Regulatory Analysis Form	This space for use by IRRC
(1) Agency Department of Health	2001 MAR 23 P 2:10
(2) I.D. Number (Governor's Office Use) DOH Reg. No.10-160	IRRC Number: 2079

(3) Short Title

Managed Care Organizations

(4) PA Code Cite	(5) Agency Contacts & Telephone Numbers
28 Pa. Code Ch. 9	Primary Contact: Stacy Mitchell, Director Bureau of Managed Care Pennsylvania Dept. of Health P.O. Box 90 Harrisburg, PA 17108-0090 (717) 787-5193 Secondary Contact: David Henry, Director Division of Quality Review Pennsylvania Dept. of Health P.O. Box 90 Harrisburg, PA 17108-0090 (717) 787-5193

(6) Type of Rulemaking (Check One)	(7) Is a 120-Day Emergency Certification Attached?
Proposed Rulemaking	√ No
√ Final Order Adopting Regulation	___ Yes: By the Attorney General
Final Order, Proposed Rulemaking Omitted	___ Yes: By the Governor

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

The Department of Health (the Department) is amending 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 final 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 the final regulations, the Department is addressing the changes in the managed care industry and implementing 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 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).

(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 violations 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).

(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 certain of the previous regulations obsolete, and created a demand for a revision of those regulations. The need for revision was highlighted by the Department's review of the regulations pursuant to Executive Order 1996-1, which required each state agency under the Governor's jurisdiction to review its existing regulations.

The final 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 final regulations affect HMOs certified to do business in the Commonwealth, since the final regulations clarify and simplify certain requirements for HMO certification. For example, the Department is changing the date for the first external quality assurance review from 1 year to 18 months in keeping with national standards and to ensure that the plan has sufficient experience to document its quality assurance efforts for a thorough and meaningful review. Managed care plans as defined by Act 68, including certified HMOs, benefit, in that the final regulations 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 final 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 final regulations, in implementing the requirements of Article XXI, also set standards for health care provider credentialing, provider participation in grievances, utilization review requirements and standards for 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.

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

Enrollees will also benefit from the Department's final regulations regarding exceptions to a plan's pharmaceutical policies. A plan's responses to drug formulary inquiries must contain information regarding the formulary alternatives so that enrollees know what drugs in the same class are covered by the plan, or must inform the enrollee how he or she can access the formulary. This makes the plan's response more useful than a simple negative response. This permits an enrollee to discuss the merits of the formulary alternatives with the enrollee's prescribing physician and allows them to make an informed decision. Decisions regarding physician requests for coverage of non-formulary drugs will be handled as prospective utilization review decisions which will greatly improve the ability of the physician to prescribe and the enrollee to receive coverage of necessary prescription drugs in a timely and clinically relevant manner.

Enrollees will also benefit from access to plan documents relevant to complaints and grievances, notice of hearings, more informational decision letters and instructions on how to pursue further appeals. This information will benefit the enrollee in understanding the appeal process and the nature of the plan's position, and will permit the enrollee to more effectively frame his arguments.

(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 final 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 previous regulations at 28 Pa. Code §9.1 et seq., however, the Department has added several additional requirements, relating, for example, to the quality assurance activities of a plan. 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. There are also additional requirements imposed by Act 68 in the areas of health care provider credentialing. The HMO medical director must be licensed in Pennsylvania, which may require additional costs for licensure and filing requirements. The quality assurance committee must include local Pennsylvania providers, which will increase coordination activities and reimbursement of expenses.

The final regulations may also be said to adversely affect managed care plans as defined by Act 68, since the regulations place new requirements on these entities to ensure their compliance with that act. For example, depending upon how plans have structured complaint and grievance processes prior to the passage of Act 68, the complaint and grievance process required by Act 68 require a certain composition of review committees, which may add to the cost of the review. Further, the Department's inclusion of its "fundamental fairness" guidelines, originally distributed to plans in 1991, may increase staff time in setting up or adjusting procedures, and in preparing for individual reviews.

(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.) (Continued.)

The additional disclosure requirements of the act may also have a fiscal impact upon managed care plans, including HMOs, in terms of staff, systems, materials and distribution costs; however, they will also greatly improve access to care and consumer awareness of coverages and limitations. These requirements include, for example, requiring plan responses to drug formulary inquiries to contain the formulary alternatives or to inform enrollees how to access the formulary, treating physician requests to the plan for coverage of a drug not on the formulary as prospective utilization review requests, requiring a response from the plan within two business days, and notification to enrollees of what coverage the plan will provide to plan-approved exceptions to the formulary.

Further, new medical management contracts and nonHMO plan contracts with providers and IDSs entered into after the effective date of the regulations must be submitted to and reviewed by the Department. This will increase filing costs for plans.

Requirements that plans provide enrollees and their representatives with access to plan documents relevant to complaints and grievances may create additional burden on plans in time, staff and materials but will add substantially to the fundamental fairness of the process and may serve to decrease the likelihood of enrollees pressing meritless cases.

Requirements for plans to notify providers of obstetrical and gynecologial services will create an added provider relations burden for plans, but will positively affect the providers' compliance and ability to provide and refer services within the confines of plan requirements. This will tend to eliminate errors that either cost plans unnecessarily or jeopardize coverage for enrollees.

The final regulations also affect entities either conducting or wishing to conduct internal or external grievance reviews, since Act 68 requires these utilization review entities to be certified by the Department. The final regulations also affect entities either conducting or wishing to conduct utilization review. Fees for certification are established. For external grievance reviews, the final regulations establish requirements for the content of grievance review decision letters, which may require additional effort for compliance. The requirements for composition of the reviewer network may increase network development activities for some CREs.

(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.) (Continued.)

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.

(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 will be required to comply with the final regulations, as will 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) will be required to comply with the final regulations.

Health care providers wishing to provide or providing services through a managed care arrangement will be required to comply with the final 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 will be required to comply with the final regulations as will utilization review entities that conduct internal or external grievance reviews.

Approximately 5.3 million enrollees of managed care plans covered by Act 68 will be required to comply with the final 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.

