enrollee, or a health care provider with the written consent of the enrollee, may appeal the denial of a second level grievance following receipt of the second level grievance review decision.

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

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

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

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

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

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

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

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

(iii) The name of the plan.

(iv) The enrollee's plan ID number.

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

(vi) The remedy being sought.

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

(viii) Other reasonably necessary supporting documentation.

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

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

(i) The decision.

(ii) All reasonably necessary supporting information.

(iii) A summary of applicable issues.

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

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

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

consider the additional information. The plan shall expeditiously provide the enrollee's or health care provider's information to the CRE.

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

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

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

(f) If the Department fails to select a CRE within 2 business days of receipt of the external grievance, the plan may designate a CRE to conduct a review from the list of CREs approved by the Department. No CRE affiliated directly or indirectly with the plan may be selected by the plan to review the external grievance.

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

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

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

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

Department.

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

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

§9.708. Grievance reviews by certified utilization review entities (CRE).

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

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

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

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

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

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

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

§9.709. Expedited review.

(a) A plan shall make an expedited review procedure-available to 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. An enrollee may request from the plan an expedited review at any stage of the plan's review process.

(b) The plan's internal expedited review process shall be bound by the same rules and procedures as the second level grievance review process with the exception of time frames. It shall be 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.

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

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

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

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

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

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

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

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

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

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

Secretary.

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

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

§9.711. Alternative provider dispute resolution systems.

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

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

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

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

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

(1) Be impartial.

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

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

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

Subchapter J. HEALTH CARE PROVIDER CONTRACTS

§9.721. Applicability.

§9.722. Plan and health care provider contracts.

§9.723. Integrated delivery systems (IDS)

§9.724. HMO-IDS provider contract.

§9.725. IDS-provider contracts.

§9.712. Applicability.

This subchapter shall apply to provider contracts between managed care plans subject to Act 68

and health care providers; HMOs subject to the HMO Act and IDSs; and IDSs and health care providers.

§9.722. Plan and health care provider contracts.

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

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

(c) In order to be approved by the Department, a health care provider contract may not contain any provision 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 any other action specifically permitted by §2113 of Article XXI (40 P.S. §991.2113).

(d) To be approved by the Department, a health care provider contract may not contain any provision permitting the plan to penalize or restrict a health care provider from discussing any of the information health care providers are permitted to discuss under §2113 of Article XXI (40

P.S. §991.2113) or any other information the health care provider reasonably believes is necessary to provide to an enrollee full information concerning the health care of the enrollee.

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

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

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

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

(iii) Language to the following effect:

> "In no event including, but not limited to, 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 copayments 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 §2131 of Article XXI (40 P.S §991.2131) and all applicable State and Federal laws and regulations, which shall include:

(i) Language permitting the Department, the Department of Insurance, 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, utilization review, and enrollee complaint and grievance systems.

(4) Language addressing any alternative dispute resolution systems.

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

(6) Language concerning prompt payment of claims.

(7) Language requiring that the health care provider give no less than 60 days advance written notice to the plan of termination of the provider contract.

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

(1) Include the reimbursement method being used to reimburse a participating provider under the contract. If a provider reimbursement is subject to variability due to economic incentives, including bonus incentive systems, withhold pools, or similar systems, the plan shall describe such 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 weight 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. Integrated delivery systems (IDS)

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

(b) An HMO and an IDS entering into an arrangement under this subchapter shall notify the Department in writing at least 60 days in advance of any proposed action which would result in the IDS's participating providers being unavailable to provide covered services to enrollees, including, institution of litigation, termination, or non-renewal notice by either party.

§9.724. HMO-IDS provider contract.

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

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

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

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

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

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

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

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

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

(5) The IDS shall acknowledge and agree that the HMO is required to establish,

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

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

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

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

(9) The IDS shall agree to comply with data reporting requirements, including

encounter, utilization and reimbursement methodology required by the Department.

(10) The IDS shall obtain and maintain Department certification as a utilization review entity if performing utilization review activities in subchapter F (relating to utilization review entities) and §§2151-2152 of Article XXI (40 P. S. §§991.2151-2152).

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

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

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

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

§9.725. IDS-provider contracts.

In addition to the HMO-IDS contract, the health care provider contracts between the IDS and its

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

(1) The health care provider shall acknowledge and agree that nothing contained in the IDS-provider contract shall be construed to limit the following:

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

(ii) The Department's authority to monitor the effectiveness of the HMO's system and procedures or the extent to which the HMO adequately monitors any function delegated to the IDS, or to require the HMO to take prompt corrective action regarding quality of care or consumer grievances and complaints.

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

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

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

provider's participation in the HMO may also be terminated.

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

Subchapter K. UTILIZATION REVIEW ENTITIES

§9.741. Applicability.

This subchapter sets standards for the certification of utilization review entities and the maintenance of that certification.

§9.742. Certified utilization review entities (CREs).

(a) To conduct utilization review 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 utilization review entity 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 the terms of Act 68 and this chapter.

(c) A licensed insurer or a plan with a certificate of authority shall comply with the standards and procedures of §2152 of Article XXI (40 P.S. §991.2152), but shall not be required to obtain separate certification as a utilization review entity.

§9.743. Content of an application for certification as a utilization review entity.

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

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

(c) The application shall contain the following:

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

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

(i) Location of the principal office handling utilization review;

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

(iii) If the applicant is a public corporation, the name of each owner of more than 5% of the shares of the corporation; and

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

(3) 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 utilization review.