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 over 1400 comments it has received on the proposed regulations from 77 various groups of stakeholders, again including consumers, plans, health care providers.

(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 final regulations relating to HMOs do 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 is implementing through the final 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 required by Act 68 and the regulations may increase cost. Among other things, the regulations and Act 68 require a certain composition of review committees, which may add to the cost of the review. Further, the Deparment's inclusion of its "fundamental fairness" guidelines, originally distributed to plans in 1991, may increase staff time in setting up or adjusting procedures, and in preparing for individual reviews.

The additional disclosure requirements of the act may also have a fiscal impact upon managed care plans, including HMOs. These requirements include, for example, requiring plan responses to drug formulary inquiries to contain the formulary alternatives or information on how to access the formulary, treating physician requests to the plan for coverage of a drug not on the formulary as prospective utilization review requests, requiring a response from the plan within one business day, and notification to enrollees of what coverage a plan will provide for plan-approved exceptions to the formulary requirements. Further, medical management contracts and nonHMO plan contracts with providers and IDSs entered into after the effective date of the regulations, must be submitted to and reviewed by the Department. This will increase filing costs for plans.

Requirements that plans provide enrollees and their representatives with access to plan documents relevant to complaints and grievances may create additional burden on plans in time, staff and materials but will add substantially to the fundamental fairness of the process and may serve to decrease the likelihood of enrollees pressing meritless cases.

(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.)

Requirements for plans to notify providers of obstetrical and gynecologial services will create an added provider relations burden for plans, but will positively affect the providers' compliance and ability to provide and refer services within the confines of plan requirements. This will tend to eliminate errors that either cost plans unnecessarily or jeopardize coverage for enrollees.

For most areas of potential fiscal increase, however, there is also a potential associated fiscal reduction. For example, enrollee access to relevant plan documents involving complaints and grievances may actually reduce the number of appeals being pursued when the documents clearly articulate the plans policies and procedures. Enrollee appeals will also likely be more succinctly structured and articulated, making processing less cumbersome for the plan. Information to obstetrical and gynecological services providers concerning plan policies and procedures for directly accessed services will likely reduce unnecessary utilization, improve use of plan participating providers and reduce enrollee complaints caused by out-of-pocket expenses stemming from the providers' failure to adhere to plan protocol. Processing physician formulary exception requests as prospective utilization review requests will decrease the time it takes for an enrollee to get access to a necessary medication and presumably preventing future related health care costs associated with delays in treatment. Providing an enrollee with the formulary alternatives when the subject of the inquiry is a drug that is not on the formulary, or informing the enrollee how the formulary may be accessed, will prevent multiple inquires on the part of the enrollee trying to establish what drugs are on the formulary; provides the enrollee with the covered alternatives which may reduce the number of complaints and grievances in the future; and allows the enrollee to make an informed decision about whether or not to join the plan which may increase enrollee satisfaction and reduce enrollee turnover.

For other areas, the fiscal impact should be minimal, as the regulatory requirements are largely no different from the standards of the external review organization, the National Committee on Quality Assurance (NCQA), approved by the Department for performing external quality assurance assessments. NCQA has been performing these quality assurance assessments in the Commonwealth for the past 10 years. For example, provider credentialing requirements, notice of enrollee rights, utilization review decision turnaround timeframes, content of utilization review denial letters, and the involvement of representative and practicing physicians on the quality assurance committee, are all the same as NCQA's requirements.

The final regulations 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 doing so in its proposed regulations.

(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.)

There may be additional cost because of additional paperwork for managed care plans that are not HMOs, since they will be required for the first time to submit standard provider contracts and complaint and grievance procedures to the Department. HMOs are required by the Department's previous regulations to make these submissions.

The incremental cost for an HMO of continuing the practice of filing standard form contracts is negligible. Under the final regulations, nonHMO managed care plans will also be required to file standard form contracts entered into after the effective date of the regulations. If a nonHMO plan uses provider contracts already approved for a related HMO, the requirement would place little burden on the nonHMO. It is common practice for a plan with multiple lines of business, (HMO, PPO, Point-of-Service, even indemnity) to use one standard form contract and address variations in reimbursements or terms through specific amendments or exhibits. The cost to the plan of the Department reviewing contracts is, in concrete terms, made up of minimal copying and postage fees.

Since, under the final regulations, the Department's review period will postpone use of a contract for only a 60-day period from the date the contract filing is complete, little or no expense should arise from this requirement for Department review.

Another commentator raised concerns that the Department was adding required provider provisions to its longstanding informal list of required provisions. The commentator requested that the Department consider costs associated with requiring plans to renegotiate contracts, distribute amendatory riders, inform providers of reasons for changes, and related implementation issues. The commentator requested that the Department provide sufficient "lead time" for the plan to implement these changes.

The Department must be able to review the contracts discussed in this subchapter, to ensure compliance with the act, and to protect enrollees. The Department did not include information relating to cost for this subchapter, since it is not requiring plans to resubmit ~~all~~ currently approved contracts. The Department is already reviewing contracts for most of the requirements contained in this subchapter. The Department, therefore, did not anticipate great additional cost to the plans for this purpose, as discussed in the Department's response to the previous comment.

Act 68 itself creates this additional paperwork, since the plans must comply with the mandated complaint and grievance system detailed in the act, and because the Department must monitor Act 68 compliance through plan provider contracts. Depending upon how plans operated their grievance systems prior to Act 68, the act and the Department's final regulations will 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 disclosures be made to enrollees may result in an increase in paperwork.

(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.)

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 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. CREs would be required to pay a fee to the Department along with the application, and will again have to pay a fee for recertification every three years.

The final regulations concerning Act 68 create additional costs to the regulated community. The disclosure requirements in the act arguably exceed an estimated $3.00 per family contract, estimated at 2 million family contracts, 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 costs of the external grievance review if they were the non-prevailing party. Enrollees who file grievances face a $25 filing fee for external grievance reviews.

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 regulations do 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 previous regulations at 28 Pa. Code Ch. 9 (relating to health maintenance organizations) create no additional cost to the Commonwealth, since these revisions reflect the current operations of the Department. There is no fiscal impact even though there are additional monitoring duties placed on the Department by Act 68. Those duties are reflected in provisions of the final regulations relating to health care accountability and access, complaints and grievances, provider contracts, accreditation of utilization review entities, and credentialing. The Department is, among other things, 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 also coordinates the external review procedure set out in Act 68, which requires the Department to certify, appoint and monitor the operations of the certified review entity conducting the review.

(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.

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

Program	96/97	97/98	98/99	99/00
Bureau of Managed Care	$650,627	$1,061,270	$1,142,757	$1,246,438.38

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

Act 68 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 informed consumers and providers will be more satisfied and will interact more closely and appropriately with plans, thereby improving access to quality care and reducing administrative burdens associated with failure to follow policies and procedures and the resultant complaints and grievances. Further, heightened awareness and satisfaction among enrollees and providers will create stability for plans and reduce turnover costs associated with network disruptions, non-compliant providers and enrollee recruitment and retention. These benefits are expected to 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 had regulations addressing HMOs, the Department made the decision to facilitate the implementation of Act 68 through revision of those regulations. In doing so, the Department is able to both address the issue of the outdated HMO regulations, and facilitate the implementation of Act 68.

(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.

(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 Department of Health and the Insurance Department of this Commonwealth. The Department's final regulations are required by both the HMO Act and Act 68. Some states have issued provisions 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 final regulations do not affect the Department's other regulations. Under both Act 68 and the HMO Act, both the Department and the Insurance Department are required to promulgate regulations to facilitate implementation. The Insurance Department has not altered its regulations regarding HMOs at 31 P.S. ch. 301. The Department's final regulations on Act 68 issues are intended to complement the regulations of the Insurance Department on the same topic. The Insurance Department's regulations were published as final rulemaking on March 11, 2000 (30 Pa. B. 1453). They are codified at 31 Pa. Code §154.1 et seq.

(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 1999, and placed them on its website for greater public access. The Department then published proposed rulemaking in the Pennsylvania Bulletin on December 18, 1999 (29 Pa. B. 6409), and provided a 30-day public comment period.

(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 will be changes in paperwork requirements associated with the final regulations. While the regulations relating solely to HMOs do not substantially 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 are required for the first time to submit provider contracts and complaint and grievance procedures to the Department. HMOs were required by the Department's previous 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 complaint and grievance systems prior to Act 68, the act and the Department's final regulations may require additional paperwork of plans. The Department has included in the final regulations certain requirements from its 1991 guidelines relating to the conduct of grievance reviews which may require the adjustments of polices and procedures in these areas. Again, depending upon how managed care plans operated prior to Act 68, the act's requirement that certain disclosures be made to enrollees may 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 final regulations may 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 may be alterations in the manner in which an enrollee must utilize these procedures.

(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 Article XXI (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 final regulations include a section reflecting this requirement. (See §9.680) (relating to access for persons with disabilities).

(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 final regulations will 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 regulations.

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_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-160	March 23, 2001 DATE OF APPROVAL
	DATE OF ADOPTION: _____	(Deputy General Counsel) (~~Chief Counsel, Independent Agency~~) (~~Strike inapplicable title~~)
9 Check if applicable. Copy not approved. Objections attached.	BY ROBERT S. ZIMMERMAN JR. TITLE SECRETARY OF HEALTH	9 Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

TITLE 28. HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 9]

MANAGED CARE ORGANIZATIONS

The Department has made considerable changes to its proposed regulations in an attempt to address many of these issues. The Department has revised the procedures regarding complaint and grievance reviews. The Department has added more specific credentialing requirements in subchapter L (relating to credentialing requirements). The Department has clarified the section on adequacy of networks, revised the section on direct access to obstetrical and gynecological services to address issues concerning perceived limitations on access, and changed language relating to enrollee rights to reflect current requirements of NCQA. The Department has not, however, included language permitting contracts to be deemed approved if they are not reviewed by a certain date, setting provider/enrollee ratios, or defining "medical necessity."

The Department has made changes throughout the regulations where such changes were necessary to ensure consistency with the regulations promulgated by ID. The Administrative Code of 1929 (71 P.S. §§51-732) requires that "departments . . . devise a practical and working basis for cooperation and coordination of work. . ." (71 P.S. §181). Both agencies are currently, and will continue to, work together to ensure an effective and efficient application of Article XXI and its implementing regulations.

The Department's response to the comments received on specific provisions of its proposed regulation follow:

is not covered as result of an exclusion the member should be directed to file a complaint. Others commented that the denial of an exception should always be considered a complaint.

After reconsideration of this issue, the Department agrees that challenge to a plan's refusal to grant a formulary exception may not always be a grievance, however, it may not always be a complaint. If a drug, class of drugs or drugs used to treat a specific condition are specifically excluded from coverage in the enrollee contract, appeals for coverage of specific exclusions would be considered complaints, as the issue is a contractual limitation regardless of medical necessity and appropriateness. If the appeal involves the medical necessity and appropriateness of one drug versus another, the appeal is a grievance and must be processed as a grievance. The Department intends to categorize as grievances all requests for formulary exceptions that were based upon medical necessity and appropriateness. The Department has changed the language of this subsection to clarify whether an appeal is a complaint or grievance.

One commentator requested clarification of whether this provision would apply to closed formularies. This subsection applies whether or not the formulary is closed.

Section 9.674. Quality assurance standards.

The Department received many comments on this proposed section. One commentator was pleased that the proposed regulations required quality assurance programs. Several

commentator recommended that the Department include language in the regulation permitting a plan to deem the contract approved if the Department does not approve it or request further information within a specific time period.

The Department specifically removed all reference to what are referred to as "deemer provisions" from the proposed regulations, and does not intend to reintroduce them. The Department has a responsibility under the law to ensure that certain actions by plans meet the standards of Act 68 and the HMO Act. As medical management almost invariably involves utilization review, much more scrutiny of contract terms is now required given the requirements and prohibitions in Act 68. To deem something approved without actually reviewing and approving it is to abdicate responsibility under those statutes, since contracts that do not meet the standards of the regulations may be approved by this mechanism. The Department must, therefore, review these contracts.