(5) A description of the applicant's:

(i) Ability to respond to each telephone call received as required by §2152 of Article XXI (40 P.S. §991.2152), including toll-free telephone numbers and the applicant's system to provide access during non-business 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 §2131 of Article XXI (40 P.S. §991.2131) and all 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 utilization review 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 utilization review, if it has secured such approval, certification or accreditation;

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

(ix) A list of three clients for which the applicant has conducted utilization review including the name, address, position and telephone number of a contact person for each client. The Department may contact these references for an assessment of the applicant's past performance and its ability to meet the timeframes for prospective, concurrent and retrospective utilization review in §2152 of Article XXI (40 P.S. §991.2152).

(d) The applicant shall certify that:

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

(2) An approved licensed psychologist in a same or similar specialty to the health care provider of the service in question, if the review is of behavioral health services within the psychologist's scope of practice, and the psychologist's clinical experience provides sufficient experience to review that specific behavioral health car service. A licensed psychologist may not

review the denial of payment for a health care service involving inpatient care or a prescription drug.

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

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

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

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

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

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

(4) A description of the applicant's:

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

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

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

ensuring that clinical peer reviewers, when making an external appeal determination concerning medical necessity, consider the clinical standards of the health care plan, the information provided concerning the enrollee, the attending physician's recommendation, and applicable generally accepted practice guidelines developed by the federal government, national or professional medical societies, boards and associations;

(iv) 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 direct or indirect competitors to the plan being reviewed; and

(v) Fee schedule for the conduct of grievance reviews. No applicant shall be certified as utilization review entity unless the proposed fees for external reviews are determined to be reasonable by the Department.

(5) A certification that:

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

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

(b) The Department will add the name of each certified utilization review entity 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 utilization review seeking certification shall be a responsible person. 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. The Department may consider whether any of the officers, directors or management personnel have ever filed for bankruptcy, been convicted of a state or federal offense related to health care, been listed by a state or federal agency as debarred, excluded or otherwise ineligible for state or federal program participation, been convicted of a criminal offense which would call in to question the individual's ability to operate a CRE, or have a history of malpractice or civil suits, penalties, or judgments against them.

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

§9.746. Fees for certification and re-certification of utilization review entities.

(a) Applying for certification as a utilization review entity shall include a fee of $1000 payable to the Commonwealth of Pennsylvania with its application. Applicants seeking certification for external grievance reviews shall include an additional $1000. Upon the effective date of this subchapter, each utilization review entity that is already certified by the Department shall pay the fee to the Department.

(b) The fee for recertification is $500.

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

(a) The Department will review the application for certification as a utilization review entity. If the Department finds deficiencies, it shall 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.* – To determine whether a CRE is complying with the requirements of Act 68 and this subchapter, and maintaining its certification during the 3-year certification period, the Department may do any or all 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 on-site inspection 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; and

(iv) A re-affirmation of certifications included in the CRE's original application.

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

Subchapter L. CREDENTIALING

§9.761. Provider credentialing.

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

(1) Initial credentialing.

(2) Re-credentialing at least every 2 years.

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

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

(5) Restrictions or limitations.

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

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

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

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

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

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

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

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

(f) A plan shall comply with all requirements of §2121 of Article XXI (40 P.S. §991.2121).

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

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SECRETARY OF HEALTH

December 8, 1999

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Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health Proposed Regulations No. 10-160
Managed Care Organizations

Dear Mr. Nyce:

Attached are proposed regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§745.1-745.15). The proposed regulations implement Article XXI of the Insurance Company Law of 1921 (40 P.S. §§991.2101-2193), dealing with health care accountability and protection. The proposed regulations also include changes to the Department of Health's regulations relating to health maintenance organizations ("HMOs") currently set out at 28 Pa. Code §9.1 et seq. As required by Executive Order 1996-1, the Department is attempting to revise and update its regulations governing HMOs to eliminate unnecessary provisions, and to reflect the developments in the industry which have occurred since the regulations were first implemented.

Section 5(g) of the Regulatory Review Act (71 P.S. §745.5(g)), provides that the Commission shall, within 10 days after expiration of the Standing Committee review period, notify the proposing agency of any objections to the proposed regulations. The regulations are expected to be published December 18, 1999. A 30-day comment period is provided.

Section 5.1(a) of the Regulatory Review Act (71 P.S. §745.5a(a)), provides that upon completion of the agency's review of comments, the agency shall submit to the Commission a copy of the agency's response to the comments received, the names and addresses of commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

The Department will provide the Commission within 5 days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the

Commission with any assistance it requires to facilitate a thorough review of the proposed regulations. If you have any questions, please contact Deborah Griffiths, Director of the Office of Legislative Affairs at (717) 783-3985.

Sincerely,

Robert S. Zimmerman, Jr.
Secretary

Attachments

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

RECEIVED
1999 DEC -8 PM 3:17
INDEPENDENT REGULATORY REVIEW COMMISSION

I.D. NUMBER:	10-160
SUBJECT:	Managed Care Organizations
AGENCY:	DEPARTMENT OF HEALTH

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
12-8-99	Lisa J. Burris 2:54 pm	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
12/8/99	Jane L. Ruckert 3:07 pm	
12/8/99	Kristi Kreiser 2:56 pm	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
12/7/99	Debbi Sohn 3:00 p m	
12/8/99	Kim C. Kaufman	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
12/8/99	Mayra Cares 2:50 pm	LEGISLATIVE REFERENCE BUREAU

December 8, 1999