The Department is aware, however, of the concerns of plans that delay on the Department's part could create difficulties for plan operations. The Department has, therefore, included language that will require a plan to submit a contract prior to its use, but if the Department fails to review the contract within that time frame, the plan may use the contract. The contract will be presumed to meet the requirements of all applicable laws. If the contract is in violation of law, the plan must correct that violation. The plan is responsible for ensuring that the contract meets the requirements of Act 68, and any other applicable law. The

Department may, within that 45-day period, request further information or changes from the plan; such a request would toll the 45-day review period.

One commentator also raised concerns that plans have contracts in place without previously being required to obtain Department approval. The commentator asked whether the Department intended to "grandfather-in" existing contracts, and strongly urged that this proposed section should only apply to contracts coming into existence or renewed after the effective date of the regulation. The commentator also raised concerns that plans that have contracts in effect at the time of the effective date of the regulations could face sanctions if language changes were not made to the proposed regulations. The Department will not require refiling of contracts already approved.

One commentator requested that the Department clarify its statutory authority to require submission and prior review of medical management contracts between a plan and a contractor. The commentator stated that plans should be free to contract with vendors without prior review and approval by the Department, and that it was the Department's responsibility to review the results of the medical management, and not the vendor relationships. The commentator also raised concerns regarding confidential and proprietary nature of the information contained in the contracts.

requiring a written notice to alert an enrollee that the enrollee's primary care provider is a CRNP, and not a physician. IRRC recommended that the notice include name of the physician with whom the CRNP has a written agreement to provide services.

The Department has not changed the proposed subsection based on these comments. Enrollees are permitted to choose from a variety of provider types approved and credentialed by a plan as a primary care provider in such areas as pediatrics, family practice and general internal medicine. Any enrollee who has a choice of a CRNP also has a choice of all other types of primary care providers. Provider directories, which are reviewed by ID, list providers by practice area (specialty) and provider name, including credentials, address and telephone number. Practitioners are identified with their proper credentials as an M.D., D.O., CRNP, and so on. Therefore, enrollees will know who and what they are selecting for their primary care provider.

IRRC has recommended that the Department either cross-reference to the state law and regulations which list the scope of licensure for a CRNP, or specifically state that CRNPs are only permitted to perform certain functions in collaboration with and under the direction of a licensed physician.

The Department is aware of the practice requirements attached to the practice of a CRNP in the Commonwealth. The Department has stated in this regulation that a CRNP must practice

in accordance with state law, which, as IRRC commented, requires collaboration and direction of a physician for certain purposes. The Department intended to reference the scope of practice of a CRNP by including in the proposed section the language: "practices in accordance with state law." To clarify this, the Department will replace the language which IRRC has suggested is unnecessary and should be deleted, with the specific citations to the Medical Practice Act (63 P.S. §§422.1-422.45) and the Nurse Practice Act (63 P.S. §§211-225) and the relevant regulations.

One commentator commented that in community-based nurse managed health centers, nurses practice as primary care providers independently in collaboration with a physician. Physician supervision is not consistent with current practice. It has requested that the Department's comments in its Preamble to this section concerning supervision be clarified.

The language to which the commentator refers regarding supervision was taken out of context from the Preamble. It was meant to refer to the supervision and coordination of the care of the individual patient's needs by a primary care provider. This is the role of the primary care provider in managed care.

One commentator recommended the revision of language in proposed subsection (e) to take into account concerns that it could be interpreted as requiring directories to advise members of the implications of any referral changes on a provider by provider basis. The commentator

One commentator, although recognizing the need for the Department to be aware of potential service disruptions, raised concerns that the immediate notification requirement in proposed subsection (d) would be burdensome. The commentator recommended that the Department require a report within a reasonable time.

The Department agrees with the comment, and has deleted the word "immediately" from the proposed subsection, which is now subsection (c). The Department has also changed the word "potential" to "probable" to reflect the Department's intention to only require notice of those threatened terminations that are likely to become actual terminations.

The commentator also commented that it was unclear how the proposed requirement to report a serious change in the plan's ability to provide services affecting 10% or more of the enrollees in a service area would be applied to plans with service areas that cover more than one county and different geographic regions.

The Department, after reviewing this comment, agrees that the 10% requirement could be broadly interpreted, and, therefore, difficult to apply. The Department has also decided that a service area is too broad an area that needs to be updated to trigger a reporting duty, and may allow plans to avoid providing notice when a provider in a small community with many enrollees terminates and the community and the plan are without alternatives. The remaining

Another commentator requested that the Department clarify how to treat an enrollee's cancellations or failures to participate in a meeting scheduled for a second level review. The commentator asked how an enrollee's failure to participate affected the compliance time frames.

The Department believes that an enrollee must be given ample opportunity to participate in the process, and that if the enrollee requests that a hearing be rescheduled, the plan should reschedule the hearing at least once as a courtesy to the enrollee. The plan should also reschedule the hearing after that if the enrollee has an unforeseen complication preventing the enrollee's attendance such as illness or transportation breakdowns. Since the plan sets the hearing date, often times without consulting the enrollee, the plan must make reasonable efforts to reschedule to accommodate the enrollee. If the enrollee fails to appear at the hearing after the plan has rescheduled the hearing for the convenience of the enrollee, the plan could put its case on the record, and may provide the enrollee with the ability to add information to the record prior to the review committee's decision. As the plan faces statutory deadlines, it must render a decision based on the record at the time of the deadline. As the deadline is for the benefit of the enrollee, the enrollee may agree to allow the plan to exceed this deadline to submit additional information or to facilitate enrollee participation at the review. Both parties must consent in order to extend the time. The Department will not

impose a penalty if the plan refuses to agree to an extension of time and completes the review within the time period permitted in the statute.

One commentator suggested that proposed subsection (a) ignored Act 68's clear instructions that complaints were the responsibility of ID and not the Department, and stated generally that the other proposed provisions were unduly vague.

It is incorrect to say that Act 68 clearly requires complaints to be exclusively under the jurisdiction of ID. Act 68 specifically gives the authority over complaints to the appropriate agency, either the Department of Health or ID, 40 P.S. §991.2142(a). Act 68 also gives both agencies the authority to investigate violations of Act 68, including the sections relating to complaints. 40 P.S. §991.2181(d). The Department disagrees that the remainder of the provisions are vague.

IRRC commented that Department should either explain what additional requirements the Secretary may impose on the complaint and grievance procedure, or delete the phrase: "and is satisfactory to the Secretary" from subsection (a)(1). IRRC also recommended that for clarity the Department should use the plural word "procedures" rather than the singular word "procedure" to emphasize that complaints and grievances are separate procedures.

permitted to question the plan's spokesperson. The commentator stated that the purpose of Act 68 would be defeated by reviewers prejudiced by a one-sided, open-ended presentation by the plan occurring without the enrollee being permitted to take part in that presentation.

The Department agrees that the regulations should contain more requirements aimed at ensuring the impartial nature of the review. The Department has included language requiring that the second level review committee base its decision on the grievance on the materials and testimony presented at the review. Subsection (c)(2)(iii)(L). The Department has also included language in this subsection prohibiting the committee from basing its decision on any document obtained on behalf of the plan that sets out medical policies, standards or opinions or that specifies opinions supporting the decision of the plan unless the plan makes available for questioning at the review by both the committee and the enrollee an individual who is familiar with those policies, standards or opinions included in the document. The plan may choose the individual who will appear, so long as the individual is familiar with the information in question, and the individual need not appear in person, but may be present at the review by telephone.

The Department has also included several recommendations from its 1991 guidelines in the regulations for the purpose of emphasizing the need for a fair and impartial review of the case. A committee member who does not personally attend the review meeting may not vote on the case unless that person actively participates in the review meeting by telephone or

introduced at the review meeting prior to the vote. See subsection (c)(3)(ii). The matched specialist's opinion must be read into the record, however, to become part of the review proceedings.

IRRC and another commentator have requested that the Department clarify the term "same or similar" in proposed subsection (c)(3)(i). That proposed paragraph stated that both the initial and second level grievance review committees were to 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.

The intent of Act 68, by leaving the language open in section 2161(d) and 2162(c)(4) (40 P.S. §§991.2161(d) and 991.2162(c)(4)) was to provide plans some flexibility in obtaining individuals in a same or similar specialty to review grievances. The Department has chosen not to attempt to refine this language, because of the great danger of setting in regulation comparisons between specialties, subspecialties, education, experience, and so forth. For example, by introducing such language, the Department would be regulating when an orthopedist must be used as opposed to a neurosurgeon for spine surgery cases, and whether an ordinary orthopedist will do, or whether the orthopedist must have a fellowship in spine surgery, and whether a Harvard degree is comparable to a Yale degree. This is not appropriate material for regulation. The Department will require that plans use a specialist in a same or similar specialty when the service was provided by a specialist who is a physician

or psychologist. See subsection (c)(3)(v). The Department's intention is to have physician-specialists and psychologist-specialists reviewing specialty areas, and primary care providers reviewing primary care areas. Family practitioners should not be providing expert medical opinion on brain surgery, pediatricians should not be providing expert medical opinion on cancer treatment, general internists should not be providing expert medical opinion on spine surgery. Every enrollee in a managed care plan has a primary care provider who serves as the enrollee's medical manager, providing treatment as appropriate and managing the enrollee's care through referrals to specialists as necessary. This does not make the provider a specialist in the "same or similar specialty" by virtue of the fact that the provider coordinates referrals.

The Department received several comments on proposed subsection (c)(3)(ii), which stated that the matched specialist need not personally attend at the review, but had to be included in the hearing, discussion, and decisionmaking by written report, telephone, or videoconference.

Two commentators requested that the Department clarify whether a matched specialist has to be a voting member of the committee.

One commentator stated that the proposed regulations would allow the matched specialist to vote without being present at the review. The commentator commented that this would seriously erode the protections of the statute.

recommended that language be added providing that if the Department did not take additional action in the form of specific approval within 30 days after receipt of additional information or a written request for clarification, the contract would be deemed approved.

The Department has not included "deemer" language in the regulations. The Department has the responsibility under statute to review and approve provider contracts, as well as implementing certain provisions of Act 68, including, for example, provisions prohibiting financial incentives, prohibiting gag clauses, and requiring confidentiality of medical records. For the Department to require itself to deem as acceptable a contract containing illegal language, simply because a regulatory, not statutory, time frame has run, is an abdication of the Department's responsibility under Act 68 and the HMO Act. Although the Department is requiring plans to submit contracts in place prior to the effective date of the regulations for review and approval, it will permit plans to continue using those contracts. See §9.722(a). The Department has added a provision to the regulations that states that the Department will review contracts within a 45-day period, and that if the Department fails to approve or disapprove the contract within that time frame, the plan may use the contract. The contract will be presumed to meet the requirements of all applicable laws. If the Department finds at any time that the contract contains violations of law, the plan must correct those violations. The plan is, of course, responsible for ensuring that it complies with Act 68 and any other law applicable to it, for example, the HMO Act.

operational standards. The Department has revised the proposed regulations to include utilization review standards, and placed those in the part of the subchapter entitled "Operational standards." The Department has included three sections in the final regulations to address standards for a description of a utilization review system (see §9.749 (relating to system description)), standards for the utilization review system (see §9.750 (relating to UR system standards)) and standards for the time frames in which utilization review must be provided (see §9.751 (relating to time frames for UR)).

The Department has deleted §9.601(c) (relating to applicability), which discussed the applicability of §9.742 (relating to CREs). The Department has, instead, expanded this section, which specifically discusses the scope of this subchapter. The Department has added language to §9.741 of the regulations to clarify that the sections dealing with certification apply to CREs as defined by the act (40 P.S. §991.2102 (relating to definitions)). Sections 9.749 through 9.751 include operational standards for UR. See subsection (b).

Section 9.742. CREs.

Two commentators complained that pursuant to subsection (c), a licensed insurer would not be required to go through the certification process to become a CRE. One commentator raised concerns that an insurance company could pose as outside independent CRE for another insurance company, or its parent or subsidiary without having to be certified. Both commentators stated that the certification process was the only possible mechanism for

sorting out potential conflicts of interest. At a minimum, these commentators recommended that licensed insurers be required to comply with sections 2151 and 2152 of Article XXI (40 P.S. §§991.2151 and 991.2152) and be required to obtain certification.

The Department has deleted subsection (c). Act 68 clearly states that a licensed insurer or a managed care plan with a certificate of authority shall not be required to obtain separate certification as a utilization review entity. 40 P.S. §991.2151(e). Therefore, to require such entities to undergo certification would be a violation of Act 68. The Department has also deleted the term "licensed insurer" from §9.601 (relating to definitions) since that term no longer appears in the Department's regulations. The comments concerning conflict of interest are discussed in §9.743 (relating to content of an application for certification as a CRE).

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

The Department received one comment in support of this proposed section. Several commentators requested revisions to the proposed section.

Several commentators commented concerning what they viewed as the inability of the proposed regulations to prevent conflicts of interest from arising between plans and CREs, since this proposed section would not specifically request conflict of interest information. One commentator commented that the proposed regulations do not go far enough to

PROVIDERS.

~~(iv)~~ **(II)** ~~Assumes~~ **ASSUME** under the arrangement with the plan ~~full or partial~~ **SOME** responsibility for conducting **IN CONJUNCTION WITH THE PLAN AND UNDER COMPLIANCE MONITORING OF THE PLAN** ~~any or all of the following activities: quality~~ assurance, UR, credentialing, provider relations or ~~enrollee services~~ **RELATED FUNCTIONS.**

(II) THE IDS MAY ALSO PERFORM CLAIMS PROCESSING AND OTHER FUNCTIONS.

Inpatient services – Care, **INCLUDING PROFESSIONAL SERVICES,** at a licensed hospital, skilled nursing or rehabilitation facility, including preadmission testing, diagnostic testing ~~performed during~~ **RELATED TO** an inpatient stay, **PROFESSIONAL AND** nursing care, room and board, durable medical equipment, ancillary services, ~~inpatient~~ drugs **ADMINISTERED DURING AN INPATIENT STAY**, meals and special diets, use of operating room and ~~related facilities,~~ use of intensive care and cardiac units ~~and related services.~~

~~*Licensed insurer* – An individual, corporation, association, partnership, reciprocal exchange, inter-insurer, Lloyds insurer and other legal entity engaged in the business of insurance; fraternal benefit societies as defined in the Fraternal Benefits Societies Code (40 P.S. §§ 1142.101—1142.701), and PPOs as defined in Section 630 of the act (40 P.S. §764a).~~

Managed care plan or plan –

(i) A health care plan that ~~uses a gatekeeper to~~ **DOES EACH OF THE FOLLOWING:**

IF NO SPECIFIC EXCLUSION EXISTS, THE APPEAL OF A DENIAL OF A PHYSICIAN'S REQUEST FOR AN EXCEPTION TO THE FORMULARY BASED ON MEDICAL NECESSITY AND APPROPRIATENESS, SHALL BE CONSIDERED TO BE A GRIEVANCE.

(E) A PLAN SHALL PROVIDE AT LEAST 30 DAYS NOTICE OF FORMULARY CHANGES TO HEALTH CARE PROVIDERS, EXCEPT WHEN THE CHANGE IS DUE TO APPROVAL OR WITHDRAWAL OF APPROVAL OF THE FOOD AND DRUG ADMINISTRATION OF A DRUG.

§9.674. Quality assurance standards.

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

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

(1) The plan shall maintain a written description of its quality assurance program~~, 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~~ **OUTLINING ITS STRUCTURE AND CONTENT**.

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

(3) The activities of the plan's quality assurance program shall be overseen by

SHALL DO THE FOLLOWING:

(1) INCLUDE IN ITS QUALITY ASSURANCE PLAN REGULARLY UPDATED STANDARDS FOR THE FOLLOWING:

(I) HEALTH PROMOTION.

(II) EARLY DETECTION AND PREVENTION OF DISEASE.

(III) INJURY PREVENTION FOR ALL AGES.

(IV) SYSTEMS TO IDENTIFY SPECIAL CHRONIC AND ACUTE CARE NEEDS AT THE EARLIEST POSSIBLE TIME.

(V) ACCESS TO ROUTINE, URGENT, AND EMERGENT APPOINTMENTS THAT SHALL BE APPROVED BY THE PLAN'S QUALITY ASSURANCE COMMITTEE. THE PLAN SHALL CONDUCT ANNUAL STUDIES OF ACCESS AND AVAILABILITY, THE RESULTS OF WHICH SHALL BE INCORPORATED INTO THE REPORT REFERENCED IN SUBSECTION (B)(10).

(2) NOTIFY HEALTH CARE PROVIDERS AND ENROLLEES OF THESE STANDARDS.

(3) INVOLVE HEALTH CARE PROVIDERS AND ENROLLEES IN THE UPDATING OF ITS QUALITY ASSURANCE PLAN.

§9.675. **Delegation of medical management.**

(a) A plan may contract with an entity for the performance of medical management relating to the delivery of health care services to enrollees. **THE PLAN SHALL BE RESPONSIBLE FOR ASSURING THAT THE MEDICAL MANAGEMENT CONTRACT MEETS THE REQUIREMENTS OF ALL APPLICABLE LAWS.** The plan

shall submit the medical management contract to the Department for review and approval ~~prior to implementation.~~ **THE DEPARTMENT WILL REVIEW A MEDICAL MANAGEMENT CONTRACT WITHIN 45 DAYS OF RECEIPT OF THE CONTRACT. IF THE DEPARTMENT DOES NOT APPROVE OR DISAPPROVE A CONTRACT WITHIN 45 DAYS OF RECEIPT, THE PLAN MAY USE THE CONTRACT AND IT SHALL BE PRESUMED TO MEET THE REQUIREMENTS OF ALL APPLICABLE LAWS. IF, AT ANY TIME, THE DEPARTMENT FINDS THAT A CONTRACT IS IN VIOLATION OF LAW, THE PLAN SHALL CORRECT THE VIOLATION. REIMBURSEMENT INFORMATION SUBMITTED TO THE DEPARTMENT UNDER THIS PARAGRAPH MAY NOT BE DISCLOSED OR PRODUCED FOR INSPECTION OR COPYING TO A PERSON OTHER THAN THE SECRETARY OR THE SECRETARY'S REPRESENTATIVES WITHOUT THE CONSENT OF THE PLAN WHICH PROVIDED THE INFORMATION, UNLESS OTHERWISE ORDERED BY A COURT.**

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

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

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

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

(d) Acceptable plan oversight shall include:

(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~~ **PROBABLE** ~~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~~ **LOSS FROM THE NETWORK OF ANY GENERAL ACUTE CARE HOSPITAL AND ANY PRIMARY CARE PROVIDER, WHETHER AN INDIVIDUAL PRACTICE OR A GROUP PRACTICE, WITH 2000 OR MORE ASSIGNED ENROLLEES.**

~~(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.~~

(D) EXCEPT AS OTHERWISE AUTHORIZED IN THIS SECTION, A PLAN SHALL PROVIDE FOR AT LEAST 90% OF ITS ENROLLEES IN EACH COUNTY IN ITS SERVICE AREA, ACCESS TO COVERED SERVICES THAT ARE WITHIN 20 MILES OR 30 MINUTES TRAVEL FROM AN ENROLLEE'S RESIDENCE OR WORK IN A COUNTY DESIGNATED AS A METROPOLITAN STATISTICAL AREA (MSA) BY THE FEDERAL CENSUS BUREAU, AND WITHIN 45 MILES OR 60 MINUTES TRAVEL FROM AN ENROLLEE'S RESIDENCE OR WORK IN ANY OTHER COUNTY.

(E) A PLAN SHALL AT ALL TIMES ASSURE ENROLLEE ACCESS TO

§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.~~ **A LIST BY SPECIALTY OF THE NAME, ADDRESS AND TELEPHONE NUMBER OF PARTICIPATING HEALTH CARE PROVIDERS TO WHICH AN ENROLLEE MAY HAVE ACCESS EITHER DIRECTLY OR THROUGH A REFERRAL. THE LIST MAY BE A SEPARATE DOCUMENT, WHICH MAY BE A REGIONAL OR COUNTY DIRECTORY, AND SHALL BE UPDATED AT LEAST ANNUALLY. THE PLAN SHALL SATISFY THE FOLLOWING IN PROVIDING THE LIST:**

(1) IF IT PROVIDES A REGIONAL OR COUNTY DIRECTORY, THE PLAN SHALL MAKE ENROLLEES AWARE THAT OTHER REGIONAL DIRECTORIES OR A FULL DIRECTORY ARE AVAILABLE UPON REQUEST.

(2) IF IT PROVIDES A LIST OF PARTICIPATING PROVIDERS FOR ONLY A SPECIFIC TYPE OF PROVIDER OR SERVICE, THE PLAN SHALL INCLUDE IN THE LIST ALL PARTICIPATING PROVIDERS AUTHORIZED TO PROVIDE THOSE SERVICES. INFORMATION SHALL BE PROVIDED AS REQUIRED UNDER 31 PA. CODE §154.16 (RELATING TO INFORMATION FOR ENROLLEES).

(b) A plan shall include a clear disclaimer in the provider directories it provides to enrollees that the plan cannot guarantee continued access during the term of the enrollee's enrollment to a particular health care provider, and that if a participating health care provider used by the enrollee ceases participation, the plan will provide access to ~~alternative~~ **OTHER** providers with equivalent training and experience.

PLAN'S POSITION, OR REPRESENT THE PLAN OR PLAN STAFF.

(K) THE COMMITTEE MAY QUESTION THE ENROLLEE AND THE ENROLLEE'S REPRESENTATIVE, THE HEALTH CARE PROVIDER IF THE PROVIDER FILED THE GRIEVANCE WITH ENROLLEE CONSENT, AND PLAN STAFF REPRESENTING THE PLAN'S POSITION.

(L) THE COMMITTEE SHALL BASE ITS DECISION SOLELY UPON THE MATERIALS AND TESTIMONY PRESENTED AT THE REVIEW. THE COMMITTEE SHALL NOT BASE ITS DECISION UPON ANY DOCUMENT OBTAINED ON BEHALF OF THE PLAN WHICH SETS OUT MEDICAL POLICIES, STANDARDS OR OPINIONS OR SPECIFIES OPINIONS SUPPORTING THE DECISION OF THE PLAN UNLESS THE PLAN HAS MADE AVAILABLE FOR QUESTIONING BY THE REVIEW COMMITTEE OR THE ENROLLEE, IN PERSON OR BY TELEPHONE, AN INDIVIDUAL, OF THE PLAN'S CHOICE, WHO IS FAMILIAR WITH THE POLICIES, STANDARDS OR OPINIONS SET OUT IN THE DOCUMENT.

~~(iii)~~ **(IV)**The ~~deliberation~~ **PROCEEDINGS** of the second level review committee, including the enrollee's comments **AND THE COMMENTS OF THE ENROLLEE'S REPRESENTATIVES AND THE HEALTH CARE PROVIDER IF**

health care provider **WHO FILED THE GRIEVANCE WITH ENROLLEE CONSENT**, upon written request, a copy of the report of the licensed physician or approved licensed psychologist at least 7 days prior to the review date.

(IV) THE PLAN SHALL INCLUDE IN THE REPORT IN SUBPARAGRAPHS (II) AND (III) THE CREDENTIALS OF THE LICENSED PHYSICIAN OR APPROVED LICENSED PSYCHOLOGIST REVIEWING THE CASE. IF THE LICENSED PHYSICIAN OR APPROVED LICENSED PSYCHOLOGIST IS INCLUDED IN THE REVIEW IN SUBPARAGRAPH (II), A COPY OF THE CREDENTIALS OF THE PHYSICIAN OR APPROVED LICENSED PSYCHOLOGIST SHALL BE PROVIDED TO THE ENROLLEE, THE ENROLLEE'S REPRESENTATIVE AND TO THE HEALTH CARE PROVIDER, IF THE HEALTH CARE PROVIDER FILED THE GRIEVANCE.

(V) FOR PURPOSES OF THIS SECTION, IF A SPECIALIST WHO IS A PHYSICIAN OR PSYCHOLOGIST IS REQUESTING THE HEALTH CARE SERVICE IN DISPUTE, THE REVIEWING PHYSICIAN OR PSYCHOLOGIST MUST BE A SPECIALIST IN THE SAME OR SIMILAR SPECIALTY.

~~§9.703.~~ **§9.706. Health care provider initiated grievances.**

(A) A HEALTH CARE PROVIDER MAY, WITH THE WRITTEN CONSENT OF AN ENROLLEE THAT MEETS THE REQUIREMENTS OF SUBSECTION (G), FILE A WRITTEN GRIEVANCE WITH A PLAN.

(B) A HEALTH CARE PROVIDER MAY OBTAIN WRITTEN CONSENT FROM AN ENROLLEE OR THE ENROLLEE'S LEGAL REPRESENTATIVE TO

~~§9.712.~~ §9.721. **Applicability.**

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

§9.722. Plan and health care provider contracts.

(a) A plan shall submit the standard form of each type of health care provider contract, **INCLUDING ANY DOCUMENT INCORPORATED BY REFERENCE INTO THAT CONTRACT,** to the Department for review and approval ~~prior to~~ ~~implementation~~. **THE PLAN SHALL BE RESPONSIBLE FOR ASSURING THAT THE PROVIDER CONTRACT MEETS THE REQUIREMENTS OF ALL APPLICABLE LAWS. THE DEPARTMENT WILL REVIEW A PROVIDER CONTRACT WITHIN 45 DAYS OF RECIEPT OF THE CONTRACT. IF THE DEPARTMENT DOES NOT APPROVE OR DISAPPROVE THE CONTRACT WITHIN 45 DAYS OF RECIEPT, THE PLAN MAY USE THE CONTRACT AND IT SHALL BE PRESUMED TO MEET THE REQUIREMENTS OF ALL APPLICABLE LAWS. IF, AT ANY TIME, THE DEPARTMENT FINDS THAT A CONTRACT IS IN VIOLATION OF LAW, THE PLAN SHALL CORRECT THE VIOLATION.**

(b) The plan shall submit any **MATERIAL** change or amendment to a **STANDARD** health care provider contract, **INCLUDING A MATERIAL CHANGE OR AMENDMENT TO ANY DOCUMENT INCORPORATED BY REFERENCE INTO THE CONTRACT,** to the Department 10 days ~~prior to~~ **BEFORE** implementation of the change or amendment **EXCEPT FOR CHANGES REQUIRED BY LAW OR REGULATION.**

(A) ~~This subchapter~~ **SECTIONS 9.742 THROUGH 9.748 OF THIS SUBCHAPTER** ~~sets~~ **SET** standards for the certification of CREs and the maintenance of that certification.

(B) SECTIONS 9.749 THROUGH 9.751 SET OPERATIONAL STANDARDS FOR ENTITIES PERFORMING UTILIZATION REVIEW.

CERTIFICATION

§9.742. CREs.

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

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

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

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

(a) A CRE seeking certification shall submit ~~two~~ **2** copies of the Department's application to the Department's Bureau of Managed Care.

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

ROBERT S. ZIMMERMAN, JR., MPH
SECRETARY OF HEALTH

March 23, 2001

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, PA 17101

Dear Mr. Nyce:

Enclosed is a copy of revisions to the tolled final form regulations for review by the Independent Regulatory Review Commission (Commission) pursuant to the Regulatory Review Act (Act) (71 P.S. §§745.1- 745.15). Section 5.1(g)(1) of the Act provides that an agency may, unless the Commission objects, toll the time for the Standing Committees' or the Commission's review of final-form regulations in order to allow the agency time to consider revisions to the final-form regulations recommended by the Committees or the Commission. If the agency chooses to make revisions, the agency must submit those revisions within 30 days of the date of tolling or notify the Committees and the Commission that it will not submit revisions, or the final-form regulation will be deemed withdrawn.

The Department tolled the regulations on Tuesday, March 20, 2001, during the review period of the Standing Committees, in order to consider revisions recommended by those committees. The Commission did not object to tolling. The Department is now submitting revisions to the Committees and to IRRC for their review. As we requested, we are only submitting the pages of the preamble and regulations which contain revisions. We have also provided you with a highlighted version to assist you in your review.

Section 5.1(g)(3) provides that the Committees shall have the remainder of their 20 day review period or 10 days from the date of receipt of the revised final-form regulations, whichever is longer. Section 5.1(g)(3) also provides that the Commission shall have 10 days after the expiration of the Committee review period or until its next regularly scheduled meeting, whichever is longer, to review the final-form regulation with revisions. If the Committees or the Commission fail to disapprove the final-form

regulations with revisions during their respective review periods, the regulations are deemed approved.

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please do not hesitate to contact Deborah Griffiths, Director, Office of Legislative Affairs, at (717) 783-3985.

Sincerely,

Robert S. Zimmerman, Jr.
Secretary of Health

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	10-160
SUBJECT:	Managed Care Organizations
AGENCY:	Department of Health

TYPE OF REGULATION

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

X Delivery of Tolled Regulation
X a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
3/23/01	Lynd Hoverstuhl	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
3/23/01	Mattie McKinney	
3/23/01	Kristi Kreiser	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
3/23/01	Carole A. Heikel	
3/23/01	Sheila J. Hoffman	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU