HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

January 18, 2000

Ms. Stacy Mitchell
Director, Bureau of Managed Care
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108-0090

Dear Ms. Mitchell:

The Hospital & Healthsystem Association of Pennsylvania (HAP), on behalf of its members—more than 225 acute and specialty hospitals and health systems—and the patients they serve, appreciates the opportunity to comment on the Department of Health's proposed regulations to implement the Quality Health Care Accountability and Protection provisions of Act 68, as well as to update HMO regulations.

Hospitals and health systems believe that Act 68 is an important first step to providing managed care accountability. Effective implementation of Act 68 can benefit patients by fostering greater coordination and cooperation among health plans and health care providers. We support the establishment of regulations that will provide managed care accountability and assure appropriate health insurance practices. We believe this is vitally important to Pennsylvania hospitals and health systems, as they strive to deliver appropriate and necessary health care to patients and serve community health needs.

In reviewing the proposed regulations, we want to commend the Department for including the following requirements in the proposed regulations:

- Establishing plan reporting requirements that will help ensure effective oversight as well as provide the public with data on plan performance;
- Requiring that a health plan's definition of medical necessity be the same across all relevant documents (e.g., marketing literature, subscriber handbooks, provider contracts, etc.) to ensure consistent and uniform decision-making related to health care services, particularly concerning coverage and exclusions that are dependent upon evidence of medical necessity; and
- Reinforcing that managed care plans can establish informal dispute resolution mechanisms with health care providers to resolve routine procedural issues and service denials without the need to involve the enrollee.

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However, we have significant concerns about the following provisions:

- **Language in the summary of the proposed rulemaking in the area of emergency services (9.672) and health care providers (9.681), which misinterprets the regulations** - The regulations state that enrollees are to receive the same benefit level for either emergency services provided by non-participating providers or services for which there are no participating health care providers in the plan's network capable of performing the needed services. The language in the summary of the proposed rulemaking states that emergency services will be at the "same rate" and that services for which there are no participating health care providers in the network will be at the "same terms or conditions." These interpretations are in conflict with the regulation's intent to protect the enrollee by assuring that services in these two cases are provided at the same *benefit level* to the enrollee. In both cases, the summary could be interpreted to establish "default" payment rates for non-participating providers. Not only is this interpretation in error, it is also beyond the statutory authority of the Department to dictate provider payments. Further, any attempt by the Department to establish payment standards would interfere in the contracting process between health care plans and health care providers, thus, removing any incentive to negotiate fair payment rates.
- **The lack of on-going operational standards for utilization management** - Licensed insurers, managed care plans, and certified utilization review entities are required under Act 68 to comply with utilization management operational standards. HAP does not believe that the proposed regulations provide adequate standards for on-going utilization review processes. Just as the Department outlines on-going quality assurance standards, it should do so for utilization management as well. HAP views the standardization of utilization management processes as a major component of Act 68 and believes that establishing a section for on-going operational utilization management standards is a critical part of assuring managed care accountability.
- **The ability of providers to advocate for their patients** - Act 68 created the ability for health care providers to advocate for their patients' health care needs. The regulations should prevent health plans from establishing inappropriate barriers for providers seeking to advocate for patient care. Health care providers should explicitly be permitted to obtain written consent at the time of treatment in order to appropriately and effectively advocate for their patients. The regulations also should clearly state what is required in the consent so that providers may create their own forms.

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- **The lack of consistency between Department of Health and Insurance Department regulations regarding emergency services, continuity of care, and direct access to obstetric and gynecologic care** - While HAP recognizes that each Department has different regulatory authority under Act 68, it is essential that the requirements for emergency services, continuity of care, and direct access to obstetric and gynecologic care be consistent. This will ensure more uniformity in interpretation by health plans, providers, and enrollees, as well as improved oversight of health plans by the regulating agencies. HAP urges that the Department of Health proposed regulations be modified to be consistent with the Insurance Department's regulations in each of these areas.
- **The need to ensure that there is effective monitoring, validation, and enforcement of managed care plan practices** - Another critical piece of Act 68 is the establishment of enforcement by both the Department of Health and the Insurance Department. The regulations need to clearly articulate how the Department of Health will ensure that there is effective on-going monitoring of plan practices; validation of accreditation when used in lieu of Department inspections; and enforcement of managed care plan accountability.
- **The need to assure that applicability of each section of the regulations is consistent with state statutory requirements** - In the Department's ambitious effort to streamline and consolidate HMO and managed care regulations, extreme care must be taken to ensure that the applicability of regulations is consistent with statutory authority. HAP has identified three areas in the regulations where the applicability is not consistent with state statute. These include: 1) the section dealing with investigations which solely identifies HMOs, even though Act 68 granted the Department the ability to enforce compliance for other managed care plans; 2) the section on complaints and grievances which identifies authority under the PPO Act, but only includes "gatekeeper" PPOs; and 3) the section on health care provider contracts in which the Department inappropriately extends HMO hold-harmless requirements to other types of managed care plans. Further, it is unclear in these regulations, what happens to existing regulations for PPO entities that are not "gatekeeper" PPOs, but are otherwise subject to the 1986 amendments (P.L. 226, No. 64) to the Insurance Company Law of 1921. It appears that non-gatekeeper or "passive" PPOs no longer have any regulations. Finally, while HAP commends the Department for recognizing that plans and providers can adopt informal dispute resolution mechanisms, the provision doing so is in the wrong section of the regulation. The informal dispute resolution mechanism is in § 9.711 on alternative provider dispute resolution, which in Act 68 was solely related to external grievance.

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In addition, we have attached detailed comments that further describe HAP's above concerns, as well as other issues we believe must be addressed to assure Pennsylvanians that licensed insurers and managed care plans are accountable under the provisions of the state's HMO Act and Act 68. The detailed comments relate to areas that we believe are not sufficiently clear, not addressed appropriately, or need to be strengthened to ensure enrollee protections. Comments are provided for each subchapter of the proposed regulations.

Again, I appreciate the opportunity to comment on the Department's proposed regulations. HAP is committed to improving the accountability to patients receiving care in hospitals and health systems across the commonwealth. We strongly encourage the Department of Health to establish regulations that require health insurers and managed care plans to demonstrate their accountability and effective compliance with the HMO Act and Act 68.

We look forward to working with the Department during the promulgation of these regulations. Please feel free to contact me at (717) 561-5344, if you need further clarification on our comments.

Sincerely,

Paula A. Bussard

PAULA A. BUSSARD
Senior Vice President
Policy and Regulatory Services

PAB/mns

Attachment

c: Robert S. Zimmerman, Jr., Secretary of Health
Richard Lee, Deputy Secretary for Quality Assurance, DOH
John R. McGinley, Jr., Chairman, IRRC
Melia Belonus, Senior Policy Analyst, Governor's Policy Office
Howard A. Burde, Esq., Deputy General Counsel, Office of General Counsel
Diane Koken, Insurance Commissioner
Harold F. Mowery, Majority Chairman, Senate Health & Welfare Committee

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c's: Vincent J. Hughes, Minority Chairman, Senate Health & Welfare Committee
Dennis M. O'Brien, Majority Chairman, House Health & Human Services Committee
Frank L. Oliver, Minority Chairman, House Health & Human Services Committee

The Hospital and Healthsystem Association of Pennsylvania Comments on the Department of Health Managed Care Organization Regulations

In reviewing the Department of Health's proposed regulations, The Hospital & Healthsystem Association of Pennsylvania (HAP) has identified several areas where we believe additional clarification or changes should be made. HAP believes that these changes will assure Pennsylvanians that licensed insurers and managed care plans are accountable under the provisions of the state's HMO Act and Act 68—the Quality Health Care Accountability and Protection Act.

Subchapter F. General

§ 9.602 Definitions

Most of the definitions are derived from either the HMO Act or Act 68. However, there are several definitions that the Department of Health has developed that we believe are problematic, including:

❶ Emergency services – The definition of emergency services must be made clear so that consumers trust that emergency care is there when they perceive a need, and that providers receive appropriate reimbursement. *HAP believes that this definition must be the same as the Insurance Department's definition to ensure consistency as to what constitutes an emergency, and subsequently, what costs will be construed by insurers as reasonably necessary but to also allow for greater clarification and understanding by enrollees and providers.*

❷ Inpatient services - This is a new definition in which the department has included care provided in skilled nursing facilities. Skilled nursing services are entirely different from inpatient services and should be defined separately. *Therefore, HAP strongly recommends that the Department delete reference to skilled nursing services in the definition of inpatient services.*

❸ *HAP also recommends that the regulations more broadly define PPOs, both "gatekeeper" and "passive" PPOs. It is unclear in these regulations, what happens to existing regulations for PPO entities that are not "gatekeeper" PPOs, but are otherwise subject to the 1986 amendments (P.L. 226, No. 64) to the Insurance Company Law of 1921. It appears that non-gatekeeper or "passive" PPOs no longer have any regulations.*

§ 9.603 Technical Advisories

The regulations state that the department has the authority to issue technical advisories to assist plans in complying with the HMO Act, Act 68, and other regulations. HAP contends that these technical advisories are not regulations. Also, it is unclear whether the public protections afforded under Pennsylvania's regulatory review act would be provided, particularly the opportunity for public review and comment. *Therefore, HAP recommends that this section be deleted.*

§ 9.604 Plan Reporting Requirements

These reporting requirements are essential for ensuring public accountability of managed care plan practices. *However, HAP would recommend that the department establish requirements for the reporting of utilization review timeliness, how the plan tests for reviewer reliability in making quality of care decisions, and a summary of the content of grievances and complaints (e.g., how many were brought by consumers versus providers, how many grievances and complaints were resolved at initial and subsequent levels, etc.).* HAP believes these additional reporting requirements not only will enhance the department's ability to oversee managed care quality but also will provide important information for consumer decision-making.

§ 9.605 and § 9.606 Investigation/Penalties and Sanctions

❶ HAP believes that these requirements are essential to ensure appropriate oversight by the Department of Health of managed care plan practices. *In addition, HAP recommends that §9.605(a) be modified to include provider complaints relating to quality of care or service as well.*

❷ §9.605 provides the department the authority to conduct investigations. Since the subchapter is applicable to managed care plans, (b), (c), (d), and (e) should not be limited solely to HMOs. Further, in (b) the department should not limit its onsite investigation only to IDS subcontractors, but rather should include the right to investigate all subcontractors, whether they assume risk or not. *Therefore, HAP recommends that this subsection be modified to reflect the department's broader investigatory responsibilities under Act 68 and (b) should be modified to allow the department to investigate any subcontractor.*

Subchapter G. HMOs

The requirements in the section regarding the application for certificate of authority update existing Department of Health standards. *However, HAP believes the department should incorporate a requirement in this section that HMOs are required to notify the Department of Health of any significant change in its operations or structure from that reported in the application for a certificate of authority.*

§ 9.634 Location of HMO activities, staff and materials

HAP commends the Department for requiring HMO medical directors to be licensed in Pennsylvania. *HAP also would recommend that the HMO quality assurance/ improvement committee shall only include Pennsylvania licensed health care providers.*

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

While the operational standards generally update existing HMO requirements, HAP believes that the inclusion of skilled nursing care in the definition of an inpatient service creates a problem. Since skilled nursing care is included in the definition of inpatient services, should it be interpreted that skilled nursing care is now to be construed as a basic health service for all HMO enrollees? Further, skilled nursing care is **not, and should not be considered,** a substitute for inpatient acute care or rehabilitation care. *Therefore, HAP again recommends that skilled nursing care should be deleted from the definition of inpatient service.*

§9.653 Use of co-payments and co-insurance in HMOs

HAP feels this section is vague. HMO co-payment requirements can be used to establish a "gate" by requiring significant co-payments for out-of-network care (such as a 50/50 co-payment arrangement). It is imperative that these arrangements are looked at carefully for their impact on access to care and that the regulations reflect that the department will be doing so.

§9.655 HMO external quality assurance assessment

While it is applaudable that the department has established standards for external quality assessment, HAP believes that the regulations should clearly provide linkage to the Department's enforcement and sanction authority. HAP also does not believe it is appropriate to extend the initial external quality review of the HMO, by the department from 12 months to 18 months.

Subchapter H. Availability and Access

§ 9.672 Emergency Services

As drafted, these regulations are different than those included in the Insurance Department regulations. The requirements must be consistent between both departments' regulations, not only to ensure more uniformity in the interpretation as to what constitutes an emergency and subsequently what costs will be construed as reasonably necessary, but to also allow for greater clarification and understanding by enrollees and providers.

HAP strongly recommends that the Department of Health regulations be modified to reflect recognition that emergency services also include the evaluation, stabilization, and treatment of the individual meeting the prudent layperson definition of emergency service. Therefore, HAP proposes the following language be added to this section:

> Plans are required to pay all reasonably necessary costs for patients meeting the prudent layperson definition of emergency services, to include: emergency transportation, services reasonably necessary to screen the patient, services reasonably necessary to diagnose, stabilize and treat the patient.

HAP would also like to point out that the regulations state at § 9.672(f) that the benefit for emergency care provided by a non-participating provider be at the same benefit level as that provided by a participating health care provider. However, on page 6414 of the summary of the proposed rulemaking, it states that the plan pay for emergency services provided by a non-participating provider at "the same rate." *HAP contends that the statement in the summary is incorrect and reflects an inaccurate interpretation of the regulation.*

It is the benefit level to the enrollee that must be the same, not the provider payment rate. The regulation is designed to protect consumers from additional out-of-pocket expenses, not to establish payment rates for plans for non-participating providers. Non-participating providers are entitled to bill managed care plans for their services, and the Department of Health does not have the statutory authority to establish a "default" payment rate for emergency services. Non-participating providers are entitled to fair and reasonable payments and billing charges to the plan as appropriate.

Further, the statement in the summary presumes that only a single "payment rate" exists. Every participating hospital and emergency physician may negotiate a different

payment rate with a health plan. *Thus, even if the department had the statutory authority to implement such a requirement, it is simply unworkable.*

Therefore, it is imperative that the language in the summary of the proposed rulemaking be corrected to reflect the appropriate interpretation of the regulation.

§ 9.675 Delegation of Medical Management

HAP supports the inclusion of this section to protect both managed care enrollees, as well as health care providers. *However, HAP would suggest that the Department of Health require plans to disclose in communications to enrollees and health care providers when medical management decision-making is delegated. This is important to ensure that enrollees and/or providers know whom and how they should contact when questioning or disputing a decision about medical necessity or appropriateness of care—the subcontractor or the plan.*

§ 9.677 Medical Necessity

❶ HAP believes that this section is essential as consumers and health care providers have experienced the use of differing definitions of medical necessity in various contracts and other documents used by a health plan. This has resulted in health plans not applying a uniform definition of medical necessity, thus creating barriers to care and/or denying appropriate reimbursement.

❷ *HAP also would encourage the department to include a provision stating that it will periodically evaluate the process by which a plan makes decisions on medical necessity (e.g., testing reliability) to ensure that different clinicians would likely make the same decision given the same information.*

§ 9.679 Access requirements

❶ The access standard implies use of a motor vehicle to access care. *Therefore, the regulations should clearly state this, and also state that the standard will be modified in areas where there is no accessible or affordable public transportation.*

❷ Subsection (e) states that access shall be ensured based on specific distance standards "or based on the availability of health care providers." *HAP believes that this statement is too broad and vague and should be clarified in the regulation.*

§ 9.681 Health Care Providers

❶ HAP, again, would like to point out that the interpretation found in the summary of the proposed rulemaking on subsection (c) is similar to the section regarding emergency services, and again, could be construed as establishing a "default" payment rate for services provided by non-participating providers. The intent of the regulation is to protect the enrollee from additional out-of-pocket expenses. In the summary of the proposed rulemaking, this section is interpreted to be at the same "terms and conditions," an inappropriate interpretation that clearly exceeds the statutory authority of the department. Further, imposing this provision would remove any incentive for a plan to negotiate with health care providers needed to assure access to appropriate and necessary services within the network and would impose contract terms, including payment rates, on providers who in no way have agreed to such terms and conditions. *Therefore, it is imperative that the language in the summary of the proposed rulemaking be modified to accurately reflect the interpretation of the regulation.*

❷ Further, subsection (c) states that a health plan "that has no participating health care provider available . . . shall arrange for and provide coverage for services by a non-participating health care provider." *As written, this is confusing since it is by contract or agreement—including a limited participation agreement (i.e., one limited to payments for certain services or circumstances)—through which plans "arrange for" available services. Subsection (v) should instead state:*

> If no participating provider is available, the health plan shall cover benefits and services obtained by a beneficiary from a non-participating provider without financial penalty to the enrollee.

❸ *HAP also recommends that the requirement related to written procedures be modified to reflect the definition of emergency services, specifically recognizing serious injury, impairment or dysfunction.*

§ 9.682 Direct Access to Obstetric and Gynecologic Care

The regulations as drafted allow plans to establish prior authorization requirements for services not considered to be "routine."

HAP believes that it is inappropriate for the Department of Health to distinguish between routine and non-routine obstetric and gynecologic care, as Act 68 did not make any differentiation.

Further, the department is proposing to allow managed care plans to define "routine." This will result in differing definitions across managed care plans and thus, create differing access to these services by women.

The issue of direct access to obstetric and gynecologic care also has been approached differently by the Department of Health as compared to the Insurance Department. At a minimum, the provisions for both departments must be the same; otherwise there will be inconsistent application and enforcement of this consumer right. HAP supports the provisions incorporated in the Insurance Department regulations and believes that they will result in more consistent application of this requirement. Therefore, HAP recommends that this section be amended as follows:

> Managed care plans shall permit enrollees direct access to obstetric and gynecological services for maternity and gynecological care, including medically necessary and appropriate follow-up care and referrals, for diagnostic testing related to maternity and gynecological care from participating health care providers without prior approval from a primary care provider. No time restrictions shall apply to the direct accessing of these services by enrollees.
>
> A managed care plan may require a provider of obstetrical or gynecological services to obtain prior authorization for selected services such as diagnostic testing or subspecialty care (e.g., reproductive endocrinology, oncologic gynecology and maternal and fetal medicine.

§ 9.683 Standing Referrals

The regulations omit reference to the requirement under Act 68 that the treatment plan be approved by the plan "in consultation with the primary care provider, the enrollee, and, as appropriate, the specialist. *HAP recommends that this requirement be included in this section.*

§ 9.684 Continuity of Care

HAP believes that the Department of Health and Insurance Department requirements for provisions related to continuity of care must ensure consistent application and enforcement of this consumer right, as well as to allow for greater clarification and understanding by enrollees and providers.

Subchapter I. Complaints and Grievances

§ 9.702 Complaints and grievances

HAP recommends that this section be clarified as to which entities this subchapter applies. The PPO Act does not distinguish between "gatekeeper" and "passive gatekeeper." As such, it is imperative that this clarification on applicability be made and specifically state whether PPOs will be required to maintain grievance systems under these regulations or under other existing Department of Health PPO regulations.

§ 9.703 Health care provider grievances

The implementation of this new requirement under Act 68 has been problematic. Several plans have not accepted written consents obtained by the provider at the time of treatment and instead are requiring the consent to be obtained at a date subsequent to the treatment. Several plans are requiring providers to use the plan's consent form, even after the provider has obtained written consent from the patient. Some plans are treating every provider dispute as a grievance needing the patient's written consent. These types of requirements create barriers for providers, who are seeking to advocate on behalf of the patient, which is the intent of Act 68. Further, the lack of clarity also creates situations where the patient is caught between the managed care plan and the health care provider, which Act 68 was explicitly drafted to prevent.

❶ *The regulations need to clearly ensure that providers are able to advocate on behalf of their patients and that unreasonable or inappropriate barriers are not put in the way by managed care plans. The regulations should clearly state written consent may be obtained at the time of treatment. Therefore, § 9.703 (b) must be modified to read:*

> (b) A health care provider is permitted to obtain consent at the time of treatment. A health care provider may not require an enrollee to sign a[n] document authorizing the health care provider to file a grievance as a condition of providing a health care service.

❷ *HAP agrees that once a health care provider files a grievance, the health care provider needs to see the grievance through the grievance process. Therefore, § 9.703 (c) should be modified to read:*

> (c) Once a health care provider files [assumes responsibility for filing] a grievance . . .

❸ *Additionally, subsection (d) states that providers may not bill enrollees once a grievance has been initiated by the health care provider until the grievance is completed. This subsection only applies to provider-initiated grievances. It is HAP's understanding that the provider may bill the patient if the grievance is initiated by enrollee or if the enrollee rescinds the consent for the provider to grieve. Further, it is HAP's understanding that the provider may bill the patient if neither party grieves. It is HAP's belief that any contrary interpretation would be beyond the statutory authority of the Department of Health.*

❹ *Finally, the regulations should also specify the types of information required to be included on a written consent form and allow for providers to develop their own consent forms consistent with the regulations. The Department of Health regulations specify the language that constitutes acceptable "hold-harmless" language for inclusion in provider contracts. In a similar vein, HAP recommends that the department consider modifying § 9.703 (f) and (g) to specify acceptable language for consent to file a grievance in § 9.703 as follows:*

> (f) Pennsylvania law permits an enrollee of a managed care plan or, with the enrollee's written consent, a health care provider, to request that the plan reconsider a decision made concerning the medical necessity and appropriateness of a health care service. This request is known as a grievance.
>
> (g) (1)The consent to file a grievance must identify the enrollee, the health care provider, and the managed care plan; a brief description of the service; and the date(s) of service.
>
> (g) (2)The consent to file a grievance shall clearly disclose to the enrollee in writing that the consent precludes the enrollee from filing a grievance on the same issue unless the enrollee, during the course of the grievance, rescinds in writing the previous written consent.
>
> (g) (3) The consent to file a grievance shall inform the enrollee of the right to rescind a consent at any time during the grievance process.

9.704 Internal complaint process

In this section, the date by which the decision must be rendered is suggested but not expressly stated. *Therefore, HAP recommends that subsection (c)(1)(iii) should clearly state that the "initial review committee" shall issue a decision within 30 days.*

§ 9.705 Appeal of a complaint decision

HAP believes that the time frame for the appeal of complaint decisions to the departments by consumers is too restrictive. HAP recommends that consumers should have additional time to file their complaints and would recommend that, at a minimum consumers should have 30 days.

§ 9.706 Enrollee and provider grievance system

❶ The letters used by most managed care plans are form letters and do not take into account the patient's individual medical or behavioral health situation. During the past year, HAP has provided the Department of Health with examples of denial letters that do not include the clinical rationale for the decision to deny. *HAP recommends that what is expected in the content of the denial letters be more clearly specified in the regulations. It is imperative that health care providers receive this information in order to change or improve health care delivery, or to clarify the information provided to the plan for determination.*

❷ Each individual patient has unique circumstances that may or may not be addressed through review criteria. *Therefore, HAP also believes that the regulations should state that utilization review criteria may be used as a tool in decision-making, but are not appropriate as the sole mechanism on which decisions are made.*

❸ Act 68 was designed to improve managed care accountability regarding decisions on medically appropriate treatment. It is problematic that plans approve services prospectively and/or concurrently, and then retrospectively deny those services. *To make the process truly accountable, plans should be required to abide by their prospective and/or concurrent decisions, unless the provider was derelict in providing information needed to make an appropriate decision. Failure to include this requirement also discourages providers and patients from exercising their due process rights to appeal decisions, because the plan may essentially change their decision at any time.*

❹ In this section, the date by which the decision must be rendered is suggested but not expressly stated. *Therefore, HAP recommends that subsection (c)(1)(iii) should clearly state that the "initial review committee" shall issue a decision within 30 days.*

❺ While HAP would agree that the physician or licensed psychologist need not personally attend on-site the second level review, their participation in the decision making should be via telephone or teleconference, and not be written. Allowing the latter does not foster two-way discussion during the review and also defeats the purpose of the act which states, "any initial review or second lever review conducted under this section shall include a licensed physician, or, where appropriate, an approved licensed psychologist, ..." *Therefore, HAP recommends that the regulation be modified to delete the use of written involvement and that the requirement that any such written report be prepared in advance of the review be deleted as well.*

❻ *Since health care providers can grieve on behalf of an enrollee, (c)(2)(ii)(A) must be modified as follows:*

> (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 or health care provider's attendance.

§ 9.707 External grievance process

❶ *For purposes of clarity, subsection (g) should state that the 3 business days to object apply when the CRE is assigned by the department or by the plan.*

❷ Act 68 is silent on what fees the prevailing party is to pay. *Therefore, HAP believes that it is beyond the scope of the Department of Health's statutory responsibilities to determine that attorney's fees are not included in the fees that are imposed on the nonprevailing party. This language must be deleted from subsection (l).*

❸ *Further, the regulations fail to indicate what occurs if the provider prevails on some, but not all, disputed issues. The regulations either should be modified to allow for proration in such circumstances or else "prevailing" must be defined more clearly.*

§ 9.708 Grievance reviews by CRE

It is unclear what is meant in subsection (e) by the definition of emergency in the enrollee's certificate of coverage. Act 68 defines emergency services and that should be the definition used by the external review entity.

§ 9.709 Expedited Review

Subsection (a) authorizes expedited review for disputes that jeopardize "the enrollee's life, health or ability to regain maximum function," but fails to identify the party responsible for making that determination. *HAP believes that the regulation needs to address this issue so that enrollee's immediate health needs are not unduly jeopardized by a health plan.*

§ 9.711 Alternative provider dispute resolution system

❶ *HAP recommended that the department clearly state that the regulations do not preclude informal dispute resolution processes that would encourage plans and providers to resolve any contractual disputes that may arise at the least adversarial basis. HAP commends the department on the inclusion of this provision.* ***However, it is not appropriate for this provision to be included in this section of the regulation.*** *The section in Act 68 on alternative dispute resolution was solely related to the external grievance process. Therefore, HAP recommends that the provision allowing an informal dispute resolution between providers and health plans be moved to § 9.702.*

❷ *Further, an informal dispute resolution mechanism is voluntary and involves a waiver of rights. Accordingly, there is no valid reason for the department to mandate that a decision reached in the informal dispute resolution mechanism be "final and binding."*

❸ *A new section on alternative dispute resolution to the external grievance process, including requirements/standards that needs to be developed. This new section should make clear that the alternative dispute resolution to the external grievance may not be utilized for grievances brought by an enrollee.*

❹ *HAP does not believe that denials based on procedural errors or administrative denials should require written consent by the enrollee for the provider to seek resolution of these issues. These are just the types of issues that should be handled through an informal dispute resolution mechanism and that reference should be included under*
§ 9.702.

❺ *Additionally, the regulations state that the alternative provider dispute resolution would include denials based on procedural errors and administrative denials involving the level or types of health care services provided. Act 68 intended the alternate dispute*

process to be agreed to by a provider and a plan through contract in lieu of an external grievance process. Therefore, an alternative process could include any issue to which providers are entitled to grieve and the regulations should be modified to clearly state this.

❺ *It is also unclear why the department included 9.711(b) in this section. Again, the alternative dispute resolution was envisioned under Act 68 to be in lieu of the external review and it is inappropriate to include § 9.711(b) in this section.*

Subchapter J. Health Care Provider Contracts

§ 9.722 Plan and health care provider contracts

❶ § 9.712 states that this "subchapter applies to provider contracts between managed care plans subject to Act 68 and health care providers." *HAP believes that in § 9.722, the department has inappropriately extended certain statutory requirements for HMOs to those managed care plans subject to Act 68, which are not HMOs. In particular, (e)(1), which is the traditional HMO hold-harmless language, is being extended to other managed care plans, absent statutory action that authorizes the department to do so. Therefore, the department needs to identify that § 9.722(e)(1)* ***only*** *applies to provider contracts with HMOs.*

❷ In addition, HAP acknowledges that the language used in § 9.722(e)(1)(iii) is the traditional hold-harmless language that evolved in state application from federal HMO law and regulation. It is HAP's understanding that this language is designed solely to protect enrollees from being billed by health care providers in the event of plan insolvency or a breach by a plan of the provider contract. *It is HAP's opinion that any other application of this regulatory language in a health care provider contract is inconsistent with the historical intent and interpretation of "hold-harmless" provisions.*

❸ *HAP recommends that the department should require that any changes to contract terms are mutually agreed to and resulting policy/procedure changes are communicated to providers at least 60 days in advance. This will enable providers to respond to contract changes on a more timely basis. Further, HAP believes that a provider contract should be voidable by the provider if the contract is not approved by the department of Health prior to its implementation. Therefore, HAP recommends that the following language be added to § 9.722 (e):*

(e)(8) Language requiring that any amendment to the contract must be mutually agreed to and confirmed in writing, except in the event of an amendment that is required by court order or by Federal or State Law.

(e)(9) Language requiring that the plan must give at least 60 days notice to an enrollee and provider prior to adding, modifying or withdrawing any policy or procedure implemented pursuant to the contract, except in the event that a policy or procedure that is required by court order or by Federal of State Law.

(e)(10)Language stating that a contract is voidable by the provider if its not approved by the Department of Health prior to the contract's implementation.

- Further, in § 9.721, the summary of proposed rulemaking discusses the Secretary's "authority to require re-negotiation of provider contracts when they require excessive payments." To be fair, and for reasons of protecting public health, the department's review rights and re-negotiation authority should equally encompass situations where rates appear to be inadequate and could jeopardize the quality of care. This is especially important since a small number of dominant health plans insure the vast proportion of lives covered under managed care arrangements in Pennsylvania. The department's general rulemaking authority is this area extends beyond its mandate under 40 P.S. § 764a(e) to ensure that risk assumption by a PPO will not lead to under-treatment. See 71 P.S. § 532(g). Under-reimbursement also is encompassed by provisions of 40 P.S. § 1558(a), which permits the Secretary to require re-negotiation of contracts that are inconsistent with purposes of the HMO Act. *§ 9.722 (f) should be amended to include:*

  (4) Include no reimbursement system that will lead to under-treatment or jeopardize the quality of care.

Subchapter K. Utilization Review Entities

§ 9.742 Certified utilization review entities

HAP recommends that a new section, titled Utilization Management Standards, *be added. Such a section should clearly articulate the on-going utilization management standards that apply to licensed insurers, managed care plans, or certified utilization review entities. All three types of entities are required to comply with the utilization management operational standards outlined in Act 68, but the department does not provide adequate interpretation of some of those standards or how it will validate or enforce compliance with those standards on an on-going basis.*

Additionally, the department's regulations outline on-going quality assurance standards for HMOs, and HAP believes that on-going standards should be articulated for utilization management. It is imperative that on-going utilization review standards for licensed insurers and managed care plans or utilization review entities be stated. HAP views the utilization management requirements as a major component of Act 68 and believes that such standards are a critical part of a managed care plan's overall responsibility in the area of quality assurance.

Therefore, the regulations should clearly specify the utilization management requirements consistent with the HMO Act and Act 68 that managed care plans, licensed insurers or certified utilization review entities are expected to adhere to, and how the department intends to validate adherence to and enforcement of these provisions. At a minimum, this new section should include: 1) utilization management structure; 2) clinical criteria for utilization management decisions; 3) qualified professionals; 4) timeliness of utilization management decisions; 5) and the other operational standards described in Act 68.

- **Utilization Management Structure**

HAP recommends that the department consider adding the following language with regard to utilization management structure. This would be consistent with the way the department has dealt with quality assurance standards.

The managed care plan's, licensed insurer's and CRE's utilization management structures and processes shall be clearly defined. The managed care plan, licensed insurer or CRE will have a written description of its utilization management program, including the program's structure and individuals' responsibility and accountability within that structure.

Responsibility for the conduct of the utilization management activities shall be assigned to appropriate individuals, and the managed care plan, licensed insurer or CRE shall ensure that mechanisms are in place whereby a health care provider is able to verify that an individual requesting information on behalf of that entity is a legitimate representative of the managed care plan, licensed insurer or CRE.

The utilization management plan shall be evaluated and approved annually by an appropriate committee(s) as outlined in the managed care plan, licensed insurer, or CRE utilization management program.

❷ Clinical Criteria for Utilization Management Decisions

HAP is aware that utilization management decisions that result in denial of payment are often made on the basis of utilization review criteria and that use of utilization review criteria often guide the determination of medical necessity. HAP believes that the department needs to make clear in regulations that utilization review criteria may be used as tools in decision-making, but that other factors which play into the issue of medical necessity must also be considered in those decisions. For instance, nationally developed utilization management criteria are often designed to be appropriate for the uncomplicated patient and for a very complete delivery system. They may not be appropriate for the patient with complications or for a delivery system that does not include sufficient alternatives to inpatient care for that particular patient. Therefore, HAP believes that the department's regulations should spell out that other factors should be considered when applying criteria to a given individual as these factors will often assist in making the determinations of what is medically necessary care.

The use and procedures for the application of utilization management criteria provide the basis for decision-making, and ultimately the determination of medical necessity. It is often the basis around which a denial for requested services is made. HAP believes the department has the authority to promulgate utilization management standards in the same manner that is has for quality assurance, credentialing and access requirements under the HMO Act and to strengthen the interpretation of the provisions included in Act 68.

Therefore, HAP recommends that it is imperative that the department consider including the following utilization management standards to address criteria for utilization management decision-making.

The managed care plan, licensed insurer or CRE shall use written criteria based on sound clinical evidence and specify procedures for applying those criteria in an appropriate manner.

The criteria for determining medical appropriateness shall be clearly documented and include procedures for applying criteria based on the needs of the individual patient, such as age, comorbidities, complications, progress of treatment, psychosocial situation and home environment as well as characteristics of the local delivery system that are available for that particular patient.

Participating providers actively engaged in the delivery of health care shall be involved in the development or selection of the criteria, and in the development and review of procedures for applying the criteria.

The utilization review criteria shall be reviewed at regular intervals and updated as necessary.

The licensed insurer, managed care plan or CRE shall state in writing how health care providers can obtain the utilization management criteria and make the criteria available upon request.

The licensed insurer, managed care plan or CRE shall evaluate the consistency with which the health care professionals involved in utilization management apply the criteria in decision making.

The managed care plan, licensed insurer or CRE must demonstrate that utilization management decisions are appropriate and that there is consistency in application of utilization management clinical criteria and procedures among the managed care plan's, licensed insurer's or CRE's designated physician and non-physician professional review staff.

- **Timeliness of Decision-Making and Communication of Utilization Management Decisions**

HAP believes that the issue regarding the communication of utilization management decision needs to be further delineated in the Department of Health regulations. Act 68 indicates that prospective, concurrent and retrospective utilization review decisions must be communicated within a certain time frame after the plan receives all supporting information reasonably necessary to make the decision. However, it is still unclear whether that decision should be verbally communicated first within the original time frames outlined in the act or whether the decision needs to be communicated in writing within the time frames outlined in the act. Ultimately, the act does indicate that all decisions must be communicated in writing. HAP would encourage the department to more explicitly spell out the time frames for decision-making and written communication of those decisions. Further, it is incumbent upon the department to ensure that managed care plans, licensed insurers and certified utilization review entities are adhering to those standards by requiring periodic reporting. The department should periodically review those reports, validate the information, and take appropriate action when managed care plans, licensed insurers or CREs fail to meet

decision-making and communication standards. HAP recommends the following language with respect to utilization management decision making and communication of those decisions.

The licensed insurer, managed care plan or CRE conducts utilization review based on the medical necessity and appropriateness of the health care service being requested, makes utilization management decisions in a timely manner and communicates its decisions in writing to enrollee and health care providers.

The licensed insurer, managed care plan or CRE shall notify the health care provider of additional facts or information required to complete the utilization review within forty-eight (48) hours of receipt of the request for service.

A prospective utilization review decision shall be communicated within two (2) business days of the receipt of all supporting information reasonably necessary to complete the review. The licensed insurer, managed care plan or CRE shall give enrollees and providers written or electronic confirmation of its decisions within two (2) business days of communicating its decision.

A concurrent utilization review decision shall be communicated within one (1) business day of the receipt of all supporting information reasonably necessary to complete the review. The licensed insurer, managed care plan or CRE shall give enrollees and providers written or electronic confirmation of its decisions within one (1) business day of communicating its decision.

A retrospective utilization review decision shall be communicated within thirty (30) days of the receipt of all supporting information reasonably necessary to complete the review. The licensed insurer, managed care plan or CRE shall give enrollees and providers written or electronic confirmation of its decision within five (5) days of communicating its decision.

The managed care plan, licensed insurer or CRE shall have systems and procedures in place, including sufficiently qualified physicians, non-physician staff and resources, to meet the time frame requirements for utilization management decision-making and communication of those decisions.

The department shall implement appropriate measures to ensure that managed care plans, licensed insurers or CREs are meeting the time frames required for utilization decision-making and communication of those decisions.

HAP also believes that the intent of Act 68 was to increase the managed care plans', licensed insurers' or certified utilization review entities' accountability for utilization review decision-making. As HAP stated previously, these entities should be required to abide by their prospective and/or concurrent utilization management decisions, unless the provider withheld information or did not provide the information to make an appropriate decision. Failure to include such a requirement puts providers and enrollees at risk for denial of services/care at any time. HAP recommends that the department consider language that states:

A managed care plan, licensed insurer, or CRE shall not retrospectively deny payment for a health care service if an authorized representative of that entity previously authorized provision of the service and the provider did not withhold any information reasonably necessary to grant prospective and/or concurrent authorization.

- **Qualified Professionals**

HAP recommends that the department reiterate the requirements for personnel conducting utilization review as specified in the act and that compensation to any person or entity conducting utilization review cannot contain incentives to approve or deny payment for the delivery of any health care service. The department should also again state that a utilization review that results in a denial of payment for a health care service must be conducted by a physician or psychologist within the scope of his/her practice and clinical expertise.

As articulated earlier in HAP's comments, the professional judgements and clinical rationale to support the denial determination are noticeably absent in denial letters sent to enrollees and providers. Again, HAP strongly urges the department to provide guidance as to what constitutes a clinical rationale, and to require plans to explain the clinical rationale in writing. The National Commission on Quality Assurance (NCQA), which accredits health plans, states that the managed care organization must provide the reason for the denial, including an easily understood summary of the utilization management criteria. NCQA also provides examples of appropriate reasons. NCQA also explicitly states that statements such as "The treatment is determined to be not medically necessary," " The treatment is not a covered benefit," or " The proposed

length of stay does not meet our utilization management criteria," are not acceptable reasons for the denial. It is important that the department provide such guidance. Otherwise, enrollees and providers will continue to receive form letters that simply indicate that the service was not determined to be medically necessary or appropriate.

Additionally, HAP requests that the department consider mandating that the name of the physician or psychologist who made the denial determination appears in the letter. In repeated examples of denial letters, the name of physician or psychologist who made the determination does not appear in the letter communicating the denial. It is therefore impossible for a provider or enrollee to definitively know that this same physician or psychologist is not involved in a subsequent review if the determination is appealed. Failure to identify the individual who made the determination is inconsistent with the intent of Act 68 to ensure accountability for utilization management decisions.

Finally, the department should develop mechanisms to ensure that plans, licensed insurers, and CREs are complying with these requirements. The department should impose appropriate sanctions under § 9.606, if these entities are not using physicians or psychologists to make denial determinations or failing to impart the clinical rationale for denial determinations in writing to providers and enrollees.

- **Other Operational Requirements**

HAP recommends that requirements around telephone access for utilization management, maintenance of adverse utilization management decisions for a period of three years and confidentiality requirements of medical records and other medical information used in utilization management decision-making be detailed in this section.

§ 9.747 Department review and approval of a certification request

HAP supports the "in-lieu" concept, however, the regulations should also incorporate a provision that ensures that the department has the ability to periodically validate the results of the accreditation process to ensure compliance with state law and regulation.

§ 9.748 Maintenance of Certification

The regulations state that the department may determine on-going compliance. *HAP recommends that the regulations regarding oversight be strengthened. This section should clearly demonstrate that the department will determine on-going compliance. Therefore, HAP recommends that (a) be modified to read as follows:*

Maintenance-... and maintaining its certification during the 3-year certification period, the Department [may] will do any of the following...

Subchapter L. Credentialing

HAP recommends that this section also include language that specifies how the department will monitor and validate compliance with standards of a nationally recognized accrediting body to ensure compliance with state law and regulation.

1/17/00

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FAX TRANSMISSION

27 page(s), including cover sheet

TO: Jim Smith, IRRC

FAX: 783-2664

FROM: Paula Bussard

DATE: January 18, 2000

SUBJECT: Comments on Act 68

MESSAGE:

See Attached.

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

January 18, 2000

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Ms. Stacy Mitchell
Director, Bureau of Managed Care
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108-0090

Dear Ms. Mitchell:

The Hospital & Healthsystem Association of Pennsylvania (HAP), on behalf of its members—more than 225 acute and specialty hospitals and health systems—and the patients they serve, appreciates the opportunity to comment on the Department of Health's proposed regulations to implement the Quality Health Care Accountability and Protection provisions of Act 68, as well as to update HMO regulations.

Hospitals and health systems believe that Act 68 is an important first step to providing managed care accountability. Effective implementation of Act 68 can benefit patients by fostering greater coordination and cooperation among health plans and health care providers. We support the establishment of regulations that will provide managed care accountability and assure appropriate health insurance practices. We believe this is vitally important to Pennsylvania hospitals and health systems, as they strive to deliver appropriate and necessary health care to patients and serve community health needs.

In reviewing the proposed regulations, we want to commend the Department for including the following requirements in the proposed regulations:

- Establishing plan reporting requirements that will help ensure effective oversight as well as provide the public with data on plan performance;
- Requiring that a health plan's definition of medical necessity be the same across all relevant documents (e.g., marketing literature, subscriber handbooks, provider contracts, etc.) to ensure consistent and uniform decision-making related to health care services, particularly concerning coverage and exclusions that are dependent upon evidence of medical necessity; and
- Reinforcing that managed care plans can establish informal dispute resolution mechanisms with health care providers to resolve routine procedural issues and service denials without the need to involve the enrollee.

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HAP

However, we have significant concerns about the following provisions:

- **Language in the summary of the proposed rulemaking in the area of emergency services (9.672) and health care providers (9.681), which misinterprets the regulations** - The regulations state that enrollees are to receive the same benefit level for either emergency services provided by non-participating providers or services for which there are no participating health care providers in the plan's network capable of performing the needed services. The language in the summary of the proposed rulemaking states that emergency services will be at the "same rate" and that services for which there are no participating health care providers in the network will be at the "same terms or conditions." These interpretations are in conflict with the regulation's intent to protect the enrollee by assuring that services in these two cases are provided at the same *benefit level* to the enrollee. In both cases, the summary could be interpreted to establish "default" payment rates for non-participating providers. Not only is this interpretation in error, it is also beyond the statutory authority of the Department to dictate provider payments. Further, any attempt by the Department to establish payment standards would interfere in the contracting process between health care plans and health care providers, thus, removing any incentive to negotiate fair payment rates.
- **The lack of on-going operational standards for utilization management** - Licensed insurers, managed care plans, and certified utilization review entities are required under Act 68 to comply with utilization management operational standards. HAP does not believe that the proposed regulations provide adequate standards for on-going utilization review processes. Just as the Department outlines on-going quality assurance standards, it should do so for utilization management as well. HAP views the standardization of utilization management processes as a major component of Act 68 and believes that establishing a section for on-going operational utilization management standards is a critical part of assuring managed care accountability.
- **The ability of providers to advocate for their patients** - Act 68 created the ability for health care providers to advocate for their patients' health care needs. The regulations should prevent health plans from establishing inappropriate barriers for providers seeking to advocate for patient care. Health care providers should explicitly be permitted to obtain written consent at the time of treatment in order to appropriately and effectively advocate for their patients. The regulations also should clearly state what is required in the consent so that providers may create their own forms.

- **The lack of consistency between Department of Health and Insurance Department regulations regarding emergency services, continuity of care, and direct access to obstetric and gynecologic care** - While HAP recognizes that each Department has different regulatory authority under Act 68, it is essential that the requirements for emergency services, continuity of care, and direct access to obstetric and gynecologic care be consistent. This will ensure more uniformity in interpretation by health plans, providers, and enrollees, as well as improved oversight of health plans by the regulating agencies. HAP urges that the Department of Health proposed regulations be modified to be consistent with the Insurance Department's regulations in each of these areas.
- **The need to ensure that there is effective monitoring, validation, and enforcement of managed care plan practices** - Another critical piece of Act 68 is the establishment of enforcement by both the Department of Health and the Insurance Department. The regulations need to clearly articulate how the Department of Health will ensure that there is effective on-going monitoring of plan practices; validation of accreditation when used in lieu of Department inspections; and enforcement of managed care plan accountability.
- **The need to assure that applicability of each section of the regulations is consistent with state statutory requirements** - In the Department's ambitious effort to streamline and consolidate HMO and managed care regulations, extreme care must be taken to ensure that the applicability of regulations is consistent with statutory authority. HAP has identified three areas in the regulations where the applicability is not consistent with state statute. These include: 1) the section dealing with investigations which solely identifies HMOs, even though Act 68 granted the Department the ability to enforce compliance for other managed care plans; 2) the section on complaints and grievances which identifies authority under the PPO Act, but only includes "gatekeeper" PPOs; and 3) the section on health care provider contracts in which the Department inappropriately extends HMO hold-harmless requirements to other types of managed care plans. Further, it is unclear in these regulations, what happens to existing regulations for PPO entities that are not "gatekeeper" PPOs, but are otherwise subject to the 1986 amendments (P.L. 226, No. 64) to the Insurance Company Law of 1921. It appears that non-gatekeeper or "passive" PPOs no longer have any regulations. Finally, while HAP commends the Department for recognizing that plans and providers can adopt informal dispute resolution mechanisms, the provision doing so is in the wrong section of the regulation. The informal dispute resolution mechanism is in § 9.711 on alternative provider dispute resolution, which in Act 68 was solely related to external grievance.

HAP

In addition, we have attached detailed comments that further describe HAP's above concerns, as well as other issues we believe must be addressed to assure Pennsylvanians that licensed insurers and managed care plans are accountable under the provisions of the state's HMO Act and Act 68. The detailed comments relate to areas that we believe are not sufficiently clear, not addressed appropriately, or need to be strengthened to ensure enrollee protections. Comments are provided for each subchapter of the proposed regulations.

Again, I appreciate the opportunity to comment on the Department's proposed regulations. HAP is committed to improving the accountability to patients receiving care in hospitals and health systems across the commonwealth. We strongly encourage the Department of Health to establish regulations that require health insurers and managed care plans to demonstrate their accountability and effective compliance with the HMO Act and Act 68.

We look forward to working with the Department during the promulgation of these regulations. Please feel free to contact me at (717) 561-5344, if you need further clarification on our comments.

Sincerely,

Paula A. Bussard

PAULA A. BUSSARD
Senior Vice President
Policy and Regulatory Services

PAB/mns

Attachment

c: Robert S. Zimmerman, Jr., Secretary of Health
Richard Lee, Deputy Secretary for Quality Assurance, DOH
John R. McGinley, Jr., Chairman, IRRC
Melia Belonus, Senior Policy Analyst, Governor's Policy Office
Howard A. Burde, Esq., Deputy General Counsel, Office of General Counsel
Diane Koken, Insurance Commissioner
Harold F. Mowery, Majority Chairman, Senate Health & Welfare Committee

c's: Vincent J. Hughes, Minority Chairman, Senate Health & Welfare Committee
Dennis M. O'Brien, Majority Chairman, House Health & Human Services Committee
Frank L. Oliver, Minority Chairman, House Health & Human Services Committee

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

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The Hospital and Healthsystem Association of Pennsylvania Comments on the Department of Health Managed Care Organization Regulations

In reviewing the Department of Health's proposed regulations, The Hospital & Healthsystem Association of Pennsylvania (HAP) has identified several areas where we believe additional clarification or changes should be made. HAP believes that these changes will assure Pennsylvanians that licensed insurers and managed care plans are accountable under the provisions of the state's HMO Act and Act 68—the Quality Health Care Accountability and Protection Act.

Subchapter F. General

§ 9.602 Definitions

Most of the definitions are derived from either the HMO Act or Act 68. However, there are several definitions that the Department of Health has developed that we believe are problematic, including:

❶ Emergency services – The definition of emergency services must be made clear so that consumers trust that emergency care is there when they perceive a need, and that providers receive appropriate reimbursement. *HAP believes that this definition must be the same as the Insurance Department's definition to ensure consistency as to what constitutes an emergency, and subsequently, what costs will be construed by insurers as reasonably necessary but to also allow for greater clarification and understanding by enrollees and providers.*

❷ Inpatient services - This is a new definition in which the department has included care provided in skilled nursing facilities. Skilled nursing services are entirely different from inpatient services and should be defined separately. *Therefore, HAP strongly recommends that the Department delete reference to skilled nursing services in the definition of inpatient services.*

❸ *HAP also recommends that the regulations more broadly define PPOs, both "gatekeeper" and "passive" PPOs. It is unclear in these regulations, what happens to existing regulations for PPO entities that are not "gatekeeper" PPOs, but are otherwise subject to the 1986 amendments (P.L. 226, No. 64) to the Insurance Company Law of 1921. It appears that non-gatekeeper or "passive" PPOs no longer have any regulations.*

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§ 9.603 Technical Advisories

The regulations state that the department has the authority to issue technical advisories to assist plans in complying with the HMO Act, Act 68, and other regulations. HAP contends that these technical advisories are not regulations. Also, it is unclear whether the public protections afforded under Pennsylvania's regulatory review act would be provided, particularly the opportunity for public review and comment. *Therefore, HAP recommends that this section be deleted.*

§ 9.604 Plan Reporting Requirements

These reporting requirements are essential for ensuring public accountability of managed care plan practices. *However, HAP would recommend that the department establish requirements for the reporting of utilization review timeliness, how the plan tests for reviewer reliability in making quality of care decisions, and a summary of the content of grievances and complaints (e.g., how many were brought by consumers versus providers, how many grievances and complaints were resolved at initial and subsequent levels, etc.).* HAP believes these additional reporting requirements not only will enhance the department's ability to oversee managed care quality but also will provide important information for consumer decision-making.

§ 9.605 and § 9.606 Investigation/Penalties and Sanctions

❶ HAP believes that these requirements are essential to ensure appropriate oversight by the Department of Health of managed care plan practices. *In addition, HAP recommends that §9.605(a) be modified to include provider complaints relating to quality of care or service as well.*

❷ §9.605 provides the department the authority to conduct investigations. Since the subchapter is applicable to managed care plans, (b), (c), (d), and (e) should not be limited solely to HMOs. Further, in (b) the department should not limit its onsite investigation only to IDS subcontractors, but rather should include the right to investigate all subcontractors, whether they assume risk or not. *Therefore, HAP recommends that this subsection be modified to reflect the department's broader investigatory responsibilities under Act 68 and (b) should be modified to allow the department to investigate any subcontractor.*

Subchapter G. HMOs

The requirements in the section regarding the application for certificate of authority update existing Department of Health standards. *However, HAP believes the department should incorporate a requirement in this section that HMOs are required to notify the Department of Health of any significant change in its operations or structure from that reported in the application for a certificate of authority.*

§ 9.634 Location of HMO activities, staff and materials

HAP commends the Department for requiring HMO medical directors to be licensed in Pennsylvania. *HAP also would recommend that the HMO quality assurance/ improvement committee shall only include Pennsylvania licensed health care providers.*

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

While the operational standards generally update existing HMO requirements, HAP believes that the inclusion of skilled nursing care in the definition of an inpatient service creates a problem. Since skilled nursing care is included in the definition of inpatient services, should it be interpreted that skilled nursing care is now to be construed as a basic health service for all HMO enrollees? Further, skilled nursing care is **not, and should not be considered,** a substitute for inpatient acute care or rehabilitation care. *Therefore, HAP again recommends that skilled nursing care should be deleted from the definition of inpatient service.*

§9.653 Use of co-payments and co-insurance in HMOs

HAP feels this section is vague. HMO co-payment requirements can be used to establish a "gate" by requiring significant co-payments for out-of-network care (such as a 50/50 co-payment arrangement). It is imperative that these arrangements are looked at carefully for their impact on access to care and that the regulations reflect that the department will be doing so.

§9.655 HMO external quality assurance assessment

While it is applaudable that the department has established standards for external quality assessment, HAP believes that the regulations should clearly provide linkage to the Department's enforcement and sanction authority. HAP also does not believe it is appropriate to extend the initial external quality review of the HMO, by the department from 12 months to 18 months.

Subchapter H. Availability and Access

§ 9.672 Emergency Services

As drafted, these regulations are different than those included in the Insurance Department regulations. The requirements must be consistent between both departments' regulations, not only to ensure more uniformity in the interpretation as to what constitutes an emergency and subsequently what costs will be construed as reasonably necessary, but to also allow for greater clarification and understanding by enrollees and providers.

HAP strongly recommends that the Department of Health regulations be modified to reflect recognition that emergency services also include the evaluation, stabilization, and treatment of the individual meeting the prudent layperson definition of emergency service. Therefore, HAP proposes the following language be added to this section:

> Plans are required to pay all reasonably necessary costs for patients meeting the prudent layperson definition of emergency services, to include: emergency transportation, services reasonably necessary to screen the patient, services reasonably necessary to diagnose, stabilize and treat the patient.

HAP would also like to point out that the regulations state at § 9.672(f) that the benefit for emergency care provided by a non-participating provider be at the same benefit level as that provided by a participating health care provider. However, on page 6414 of the summary of the proposed rulemaking, it states that the plan pay for emergency services provided by a non-participating provider at "the same rate." *HAP contends that the statement in the summary is incorrect and reflects an inaccurate interpretation of the regulation.*

It is the benefit level to the enrollee that must be the same, not the provider payment rate. The regulation is designed to protect consumers from additional out-of-pocket expenses, not to establish payment rates for plans for non-participating providers. Non-participating providers are entitled to bill managed care plans for their services, and the Department of Health does not have the statutory authority to establish a "default" payment rate for emergency services. Non-participating providers are entitled to fair and reasonable payments and billing charges to the plan as appropriate.

Further, the statement in the summary presumes that only a single "payment rate" exists. Every participating hospital and emergency physician may negotiate a different

payment rate with a health plan. *Thus, even if the department had the statutory authority to implement such a requirement, it is simply unworkable.*

Therefore, it is imperative that the language in the summary of the proposed rulemaking be corrected to reflect the appropriate interpretation of the regulation.

§ 9.675 Delegation of Medical Management

HAP supports the inclusion of this section to protect both managed care enrollees, as well as health care providers. *However, HAP would suggest that the Department of Health require plans to disclose in communications to enrollees and health care providers when medical management decision-making is delegated. This is important to ensure that enrollees and/or providers know whom and how they should contact when questioning or disputing a decision about medical necessity or appropriateness of care—the subcontractor or the plan.*

§ 9.677 Medical Necessity

❶ HAP believes that this section is essential as consumers and health care providers have experienced the use of differing definitions of medical necessity in various contracts and other documents used by a health plan. This has resulted in health plans not applying a uniform definition of medical necessity, thus creating barriers to care and/or denying appropriate reimbursement.

❷ *HAP also would encourage the department to include a provision stating that it will periodically evaluate the process by which a plan makes decisions on medical necessity (e.g., testing reliability) to ensure that different clinicians would likely make the same decision given the same information.*

§ 9.679 Access requirements

❶ The access standard implies use of a motor vehicle to access care. *Therefore, the regulations should clearly state this, and also state that the standard will be modified in areas where there is no accessible or affordable public transportation.*

❷ Subsection (e) states that access shall be ensured based on specific distance standards "or based on the availability of health care providers." *HAP believes that this statement is too broad and vague and should be clarified in the regulation.*

§ 9.681 Health Care Providers

❶ HAP, again, would like to point out that the interpretation found in the summary of the proposed rulemaking on subsection (c) is similar to the section regarding emergency services, and again, could be construed as establishing a "default" payment rate for services provided by non-participating providers. The intent of the regulation is to protect the enrollee from additional out-of-pocket expenses. In the summary of the proposed rulemaking, this section is interpreted to be at the same "terms and conditions," an inappropriate interpretation that clearly exceeds the statutory authority of the department. Further, imposing this provision would remove any incentive for a plan to negotiate with health care providers needed to assure access to appropriate and necessary services within the network and would impose contract terms, including payment rates, on providers who in no way have agreed to such terms and conditions. *Therefore, it is imperative that the language in the summary of the proposed rulemaking be modified to accurately reflect the interpretation of the regulation.*

❷ Further, subsection (c) states that a health plan "that has no participating health care provider available . . . shall arrange for and provide coverage for services by a non-participating health care provider." *As written, this is confusing since it is by contract or agreement—including a limited participation agreement (i.e., one limited to payments for certain services or circumstances)—through which plans "arrange for" available services. Subsection (v) should instead state:*

> If no participating provider is available, the health plan shall cover benefits and services obtained by a beneficiary from a non-participating provider without financial penalty to the enrollee.

❸ *HAP also recommends that the requirement related to written procedures be modified to reflect the definition of emergency services, specifically recognizing serious injury, impairment or dysfunction.*

§ 9.682 Direct Access to Obstetric and Gynecologic Care

The regulations as drafted allow plans to establish prior authorization requirements for services not considered to be "routine."

HAP believes that it is inappropriate for the Department of Health to distinguish between routine and non-routine obstetric and gynecologic care, as Act 68 did not make any differentiation.

Further, the department is proposing to allow managed care plans to define "routine." This will result in differing definitions across managed care plans and thus, create differing access to these services by women.

The issue of direct access to obstetric and gynecologic care also has been approached differently by the Department of Health as compared to the Insurance Department. At a minimum, the provisions for both departments must be the same; otherwise there will be inconsistent application and enforcement of this consumer right. HAP supports the provisions incorporated in the Insurance Department regulations and believes that they will result in more consistent application of this requirement. Therefore, HAP recommends that this section be amended as follows:

> Managed care plans shall permit enrollees direct access to obstetric and gynecological services for maternity and gynecological care, including medically necessary and appropriate follow-up care and referrals, for diagnostic testing related to maternity and gynecological care from participating health care providers without prior approval from a primary care provider. No time restrictions shall apply to the direct accessing of these services by enrollees.
>
> A managed care plan may require a provider of obstetrical or gynecological services to obtain prior authorization for selected services such as diagnostic testing or subspecialty care (e.g., reproductive endocrinology, oncologic gynecology and maternal and fetal medicine.

§ 9.683 Standing Referrals

The regulations omit reference to the requirement under Act 68 that the treatment plan be approved by the plan "in consultation with the primary care provider, the enrollee, and, as appropriate, the specialist. *HAP recommends that this requirement be included in this section.*

§ 9.684 Continuity of Care

HAP believes that the Department of Health and Insurance Department requirements for provisions related to continuity of care must ensure consistent application and enforcement of this consumer right, as well as to allow for greater clarification and understanding by enrollees and providers.

Subchapter I. Complaints and Grievances

§ 9.702 Complaints and grievances

HAP recommends that this section be clarified as to which entities this subchapter applies. The PPO Act does not distinguish between "gatekeeper" and "passive gatekeeper." As such, it is imperative that this clarification on applicability be made and specifically state whether PPOs will be required to maintain grievance systems under these regulations or under other existing Department of Health PPO regulations.

§ 9.703 Health care provider grievances

The implementation of this new requirement under Act 68 has been problematic. Several plans have not accepted written consents obtained by the provider at the time of treatment and instead are requiring the consent to be obtained at a date subsequent to the treatment. Several plans are requiring providers to use the plan's consent form, even after the provider has obtained written consent from the patient. Some plans are treating every provider dispute as a grievance needing the patient's written consent. These types of requirements create barriers for providers, who are seeking to advocate on behalf of the patient, which is the intent of Act 68. Further, the lack of clarity also creates situations where the patient is caught between the managed care plan and the health care provider, which Act 68 was explicitly drafted to prevent.

❶ *The regulations need to clearly ensure that providers are able to advocate on behalf of their patients and that unreasonable or inappropriate barriers are not put in the way by managed care plans. <u>The regulations should clearly state written consent may be obtained at the time of treatment.</u> Therefore, § 9.703 (b) must be modified to read:*

> <u>(b) A health care provider is permitted to obtain consent at the time of treatment.</u> A health care provider may not require an enrollee to sign a[n] document authorizing the health care provider to file a grievance as a condition of providing a health care service.

❷ *HAP agrees that once a health care provider **files** a grievance, the health care provider needs to see the grievance through the grievance process. Therefore, § 9.703 (c) should be modified to read:*

> (c) Once a health care provider <u>files</u> [assumes responsibility for filing] a grievance . . .

❸ *Additionally, subsection (d) states that providers may not bill enrollees once a grievance has been initiated by the health care provider until the grievance is completed. This subsection only applies to provider-initiated grievances. It is HAP's understanding that the provider may bill the patient if the grievance is initiated by enrollee or if the enrollee rescinds the consent for the provider to grieve. Further, it is HAP's understanding that the provider may bill the patient if neither party grieves. It is HAP's belief that any contrary interpretation would be beyond the statutory authority of the Department of Health.*

❹ *Finally, the regulations should also specify the types of information required to be included on a written consent form and allow for providers to develop their own consent forms consistent with the regulations. The Department of Health regulations specify the language that constitutes acceptable "hold-harmless" language for inclusion in provider contracts. In a similar vein, HAP recommends that the department consider modifying § 9.703 (f) and (g) to specify acceptable language for consent to file a grievance in § 9.703 as follows:*

> (f) Pennsylvania law permits an enrollee of a managed care plan or, with the enrollee's written consent, a health care provider, to request that the plan reconsider a decision made concerning the medical necessity and appropriateness of a health care service. This request is known as a grievance.
>
> (g) (1)The consent to file a grievance must identify the enrollee, the health care provider, and the managed care plan; a brief description of the service; and the date(s) of service.
>
> (g) (2)The consent to file a grievance shall clearly disclose to the enrollee in writing that the consent precludes the enrollee from filing a grievance on the same issue unless the enrollee, during the course of the grievance, rescinds in writing the previous written consent.
>
> (g) (3) The consent to file a grievance shall inform the enrollee of the right to rescind a consent at any time during the grievance process.

9.704 Internal complaint process

In this section, the date by which the decision must be rendered is suggested but not expressly stated. *Therefore, HAP recommends that subsection (c)(1)(iii) should clearly state that the "initial review committee" shall issue a decision within 30 days.*

§ 9.705 Appeal of a complaint decision

HAP believes that the time frame for the appeal of complaint decisions to the departments by consumers is too restrictive. HAP recommends that consumers should have additional time to file their complaints and would recommend that, at a minimum consumers should have 30 days.

§ 9.706 Enrollee and provider grievance system

❶ The letters used by most managed care plans are form letters and do not take into account the patient's individual medical or behavioral health situation. During the past year, HAP has provided the Department of Health with examples of denial letters that do not include the clinical rationale for the decision to deny. *HAP recommends that what is expected in the content of the denial letters be more clearly specified in the regulations. It is imperative that health care providers receive this information in order to change or improve health care delivery, or to clarify the information provided to the plan for determination.*

❷ Each individual patient has unique circumstances that may or may not be addressed through review criteria. *Therefore, HAP also believes that the regulations should state that utilization review criteria may be used as a tool in decision-making, but are not appropriate as the sole mechanism on which decisions are made.*

❸ Act 68 was designed to improve managed care accountability regarding decisions on medically appropriate treatment. It is problematic that plans approve services prospectively and/or concurrently, and then retrospectively deny those services. *To make the process truly accountable, plans should be required to abide by their prospective and/or concurrent decisions, unless the provider was derelict in providing information needed to make an appropriate decision. Failure to include this requirement also discourages providers and patients from exercising their due process rights to appeal decisions, because the plan may essentially change their decision at any time.*

❹ In this section, the date by which the decision must be rendered is suggested but not expressly stated. *Therefore, HAP recommends that subsection (c)(1)(iii) should clearly state that the "initial review committee" shall issue a decision within 30 days.*

❺ While HAP would agree that the physician or licensed psychologist need not personally attend on-site the second level review, their participation in the decision making should be via telephone or teleconference, and not be written. Allowing the latter does not foster two-way discussion during the review and also defeats the purpose of the act which states, "any initial review or second lever review conducted under this section shall include a licensed physician, or, where appropriate, an approved licensed psychologist, ..." *Therefore, HAP recommends that the regulation be modified to delete the use of written involvement and that the requirement that any such written report be prepared in advance of the review be deleted as well.*

❻ *Since health care providers can grieve on behalf of an enrollee, (c)(2)(ii)(A) must be modified as follows:*

> (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 or health care provider's attendance.

§ 9.707 External grievance process

❶ *For purposes of clarity, subsection (g) should state that the 3 business days to object apply when the CRE is assigned by the department or by the plan.*

❷ Act 68 is silent on what fees the prevailing party is to pay. *Therefore, HAP believes that it is beyond the scope of the Department of Health's statutory responsibilities to determine that attorney's fees are not included in the fees that are imposed on the nonprevailing party. This language must be deleted from subsection (l).*

❸ *Further, the regulations fail to indicate what occurs if the provider prevails on some, but not all, disputed issues. The regulations either should be modified to allow for proration in such circumstances or else "prevailing" must be defined more clearly.*

§ 9.708 Grievance reviews by CRE

It is unclear what is meant in subsection (e) by the definition of emergency in the enrollee's certificate of coverage. Act 68 defines emergency services and that should be the definition used by the external review entity.

§ 9.709 Expedited Review

Subsection (a) authorizes expedited review for disputes that jeopardize "the enrollee's life, health or ability to regain maximum function," but fails to identify the party responsible for making that determination. *HAP believes that the regulation needs to address this issue so that enrollee's immediate health needs are not unduly jeopardized by a health plan.*

§ 9.711 Alternative provider dispute resolution system

❶ *HAP recommended that the department clearly state that the regulations do not preclude informal dispute resolution processes that would encourage plans and providers to resolve any contractual disputes that may arise at the least adversarial basis. HAP commends the department on the inclusion of this provision.* ***However, it is not appropriate for this provision to be included in this section of the regulation.*** *The section in Act 68 on alternative dispute resolution was solely related to the external grievance process. Therefore, HAP recommends that the provision allowing an informal dispute resolution between providers and health plans be moved to § 9.702.*

❷ *Further, an informal dispute resolution mechanism is voluntary and involves a waiver of rights. Accordingly, there is no valid reason for the department to mandate that a decision reached in the informal dispute resolution mechanism be "final and binding."*

❸ *A new section on alternative dispute resolution to the external grievance process, including requirements/standards that needs to be developed. This new section should make clear that the alternative dispute resolution to the external grievance may not be utilized for grievances brought by an enrollee.*

❹ *HAP does not believe that denials based on procedural errors or administrative denials should require written consent by the enrollee for the provider to seek resolution of these issues. These are just the types of issues that should be handled through an informal dispute resolution mechanism and that reference should be included under*
§ 9.702.

❺ *Additionally, the regulations state that the alternative provider dispute resolution would include denials based on procedural errors and administrative denials involving the level or types of health care services provided. Act 68 intended the alternate dispute*

process to be agreed to by a provider and a plan through contract in lieu of an external grievance process. Therefore, an alternative process could include any issue to which providers are entitled to grieve and the regulations should be modified to clearly state this.

❻ *It is also unclear why the department included 9.711(b) in this section. Again, the alternative dispute resolution was envisioned under Act 68 to be in lieu of the external review and it is inappropriate to include § 9.711(b) in this section.*

Subchapter J. Health Care Provider Contracts

§ 9.722 Plan and health care provider contracts

❶ § 9.712 states that this "subchapter applies to provider contracts between managed care plans subject to Act 68 and health care providers." *HAP believes that in § 9.722, the department has inappropriately extended certain statutory requirements for HMOs to those managed care plans subject to Act 68, which are not HMOs. In particular, (e)(1), which is the traditional HMO hold-harmless language, is being extended to other managed care plans, absent statutory action that authorizes the department to do so. Therefore, the department needs to identify that § 9.722(e)(1)* ***only*** *applies to provider contracts with HMOs.*

❷ In addition, HAP acknowledges that the language used in § 9.722(e)(1)(iii) is the traditional hold-harmless language that evolved in state application from federal HMO law and regulation. It is HAP's understanding that this language is designed solely to protect enrollees from being billed by health care providers in the event of plan insolvency or a breach by a plan of the provider contract. *It is HAP's opinion that any other application of this regulatory language in a health care provider contract is inconsistent with the historical intent and interpretation of "hold-harmless" provisions.*

❸ *HAP recommends that the department should require that any changes to contract terms are mutually agreed to and resulting policy/procedure changes are communicated to providers at least 60 days in advance. This will enable providers to respond to contract changes on a more timely basis. Further, HAP believes that a provider contract should be voidable by the provider if the contract is not approved by the department of Health prior to its implementation. Therefore, HAP recommends that the following language be added to § 9.722 (e):*

(e)(8) Language requiring that any amendment to the contract must be mutually agreed to and confirmed in writing, except in the event of an amendment that is required by court order or by Federal or State Law.

(e)(9) Language requiring that the plan must give at least 60 days notice to an enrollee and provider prior to adding, modifying or withdrawing any policy or procedure implemented pursuant to the contract, except in the event that a policy or procedure that is required by court order or by Federal of State Law.

(e)(10)Language stating that a contract is voidable by the provider if its not approved by the Department of Health prior to the contract's implementation.

- Further, in § 9.721, the summary of proposed rulemaking discusses the Secretary's "authority to require re-negotiation of provider contracts when they require excessive payments." To be fair, and for reasons of protecting public health, the department's review rights and re-negotiation authority should equally encompass situations where rates appear to be inadequate and could jeopardize the quality of care. This is especially important since a small number of dominant health plans insure the vast proportion of lives covered under managed care arrangements in Pennsylvania. The department's general rulemaking authority is this area extends beyond its mandate under 40 P.S. § 764a(e) to ensure that risk assumption by a PPO will not lead to under-treatment. See 71 P.S. § 532(g). Under-reimbursement also is encompassed by provisions of 40 P.S. § 1558(a), which permits the Secretary to require re-negotiation of contracts that are inconsistent with purposes of the HMO Act. *§ 9.722 (f) should be amended to include:*

  (4) Include no reimbursement system that will lead to under-treatment or jeopardize the quality of care.

Subchapter K. Utilization Review Entities

§ 9.742 Certified utilization review entities

HAP recommends that a new section, titled Utilization Management Standards, *be added. Such a section should clearly articulate the on-going utilization management standards that apply to licensed insurers, managed care plans, or certified utilization review entities. All three types of entities are required to comply with the utilization management operational standards outlined in Act 68, but the department does not provide adequate interpretation of some of those standards or how it will validate or enforce compliance with those standards on an on-going basis.*

Additionally, the department's regulations outline on-going quality assurance standards for HMOs, and HAP believes that on-going standards should be articulated for utilization management. It is imperative that on-going utilization review standards for licensed insurers and managed care plans or utilization review entities be stated. HAP views the utilization management requirements as a major component of Act 68 and believes that such standards are a critical part of a managed care plan's overall responsibility in the area of quality assurance.

Therefore, the regulations should clearly specify the utilization management requirements consistent with the HMO Act and Act 68 that managed care plans, licensed insurers or certified utilization review entities are expected to adhere to, and how the department intends to validate adherence to and enforcement of these provisions. At a minimum, this new section should include: 1) utilization management structure; 2) clinical criteria for utilization management decisions; 3) qualified professionals; 4) timeliness of utilization management decisions; 5) and the other operational standards described in Act 68.

- **Utilization Management Structure**

HAP recommends that the department consider adding the following language with regard to utilization management structure. This would be consistent with the way the department has dealt with quality assurance standards.

The managed care plan's, licensed insurer's and CRE's utilization management structures and processes shall be clearly defined. The managed care plan, licensed insurer or CRE will have a written description of its utilization management program, including the program's structure and individuals' responsibility and accountability within that structure.

Responsibility for the conduct of the utilization management activities shall be assigned to appropriate individuals, and the managed care plan, licensed insurer or CRE shall ensure that mechanisms are in place whereby a health care provider is able to verify that an individual requesting information on behalf of that entity is a legitimate representative of the managed care plan, licensed insurer or CRE.

The utilization management plan shall be evaluated and approved annually by an appropriate committee(s) as outlined in the managed care plan, licensed insurer, or CRE utilization management program.

❷ Clinical Criteria for Utilization Management Decisions

HAP is aware that utilization management decisions that result in denial of payment are often made on the basis of utilization review criteria and that use of utilization review criteria often guide the determination of medical necessity. HAP believes that the department needs to make clear in regulations that utilization review criteria may be used as tools in decision-making, but that other factors which play into the issue of medical necessity must also be considered in those decisions. For instance, nationally developed utilization management criteria are often designed to be appropriate for the uncomplicated patient and for a very complete delivery system. They may not be appropriate for the patient with complications or for a delivery system that does not include sufficient alternatives to inpatient care for that particular patient. Therefore, HAP believes that the department's regulations should spell out that other factors should be considered when applying criteria to a given individual as these factors will often assist in making the determinations of what is medically necessary care.

The use and procedures for the application of utilization management criteria provide the basis for decision-making, and ultimately the determination of medical necessity. It is often the basis around which a denial for requested services is made. HAP believes the department has the authority to promulgate utilization management standards in the same manner that is has for quality assurance, credentialing and access requirements under the HMO Act and to strengthen the interpretation of the provisions included in Act 68.

Therefore, HAP recommends that it is imperative that the department consider including the following utilization management standards to address criteria for utilization management decision-making.

The managed care plan, licensed insurer or CRE shall use written criteria based on sound clinical evidence and specify procedures for applying those criteria in an appropriate manner.

The criteria for determining medical appropriateness shall be clearly documented and include procedures for applying criteria based on the needs of the individual patient, such as age, comorbidities, complications, progress of treatment, psychosocial situation and home environment as well as characteristics of the local delivery system that are available for that particular patient.

Participating providers actively engaged in the delivery of health care shall be involved in the development or selection of the criteria, and in the development and review of procedures for applying the criteria.

The utilization review criteria shall be reviewed at regular intervals and updated as necessary.

The licensed insurer, managed care plan or CRE shall state in writing how health care providers can obtain the utilization management criteria and make the criteria available upon request.

The licensed insurer, managed care plan or CRE shall evaluate the consistency with which the health care professionals involved in utilization management apply the criteria in decision making.

The managed care plan, licensed insurer or CRE must demonstrate that utilization management decisions are appropriate and that there is consistency in application of utilization management clinical criteria and procedures among the managed care plan's, licensed insurer's or CRE's designated physician and non-physician professional review staff.

❸ **Timeliness of Decision-Making and Communication of Utilization Management Decisions**

HAP believes that the issue regarding the communication of utilization management decision needs to be further delineated in the Department of Health regulations. Act 68 indicates that prospective, concurrent and retrospective utilization review decisions must be communicated within a certain time frame after the plan receives all supporting information reasonably necessary to make the decision. However, it is still unclear whether that decision should be verbally communicated first within the original time frames outlined in the act or whether the decision needs to be communicated in writing within the time frames outlined in the act. Ultimately, the act does indicate that all decisions must be communicated in writing. HAP would encourage the department to more explicitly spell out the time frames for decision-making and written communication of those decisions. Further, it is incumbent upon the department to ensure that managed care plans, licensed insurers and certified utilization review entities are adhering to those standards by requiring periodic reporting. The department should periodically review those reports, validate the information, and take appropriate action when managed care plans, licensed insurers or CREs fail to meet

decision-making and communication standards. HAP recommends the following language with respect to utilization management decision making and communication of those decisions.

The licensed insurer, managed care plan or CRE conducts utilization review based on the medical necessity and appropriateness of the health care service being requested, makes utilization management decisions in a timely manner and communicates its decisions in writing to enrollee and health care providers.

The licensed insurer, managed care plan or CRE shall notify the health care provider of additional facts or information required to complete the utilization review within forty-eight (48) hours of receipt of the request for service.

A prospective utilization review decision shall be communicated within two (2) business days of the receipt of all supporting information reasonably necessary to complete the review. The licensed insurer, managed care plan or CRE shall give enrollees and providers written or electronic confirmation of its decisions within two (2) business days of communicating its decision.

A concurrent utilization review decision shall be communicated within one (1) business day of the receipt of all supporting information reasonably necessary to complete the review. The licensed insurer, managed care plan or CRE shall give enrollees and providers written or electronic confirmation of its decisions within one (1) business day of communicating its decision.

A retrospective utilization review decision shall be communicated within thirty (30) days of the receipt of all supporting information reasonably necessary to complete the review. The licensed insurer, managed care plan or CRE shall give enrollees and providers written or electronic confirmation of its decision within five (5) days of communicating its decision.

The managed care plan, licensed insurer or CRE shall have systems and procedures in place, including sufficiently qualified physicians, non-physician staff and resources, to meet the time frame requirements for utilization management decision-making and communication of those decisions.

The department shall implement appropriate measures to ensure that managed care plans, licensed insurers or CREs are meeting the time frames required for utilization decision-making and communication of those decisions.

HAP also believes that the intent of Act 68 was to increase the managed care plans', licensed insurers' or certified utilization review entities' accountability for utilization review decision-making. As HAP stated previously, these entities should be required to abide by their prospective and/or concurrent utilization management decisions, unless the provider withheld information or did not provide the information to make an appropriate decision. Failure to include such a requirement puts providers and enrollees at risk for denial of services/care at any time. HAP recommends that the department consider language that states:

A managed care plan, licensed insurer, or CRE shall not retrospectively deny payment for a health care service if an authorized representative of that entity previously authorized provision of the service and the provider did not withhold any information reasonably necessary to grant prospective and/or concurrent authorization.

- **Qualified Professionals**

HAP recommends that the department reiterate the requirements for personnel conducting utilization review as specified in the act and that compensation to any person or entity conducting utilization review cannot contain incentives to approve or deny payment for the delivery of any health care service. The department should also again state that a utilization review that results in a denial of payment for a health care service must be conducted by a physician or psychologist within the scope of his/her practice and clinical expertise.

As articulated earlier in HAP's comments, the professional judgements and clinical rationale to support the denial determination are noticeably absent in denial letters sent to enrollees and providers. Again, HAP strongly urges the department to provide guidance as to what constitutes a clinical rationale, and to require plans to explain the clinical rationale in writing. The National Commission on Quality Assurance (NCQA), which accredits health plans, states that the managed care organization must provide the reason for the denial, including an easily understood summary of the utilization management criteria. NCQA also provides examples of appropriate reasons. NCQA also explicitly states that statements such as "The treatment is determined to be not medically necessary," " The treatment is not a covered benefit," or " The proposed

length of stay does not meet our utilization management criteria," are not acceptable reasons for the denial. It is important that the department provide such guidance. Otherwise, enrollees and providers will continue to receive form letters that simply indicate that the service was not determined to be medically necessary or appropriate.

Additionally, HAP requests that the department consider mandating that the name of the physician or psychologist who made the denial determination appears in the letter. In repeated examples of denial letters, the name of physician or psychologist who made the determination does not appear in the letter communicating the denial. It is therefore impossible for a provider or enrollee to definitively know that this same physician or psychologist is not involved in a subsequent review if the determination is appealed. Failure to identify the individual who made the determination is inconsistent with the intent of Act 68 to ensure accountability for utilization management decisions.

Finally, the department should develop mechanisms to ensure that plans, licensed insurers, and CREs are complying with these requirements. The department should impose appropriate sanctions under § 9.606, if these entities are not using physicians or psychologists to make denial determinations or failing to impart the clinical rationale for denial determinations in writing to providers and enrollees.

- **Other Operational Requirements**

HAP recommends that requirements around telephone access for utilization management, maintenance of adverse utilization management decisions for a period of three years and confidentiality requirements of medical records and other medical information used in utilization management decision-making be detailed in this section.

§ 9.747 Department review and approval of a certification request

HAP supports the "in-lieu" concept, however, the regulations should also incorporate a provision that ensures that the department has the ability to periodically validate the results of the accreditation process to ensure compliance with state law and regulation.

§ 9.748 Maintenance of Certification

The regulations state that the department may determine on-going compliance. *HAP recommends that the regulations regarding oversight be strengthened. This section should clearly demonstrate that the department will determine on-going compliance. Therefore, HAP recommends that (a) be modified to read as follows:*

Maintenance-... and maintaining its certification during the 3-year certification period, the Department [may] will do any of the following...

Subchapter L. Credentialing

HAP recommends that this section also include language that specifies how the department will monitor and validate compliance with standards of a nationally recognized accrediting body to ensure compliance with state law and regulation.

1/17/00

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January 18, 2000

Commissioner John R. McGinley, Jr.
Independent Regulatory Review Commission
Harristown 2, 14th Floor
333 Market Street
Harrisburg, PA 17101

Re: Managed Care Proposed Regulation

Dear Commissioner McGinley:

We are submitting the enclosed comments on the proposed regulations to implement (P.L. 464, No. 68), the Managed Care Accountability Act. We are also writing in support of the comments submitted by the Pennsylvania Health Law Project as our own. These comments detail our objections.

In an overview sense, we are concerned with the following areas:

A. Limited review and minimal criteria for new HMO's license in that

- Only requires descriptions of what the plan intends to do;
- No standard for ownership's background in health care management, previous experience, etc.; i.e., virtually anyone can own and operate an HMO.
- No mandatory on-site inspection by DOH;
- No readiness review by DOH to see if what the applicant said they intend to do (e.g., adequate staff, quality assurance, phone system, etc.) is in place before they enroll members and provide health care services
- Board of Directors with 1/3 enrollees need not be in place for the first 18 months of operation. No prohibition against enrollee board members being employees;
- No requirement for the plan to use generally accepted medical standards for utilization review;
- No standards for quality assurance.

B. No assurance of adequate network: Says "a network is required for approval of a certificate of authority." but:

- No definition of what an adequate network is.
- No definition of what specialties must be covered (including whether pediatric or adult);
- No enrollee/provider ratios;
- No access standards for appointments,
- No review of travel time to appointments.

C. Very limited plan oversight by DOH in that:

- No external review by anyone for the first 18 months of HMO operation and then only by a firm hired and paid for by the plan with plan determining the scope of review;
- No requirement of corrective action, etc., if external review finds problems;
- No public access to external review;
- No assured further external review needed for three years, even if serious problems.

- No requirement that DOH regulators ever step foot in a plan – permits DOH to rely exclusively on external reviewers hired and paid for by the plan to do any external reviews;
- No standards of scope of review required by the external reviews.

DOH Investigations of Plans

- Placed financial business of the plant off limits for DOH investigations, apparently precluding an inquiry into whether reimbursement decisions impact quality of care and access to services.

DOH Review of Plans' Financial Incentives

- Applications for Certificate of Authority require a detailed description of the types of financial incentives that a plan may use, rather than a detailed description of the actual incentives that the plan will use.

Approval of Plans

- Does not permit deemed approval of plans if DOH fails to act on application for Certificate of Authority within 60 days. Plans must demonstrate that they meet DOH standards in order to gain a Certificate of Authority.

Copayments Not Limited

- Does away with limits on copayments, and provides that DOH will review the impact of copayments on access, continuity of care, quality and cost effectiveness, only upon request by the Department of Insurance.

PCPs

- No longer requires that PCPs be trained or experienced in primary care medicine.
- No longer requires a minimum number of PCPs (and total physicians in the HMO's network) based on the plan's membership.
- Requires plans to make a PCP available to each enrollee, and requires plans to have a process to allow a switch upon advance notice. Does not define advance notice. Sets minimum standards for PCP office hours, availability, hospital admitting privileges, etc.

Medical Necessity

- Eliminates language from Department of Health's 1st draft, which required that: "(a) A plan shall adopt and maintain a definition of medical necessity which is consistent with national and industry standard definitions of medical necessity, is not unduly restrictive and does not rely on the sole interpretation of the plan or the plan's medical director."
- DOH fails to require plans to consider information provided by the enrollee, the enrollee's family, the primary care practitioner, as well as other providers, programs, and agencies that have evaluated the individual.

Quality Assurance Standards

- Health plans are required to have a quality assurance process, but no specific standards or outcome measurements are mentioned. As long as the plans have a process and follow that process, DOH won't look behind it to see if the process actually results in quality care. This section does not really set out Quality Assurance Standards at all.
- Does not provide for the development of a uniform member satisfaction survey to be made available to the public, as recommended by DOH workgroup.

Quality Assurance Reviews

- Generally requires that external Quality Assurance Assessments be done by an entity appointed by the plan, after a plan has been in business for 18 months; and every three years thereafter to study the quality of care being provided and the effectiveness of the plan's Quality Assurance Program. Does not set standards relating to quality improvement and health outcomes to be the basis of assessments.

Restricted Networks

- Allows plans to make only part of their network of providers available to enrollees, upon adequate disclosure to potential enrollees. Does not require disclosure to current enrollees, and does not set minimum standards for disclosure, such as inclusion of language in provider directory and/or marketing and enrollment materials

Drug Formulary Disclosure

- Requires a plan to disclose existence of any restrictive drug formulary, and to disclose whether a specific drug is covered within 30 days of a written request of an enrollee. Does not extend this disclosure requirement to potential enrollees.

OB/GYN Access

- Limits the Act's requirement that plans must provide "direct access to OB/GYNs by permitting an enrollee to select an health care provider participating in the plan to obtain maternity and gynecological care. .without prior authorization," by prohibiting plans from requiring prior authorization for any OB/GYN services considered "routine," but allowing plans to require prior authorization for any "non-routine."

Access to Emergency Services

- Limits the Act's provision on Emergency Services by requiring that plans use the Act definition only in administering benefits, adjudicating claims, and processing complaints and grievances, thus limiting the application of the definition.
- Restates the Act's proscription on requiring prior authorization before seeking Emergency Services to state that a plan cannot deny payment of a claim for which there was no prior authorization; thus implicitly allowing plans to require prior authorization, but simply precluding them from denying payment for failure to acquire prior authorization.

Provider Access Requirements

- Retains the current requirement that hospitals, PCPs and frequently used specialists be available within 20 minutes or 20 miles in urban areas, and 30 minutes or 30 miles in rural areas. No definition of frequently used specialists. No standards for less frequently used specialists. No standards for providers who are not hospitals, PCPs or specialists (such as drug stores, home health agencies or surable medical equipment providers).

Access for Persons with Disabilities

- Requires a plan to assure ADA compliance on physical accessibility and communication.
- Does not establish specific standards to be monitored and enforced by DOH.
- Does not require special needs units.

Standards for enrollee rights and responsibilities – Non-English-speaking enrollees.

- §2136 of the Act requires plans to provide: "(5) a description of how the managed care plant addresses needs of non-English-speaking enrollees." However, the DOH-proposed reg only requires: "(2) instructions as to how non-English-speaking and visually-impaired enrollees may obtain the information in an alternative format." Does "addressing the needs of non-English-speaking enrollees" as required in the Act mean more than providing instructions as to how they can obtain the information "in an alternative format?"

Disclosure of Enrollee Rights and Responsibilities

- Generally requires plans to have policies to assure disclosure of rights under Act 68 and Insurance Department regulations, including instructions for non-English-speaking and visually-impaired persons to obtain information in alternative formats Does not specify the rights or reference specific sections of the Act or regulations.
- No longer requires the health plan to provide and notify members of rights such as: the right to get current, complete information from their physician of their diagnosis, treatment and prognosis in understandable terms (unless medically unadvisable); the right to obtain emergency services without unnecessary delay; the right to truthful and accurate written information from the plant that someone of average intelligence can understand; the right to know the name, professional status and function of anyone providing them health services.
- No longer requires the health plan to routinely tell dissatisfied members of their rights under the complaint/grievance system and how to file a complaint/grievance at each point in which a potential dispute with the HMO is identified.

Continuity of Care

- Reduces the already limited discussion of "cause" in the Act by discussing terminations for cause, but failing to define or even repeat the examples from the Act

Health Care Provider Contracts

- Fails to place any limits on conflict of interest between health care provider and patient, but instead permits huge financial incentives to providers to limit care. Bonus, withhold pools, etc., based on low utilization can constitute 51% of the total health care provider payment by the plan. Although gag clauses are banned by the regulations, these regulations permit huge financial incentives which can in and of themselves make physicians feel constrained to limit communication with patients.
- Permits financial disincentive to serve and treat expensive patients by permitting plans to base economic incentives and disincentives on non-risk adjusted factors.
- No objective standard to determine if the financial incentive compensates a health care provider for providing less than medically necessary and appropriate care to an enrollee, as prohibited by Act 68 (for instance, HCFA defines substantial financial risk which could influence provider judgement as 25% of potential payments for covered services).
- Permits plans to get around Act 68 protections by deselecting health care providers at will. Although the regulations prohibit HMO-provider contracts from containing language that permits the plan to sanction, terminate or fail to renew a provider's contract for advocating for necessary health care, filing grievances, etc., the HMOs may deselect physicians after the end of the contract year. There is no requirement that the contracts provide a reason for non-renewal and an opportunity for health care providers to appeal, if the HMO has sanctioned, terminated or failed to renew a contract for an impermissible reason.
- Permits licensed HMOs to subcontract all functions except soliciting and enrolling members and the grievance and complaint process to any unlicensed person, corporation or other entity and put that entity at risk for providing all health care services with minimal protections DOH has no direct regulatory contracting with providers, quality assurance, etc

- Permits foreign HMOs to get exceptions to PA law requirements without notice to public and opportunity to comment.

Utilization Review

- Fails to require that where plans fail to adhere to the time lines mandated by the Act, the services which has been prescribed must be deemed approved.
- Fails to require utilization review entities to comply with the requirements of the Act. The regulations request a description from each applying URE of how and whether it could meet the requirements, but do not actually required that the URE comply with the Act. Also doesn't require all UREs to disclose any business relationship they might have with a plant for whom they are doing utilization review.

Enrollee Dispute Resolution Process:

NO Expedited Complaint Review

- Does not provide for expedited review of complaints (matters involving issues other than medical necessity, such as coverage), even if the enrollee's life, health or ability to regain maximum function would be placed in jeopardy.
- No longer requires that first level complaint and grievance decisions contain: a description of the reviewer's understanding of the members dispute; clear terms and in sufficient detail for the member to respond further; references to the evidence and documentation used as a basis of decision; a statement that the decision is binding unless the person appeals.
- No longer requires that members be given at least 15 days' advance written notice of the second level complaint/grievance committee hearing, be given a description of the committee's procedures to prepare, and be re-advised that they can be assisted by an uninvolved HMO staff person if they need help preparing.
- Does not require plans to make available to the enrollee all documentation relating to the issue in dispute.
- No longer requires that the second level review committee (for complaints and grievances) be made up of at least 1/3 HMO members, and that the consumer attending to be told which of the committee is staff and which members.
- Does not require plans to make available for questioning, at the second level review, those persons who made the determination in dispute
- No longer requires that an HMO staff person knowledgeable about the grievance/complaint be present at the second level review to present the HMO's view of why the denial should be upheld, and that the staff person may be questioned by the member and by the committee.
- No longer requires that if an HMO attorney is present, he/she cannot argue the HMO's case and instead must assist the committee to assure a fair hearing and that all issues are properly addressed. No longer requiring that an HMO may only have an attorney present to represent their staff, if they provide another attorney to represent the committee.
- No longer requires all second level grievance/complaint committee members to be present at the hearing and instead allows physician members to participate in the hearing and in the decision by a written report.
- No longer requires that the second level grievance/complaint committee base their decision solely on materials and testimony presented at the hearing.
- Does not require the decision to articulate a detailed basis, including reference to the standard used and the evidence considered.
- Allows plans to send notification of decisions to either the enrollee or provider, contrary to Act 68, which requires notification to both.

Data Collection, Review and Dissemination by DOH

- Requires annual submission to DOH of data regarding enrollment/disenrollment, utilization review, complaint/grievance, number of physicians leaving the plan, but does not require the submission of HEDIS data, nor does it make any data available to the public in a user friendly format as recommended by DOH workgroup of providers, consumers, plans and government officials.

Delegation of Medical Management

- Allows the delegation of virtually any aspect of medical management (utilization review, quality assurance, case management, etc.) upon prior approval of the contract by DOH. Does not have explicit standards for delegation of these functions except for utilization review and when an integrated delivery system is involved.
- Is cumbersome in routing communication to the enrollees through the plan, rather than directly from DOH and the certified review entity. Fails to require that if the plan is successful on an enrollee-filed complaint, the plan must still pay the cost of the review, as required by Act 68.

External Grievance Process

- Fails to establish minimum provider credentialing standards for education, training, experience, record-keeping, equipment, facility, etc. Fails to require review of practitioner's substance abuse history, board certification, malpractice history, etc.
- **Lack of coordination with Insurance Dept. Regs.** The Insurance Department issues final regs which they have since withdrawn. Several sections of the Health Department regs cover the same topics as the Insurance Department regs. However, despite frequent assertions that the two Departments are working closely together, these shared sections are drafted very differently, often with conflicts between the versions of the two Departments. Some of the topics where Health and Insurance regs conflict are:

§ 9.682. Direct access for obstetrical and gynecological care;

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

§ 9.684. Continuity of care.

Attached please also find the comments of the Pennsylvania Health Law Project, which we endorse.

Sincerely,

WILLIAM M. GEORGE, President
RICHARD W. BLOOMINGDALE, Secretary-Treasurer

Attachment

cc: Robert E. Nyce, Executive Director, IRRC
Senator Harold F. Mowery, Majority Chair
Senator Timothy F. Murphy, Vice Chair
Senator Vincent J. Hughes, Minority Chair
Representative Dennis M. O'Brien, Majority Chair
Representative Frank L. Oliver, Minority Chair
Commissioner Arthur Coccodrilli, IRRC
Commissioner Robert J. Harbison, III, IRRC
Commissioner John F. Minzer, IRRC

jg/UFCW1776

PA Health Law Project
Comments to DOH Proposed Managed Care Regs

Subchapter F GENERAL

9.602 Definitions

Enrollee

The proposed definition is too narrow and fails to include parents of minor enrollees or legal representatives of those enrollees who may be incompetent. It is inconsistent with the DOI regulations which define "enrollee" to include parents and legal representatives, but only for purposes of complaints and grievances. However, even the broader DOI definition is insufficient in that these representatives must also be able to request information on drug formularies under 9.673, must be able to request a standing referral or a specialist as PCP under 9.683, must be able to act on an enrollee's behalf to obtain continuity of care under 9.684, etc

Accordingly, the definition should be revised as follows.

Enrollee—A policyholder, subscriber, covered person, member or other individual who is entitled to receive health care services under a managed care plan. **The term includes an individual authorized to act on the enrollee's behalf.**

Primary Care Provider

The proposed definition describes only the duties, and not the medical credentials required of a PCP While it is important that CRNPs be included as PCPs, it is also important for enrollees to know the medical background or experience of providers listed as "PCPs" in the plan's network. There should be some uniformity established across plans on the general background or experience required to list someone as a "PCP" in a provider directory.

The current HMO rules require a PCP to either spend half their time as a primary care provider, or have limited their practice for at least two years to general practice, family medicine, internal medicine or pediatrics. Without any guidance on PCP credentials, it would be difficult to ascertain whether or not a plan's PCP network consists of appropriately qualified providers

- *Should we recommend the current HMO standard applies? Something else?*

Gatekeeper

The definition presented here is very different from the definition originally proposed and it directly conflicts with DOI's proposed definition It permits any provider, as opposed to a primary care provider, to be a gatekeeper. It also fails to require a gatekeeper be a provider of services to an enrollee, but rather permits the gatekeeper to solely be a source of referral or approval for services. The definition should be revised as follows.

Gatekeeper—A ~~health~~ **primary** care provider **selected by an enrollee or appointed by a managed care plan,** managed care plan or agent of a managed care plan **serving as the primary care provider,** from ~~which~~ **whom** an enrollee ~~must receive referral or approval for covered health care services as a requirement for payment of the highest level of benefits~~ **shall obtain covered health care services, a referral, or approval for covered, non-emergency health services as a precondition to receiving the highest level of coverage available under the managed care plan.**

Grievance

If even one reason for a managed care plan's decision is the medical necessity or appropriateness of the health care service, an enrollee's request to reconsider that decision should be designated as a grievance. Any other reasons given for the decision and relating to the issue of medical necessity should be combined in order that the entire claim may be reviewed. Such issues clearly fall under the expertise of DOH, and not DOI, and enrollees must be allowed to obtain external review of their claim if they are not satisfied with the results of the plan's grievance process.

The proposed rule should be revised as follows:

Grievance—

(i) a request by an enrollee, or a health care provider with the written consent of an enrollee, to have a managed care plan or CRE reconsider a decision ~~solely~~ concerning the medical necessity and appropriateness of a health care service. If the managed care plan, etc.

Integrated Delivery System (IDS)

The definition proposed here is very different from the one set forth in the DOI regulations in several ways:

1. Under (iii), DOI requires that the health care services be "a defined set" and that the benefits be provided " principally through its participating providers".
2. Under (iv), the proposed rule allows an IDS to accept full responsibility for conducting quality assurance, credentialing, etc. By contrast, DOI's definition does not permit an IDS full responsibility for any of these functions and instead requires the IDS to act " in conjunction with the managed care plan and under compliance monitoring of the managed care plan's[sic]."
3. The proposed rule allows an IDS to also conduct "enrollee services" activities. The DOI rule does not
4. The DOI rule permits an IDS to perform "claims processing and other functions", while the DOH proposed definition does not include those activities.

Managed Care Plan

The definition needs to be revised as (i)(B) and(C), integration of financing and delivery and the providing of financial incentives, are not functions or duties of a gatekeeper It must also be noted that the proposed definition differs from the DOI definition The definition offered by DOI includes the following language not found in this rule: " The term includes managed care plans that require the enrollee to obtain a referral from any

primary care provider in its network as a condition to receiving the highest level of benefits for specialty care."

The definition should be revised as follows:

Managed care plan or *plan*—(i) a health care plan that uses a gatekeeper to ~~(A) M~~ manage the utilization of health care services; ~~(B) I~~ integrates the financing and delivery of health care services to enrollees by arrangements with health care providers selected to participate on the basis of specific standards; ~~(C) P~~ and 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, etc.

Service area
The proposed definition differs from the definition set forth in the Act itself. The Act states the service area is the one for which the managed care plan is licensed or has been issued a certificate of authority, and not simply the area "for which the plan has received approval". The definition should be revised accordingly.

Service area--The geographic area **for** ~~in~~ which the plan **is licensed** or has ~~received approval to operate by the Department~~ **has been issued a certificate of authority.**

Utilization review
The definition proposed goes beyond the Act in that it allows UR to be performed by any health plan, and not just a utilization review entity. The definition should also reference the "CRE" as defined earlier in the rules. Accordingly, the definition should be revised as follows:

UR—Utilization review—
(i) a system of prospective, concurrent or retrospective UR, performed by a **certified** utilization review entity (**CRE**) ~~or health care plan,~~ of the medical necessity and appropriateness of health care services prescribed, etc.

9.603 Technical advisories.
Purchasers, providers and the public should also be able to access the information that an technical advisory has been issued, as well as the content of the advisory in order to determine and monitor whether managed care plans are following the Department's guidance on how to comply with the Act and regulations. Accordingly, this section should be revised as follows

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

advisory, the availability and means for obtaining the technical advisory shall be published in the Pennsylvania Bulletin by the Department. "

9.604 Plan Reporting Requirements

These proposed reporting requirements are not sufficient to demonstrate to the Department compliance by managed care plans with Act 68 Second, this section fails to incorporate some reporting requirements regarding complaints and grievances as well as utilization data, found in the current HMO rule. See, 9.73(8); 9.91(a)(3). Third, the Department deleted an important provision detailing financial penalties for late submission of the reports. Such a provision is critical to assure plan compliance with these important reporting requirements.

Finally, this section fails to incorporate several specific data reporting recommendations made by the DOH Workgroup. The Workgroup had recommended. a phase in of Hedis data collection; the establishment of an advisory panel on data; and quarterly and annual data made available in user-friendly reports to purchasers, providers and the public to allow comparison across different managed care plans/health care providers of costs, quality and outcomes. See, 4.2.6 and 7; 4.3.4; 4.7 4.

Accordingly, this section should be revised as follows:

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 **In addition, the plan shall make the data reported available to the public in a user-friendly format approved by the Department.**

(3) Data relating to complaints and grievances **This data must include, at a minimum:**

(a) total complaints and complaint rate by medical nature of complaint (quality of care, days to appointment, specialist referrals, requests for interpreter services, denials of emergency room claims, etc) and by the non-medical nature of the complaint (plan office staff, office waiting time, etc.)

(b) Resolution of the complaints

(c) Total grievances, the grievance rate by the same indicators as above, and resolution of the grievances

(d) Total provider appeals by nature of the grievance (quality of care, denial of referrals requested, denials of claims, lack of timely payment etc.) and resolution of those appeals.

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

(12) Quality improvement reports

(13) Any change in utilization criteria since the last report

(14) Formularies and the process to obtain prior authorization or an exception

(15) The number of requests made for a standing referral or a PCP as specialist, the number granted and the number denied.

(16) A report on the monitoring activities for IDS and medical management contracts

(17) The number, type and reason for payment for procedures to out-of-network providers

(18) A report on activities to accommodate access needs for persons with disabilities, to provide services to persons with limited English, and to accommodate persons with sensory disabilities.

(19) A report on the provider complaint process, including the number of complaints filed by type of provider and the outcome of the complaints

(20) If applicable, a report on utilization for persons seeking drug and/or alcohol treatment, by type of service provided.

(21) A copy of the annual financial report given to the Commissioner.

(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 the complaint and grievance system data specified in (a)(3), by product line (e.g. Medicare, Medicaid, etc.) **The utilization data shall include, at a minimum, (1) the hospitalization experience of the plan in terms of the number of days of inpatient hospital experienced per 1,000 enrollees, on a quarterly, year-to-date and annualized basis; and (2) the average number of physician visits per enrollee on a quarterly, year-to-date and annualized basis.** Each quarterly report shall be filed with the Department within 45 days following the close of the preceding calendar quarter. The plan shall submit each quarterly report in a format specified by the Department ~~for that quarterly report~~ **and shall also make the data public in a user-friendly format.**

(c) **Financial penalties for late submissions. Plans failing to submit the annual or quarterly reports by the required deadlines shall be fined $100 per day for every day the report is overdue.**

9.605 Department investigations.
The Department must be able to investigate information contained in enrollee grievances (whether initiated by the enrollee or a provider) as well as complaints, and also in provider appeals.

The proposed language specifies that the Department must have free access to all books, plans and documents that relate to the HMO's business "other than financial business". It is not clear why the Department cannot access any financial information regarding the health plan Surely such information may be directly related to quality of care or services, or deficiencies found in those areas. The plan's financial business practices and financial solvency will likely have a clear impact on its provision of services and benefits, provider contracting and credentialing, how it operates its complaint and grievance system, etc. It is hard to imagine how the Department can adequately monitor quality of care or services or ensure health plan compliance with this Act and other laws without ever being able to access or investigate the plan's financial business practices or records.

This section should be revised as follows:

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

(d) 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~~.

9.606 Penalties and sanctions.
This section has been substantially revised and goes a long way toward complying with the DOH Workgroup recommendation for a full range of regulatory tools to ensure compliance. Some additional revisions are needed, however, to tighten these provisions and assure enrollees are informed and protected. Accordingly, this section should be revised as follows:

(a) For violations of Article XXI and this chapter, the Department may take one or more of the following actions:
(1) Impose a civil penalty of up to $5,000 per violation.
(2) Maintain an action in the name of the Commonwealth for an injunction to prohibit the activity that violates the provision. **If the Department is successful in obtaining injunctive relief, the defendant plan shall pay the reasonable costs of such action to the Commonwealth.**

(3) Issue an order temporarily prohibiting the plan from enrolling new members **until the plan comes into compliance with the provisions of the Act and regulations.**
(4) Require the plan to develop and adhere to a plan of correction approved by the Department. **The plan must notify enrollees of the presence of a plan of correction within 60 days of its approval by the Department and** ~~which~~ the plan shall make it available to enrollees upon written request. The Department will monitor **implementation and** compliance with the plan of correction.

(e) The Department shall publish annually the list of plans, by area served, with no deficiencies or plans of correction for the year.

DoH Act 68 proposed regs- Part H
[sections that raise the biggest problems are in bold, our proposed language is in italics]

§9.672 Emergency services-
(b) No denial for lack of prior authorization of emergency services- This should be supported.
(c) "A plan MAY apply the prudent layperson standard .in adjudicating related claims for emergency services " §2101 of the Act incorporates the prudent layperson standard in the definition of "emergency service". Since the regulation is dealing with "claims for emergency services" it would be contrary to the Act's definition of "emergency services" for the Department not to make mandatory the use of the prudent layperson standard. The term "related" in the regulation is unclear. "Related" to what?
(d) Ambulance in an emergency is an emergency service- This should be supported.
(e) Plan may not require use of a particular ambulance service in an emergency- This should be supported.

§9.673 Prescription drugs
(a) Disclosure of effect of formulary- This should be supported.
(b) Plans must respond to enrollee requests regarding coverage of a specific drug within 30 days- The addition of a time limit is new. Putting a time limit into the regs is probably helpful in terms of making this provision enforceable. However, 30 days seems a long time to give the HMO to respond to what should be a simple question.
(c) & (d) Exceptions process- This should be supported

§ 9.674. Quality assurance standards
*This section remains weak! As in the 1st draft, health plans are required to have a QA process but no specific standards or outcome measurements are mentioned. As long as the plans have a process and follow that process, DoH won't look behind it to see if the process actually results in quality care.
(a) Plans must have a QA plan- Failed to adopt our recommendation that the plans be acceptable to the Department.
(b) QA plan standards- Failed to adopt our recommendations that:
(a) The quality assurance plan must include regularly updated standards for health

promotion, early detection of disease and injury prevention for all ages, systems to identify special chronic and acute health care needs at the earliest possible moment. These standards shall be made known to providers and enrollees The quality assurance plan must be regularly updated with the involvement of providers and members.

(b) The quality assurance plan should include measures of consumer satisfaction (established by a review of consumer appeals, consumer requests to change a primary care provider, consumer satisfaction survey outcomes, and voluntary plan and primary care provider disenrollments), maximum appointment waiting times, at least three clinical quality improvement study activities, including one behavioral health and two population based preventive studies. Minimum quality improvement initiatives for the provision of preventive, acute and chronic care services, relevant to the health needs of the plan's members, and a minimum of 10 quality improvement initiatives.

(c) The quality assurance plan must have systems in place to identify special chronic and acute health care needs of members at the earliest possible point to assure effective and early intervention.

(d) The quality assurance plan must include the conducting of an annual member satisfaction survey with an instrument developed by the Department. The results of such surveys must be reported to the Department and to the public.

(e) Where quality assurance standards are not met, a quality improvement plan must be developed and implemented to reach the standard.

(f.) The plan's utilization standards shall :

(1) Be applied consistently and equitably;

(2) require that the member's specific individual health status be taken into account;

(3) based on sound clinical and scientific evidence,

(4) made under the direction of the plan medical director;

(5) current, subject to input from plan providers and made known to plan providers;

(6) not have financial or other incentives that adversely affect quality of care;

(7) be otherwise in compliance with Act 68 and the standards for utilization review entities set forth therein.

(k) Include a medical necessity definition that complies with the Act and Section 9 47 of these regulations that provides for quality health care for enrollees of all ages, including those with chronic health care conditions

(l) Include standard consumer satisfaction questions and survey process designated by the Department.

(l) Include quality assurance measures specific to service delivery to special populations.

(m)Include coordination requirements to behavioral health care other support systems essential for special populations, including referrals to community-based programs that could serve other enrollee needs.

The Department shall evaluate each plan's quality improvement efforts for effectiveness on an annual basis. The results of the plan's key health improvement initiatives and required interventions must be made known to consumers and providers. The Department shall recognize excellence in meeting managed care quality objectives and shall serve as a clearinghouse for best practices. The Department shall also develop a

process for regularly updating its quality improvement standards This process shall include all stakeholders, including consumers.

§ 9.675. Delegation of medical management.
(a) Unlike the 1st draft, these proposed regs require that the plan get approval from DoH of any contract to delegate medical management.
(c) DoH accepted our recommendation that compensation to contractors performing medical management not include incentives to deny payment for services.
(d) Lists the requirements for plan oversight of the medical management contractor. The list remains essentially the same as the 1st draft and fails to accept any of our recommendations including that the contractor report to the plan on a monthly basis rather than quarterly and that the random sample that the plan must perform have enough people to have validity and be done annually.

§ 9.676 Standards for enrollee rights and responsibilities
Most of the specifics regarding disclosure of information to enrollees and prospective enrollees has been eliminated because these matters are covered in the Insurance Dept regs. This is a prime example of why it is essential for the Health & Insurance regs to be considered by the IRRC at the same time.

Non-english speaking enrollees- §2136 of the Act requires plans to provide: "(5) a description of how the managed care plan addresses the needs of non-english-speaking enrollees." The DoH proposed reg only requires: "(2) Instructions as to how non-English speaking and visually-impaired enrollees may obtain the information in an alternative format." We believe that "addressing the needs of non-english-speaking enrollees" as required in the Act means more than just providing instructions to non-English speaking enrollees as to how they can obtain the information "in an alternative format." Furthermore, there does not appear to be any mention in the Insurance Dept. regs on the rights of non-english speaking enrollees.

§ 9.677. Requirements of definitions of "medical necessity."
* Eliminates very important language from the 1st draft! The 1st draft required that: "(a) A plan shall adopt and maintain a definition of medical necessity which is consistent with national and industry standard definitions of medical necessity, is not unduly restrictive and not rely on the sole interpretation of the plan or plan's medical director." That language has been eliminated!
DoH also failed to adopt our recommendation that: "*Plans must consider information provided by the enrollee, the enrollee's family, the primary care practitioner, as well as other providers, program, and agencies that have evaluated the individual*"

§ 9.678. Primary care providers
"(c) A plan MAY consider a physician in a nonprimary care specialty as a primary care provider". This provision is confusing as it makes no mention of the requirement for plans to allow specialists to serve as PCP for certain enrollees (§2111(6)(II) of the Act). This requirement is covered in §9.683 of DoH's regs and in §154.11 of the Insurance regs (now withdrawn). A reference to these sections would be useful.

§ 9.679. Access requirements in service areas

The proposed regs replace the requirement on plans, in the 1st draft, to "ascertain participating providers', . ability to provide ...care" as part of provider recredentialing, with a much vaguer requirement: "(c) A plan shall demonstrate at all times that it has an adequate number and range of health care providers...."

DoH failed to accept our recommended language: "*Urgent care appointments must be available within 24 hours and in no case should other appointments have waiting times greater than 45 days. Appointments for prenatal care should not have waiting times in excess of 30 days.*"

§ 9.680 Access for persons with disabilities

This basically tracks the act.

§ 9.681. Health care providers

"(d) A plan shall have written procedures governing the availability and accessibility of frequently utilized health care services. ." The purpose of this section, which did not appear in the 1st draft is puzzling. The services listed are basic services that every HMO is required to provide such as well patient exams & emergency care. If this provision implies that plans may impose some limits on the availability & accessibility of these services, it is extremely troubling.

§ 9.682. Direct access for obstetrical and gynecological care

The Insurance Dept. has already promulgated regs on this although they were withdrawn. Despite frequent assertions that the two Departments are working closely together, DoH's proposed regs conflict in some regards with Insurance's. For example: Insurance's regs make it clear that prior authorization is not needed for "follow-up care and referrals" while DoH's do not. Insurance regs state "no time restrictions shall apply". DoH's do not. DoH's proposed regs allow plans to require prior authorization for ""nonroutine procedures" while the Insurance regs give specific examples of the kind of ob/gyn services a plan could prior authorize and do not use the term "routine procedures". Insurance's regs prohibit plans from paying less for directly accessed ob/gyn services than for ob/gyn services which the prior authorizes. DoH's do not. Once again, a prime example of why the DoH and Insurance regs should be considered at the same time. It is not at all clear why DoH has chosen to issue proposed regs on this topic.

§ 9.683 Standing referrals or specialists as primary care providers

Insurance has already issued regs on this although they have recently been withdrawn. As with the regs on direct access to ob/gyn services, these regs conflict in some regards with Insurance's. DoH's regs require notice of the plan's decision to be made within 45 days; Insurance is silent on this point. DoH requires a denial by a plan of a request for a standing referral to include information about appeal rights, Insurance is silent DoH's are far more detailed than Insurance regarding the process for deciding whether an enrollee can get a standing referral or specialist as PCP. Once again, a prime example of why the DoH and Insurance regs should be considered at the same time.

§ 9.684. Continuity of care

Here again, DoH has issued regs on a topic already covered by Insurance and once again, there are conflicts between the two sets of regs. DoH's regs require the plan to notify patients of the right to continuity of care when they terminate a provider; Insurance's do not. Once again, a prime example of why the DoH and Insurance regs should be considered at the same time.

David Gates January 13, 2000

Subchapter K: Utilization Review

The proposed regulations do not incorporate or provide regulatory guidance on key utilization review requirements of Act 68 The proposed regulations fail to address the General Assembly's concerns over potential conflicts of interest between plans and CREs, insuring that the personnel conducting utilization review remain licensed in good standing, applying timeframes for review, and prohibiting incentives offered by plans to CREs Additionally, the Act requires that UREs meet certain criteria before they can be certified as CREs (thus, before they can conduct UR for a plan). These regulations include a mechanism for inquiring about the URE's ability to meet the criteria but, exclude any provisions that would actually require CREs to meet the criteria or hold them responsible for failure to meet the criteria.

1. **Adequate Department review of applicants and existing CREs must occur.**
   a In sections 9.747 and 9.748, the Department must clarify that it **shall** have access to the books, records, staff, facilities, and any other information it finds necessary to determine the applicants and the existing CREs' compliance with the Act and the regulations. In section 9.747, the Department of Health provides that it 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. This provision should be revised to indicate that the Department **shall** have access to these items for **all applicants**. Likewise, a provision must be added to Section 9.748 to indicate that the Department shall have access to such information with regard to **all existing CREs**.

   b. Act 68 requires the Department to implement the requirement of the Act and thus, the Department exercise its obligation to oversee the CREs. In both Section 9.747 (relating to applicants) and 9.748 (relating to existing CREs), the draft regulations provide that the Department may forego an inspection or Act 68 compliance assessment where the applicant or CRE is accredited by a nationally recognized accrediting body whose standards meet or exceed the standards of Act 68 and this subchapter. Being accredited and being overseen

are not one and the same. The Department must review the actions or inactions of existing CREs in fulfilling its obligation to implement the requirements of Act 68. Additionally, the Department must assume responsibility for insuring not that the applicant or CRE is accredited but that it complies. Accordingly, the Department should freely consider that a CRE is accredited in conducting its oversight activities but, accreditation should not be a substitute for the oversight activities. – Is there an accrediting body? – maintenance and renewal of certification must include on-site inspection

c. The Department's review of compliance with the Act and the regulations must include a review of decisions rendered by the CRE. Arguably, it might be implicit in the provision as it is written, that in having access to the books, records, staff, facilities, etc., the Department will have access to and will review the decisions rendered by the CRE for their compliance with the Act and the regulations. In actuality, the Department must review the decisions rendered by the CREs for compliance with the Act and the regulations and the regulations should explicitly state that the Department will being undertaking this level of scrutiny to assure compliance This will assure CREs, plans, and enrollees that the Department will be actively working to insure compliance with Act 68 and the regulations.

2 **Scope of Department review**. Under Section 9.742(b) the department may subject a CRE to additional review, suspension or revocation of certification if it determines that the CRE is failing to comply with the terms of Act 68 or this chapter. What about non-compliance with DOI regs? Since the Department of Health has assumed the role of certifying CREs and governing their conduct, it must act to insure compliance with **all** parts of the Act and both department regulations, to the extent that they apply to CREs.

3. **No timeframes as provided in the Act.** Section 2152 of Act 68 requires that UREs conduct utilization reviews based on the medical necessity and appropriateness of the health care services being reviewed and provide notification within set time frames These timeframes are nowhere restated, referenced, or reaffirmed in the regulations. The General Assembly believed it important enough to legislate timeframes and these timeframes must be followed. These timeframes require a CRE to render and communicate 1) a prospective decision within 2 business days, 2) a concurrent decision within 1 business day, and 3) a retrospective decision within 30 days of receipt of all supporting information reasonably necessary to complete the review. Additionally, CREs are required by the Act to notify providers within 48 hours of receipt of request for review of the need for additional information. These timeframes are in place to ensure prompt access to health care services.

4. **Regulations allow conflicts of interest with no protection for consumers from such conflicts even though the Act prohibits such conflicts.**

a. The regulations require additional information regarding potential conflicts of interest from applicants who seek to do internal and external grievance reviews but not from a CRE that would only make the initial decision. The General Assembly sought to protect against and prevent potential conflicts of interest between the entity making the utilization review and the plan, where the job is not being done by the plan. Not only do the regulations contradict the intent of the General Assembly to protect against potential conflicts of interest in only select circumstances but, it also defies logic Where there is a truly independent entity rendering the initial decision of medical necessity and appropriateness, that decision is more credible and more supportable. Both the plan and the enrollee with face a more fundamentally fair judge and the issue of bias will not need to be addressed on appeal. Additionally, the enrollee has the right to object to a CRE on the grounds of conflict of interest. The Department is impeding and, perhaps, constructively denying that right by disabling the enrollee from learning about conflicts on interest

b. A licensed insurer need not be certified as a CRE in order to conduct UR for anyone This means that an insurance company may pose as the outside, "independent" CRE for another insurance company or the parent or subsidiary of itself without having to go through the certification process. The certification process is the only possible mechanism for sorting out potential conflicts of interest. - why not require them to get a separate certification for CRE ? Additionally, section 9.742(c) allows a licensed insurer or plan to be a CRE without having to obtain a certificate as a CRE provided they comply with the standards and procedures of §2152 (the Act says comply with the subarticle and it says it in §2151) - at a minimum must be required to comply with §2151 and §2152.

c. Section 9.743 CRE application requires list of each plan for which the applicant is providing UR. The CRE must be required to update this information no less often than at the time of renewal, every 3 years

d Even though CRE applicants who would perform internal and external reviews must disclose potential conflicts of interest, the regulations do not define potential conflicts of interest. It must be made clear what is meant by these terms. For example, it must be made clear that not entity can be certified as a CRE that is participating as a reviewer for DPW fair hearings process, etc.

e. Even though an individual has a right to object to a CRE on grounds of conflict of interest, the individual has only 3 days within which to do so and has no effective way of discovering conflicts, especially where not all CREs must disclose them.

5. **Other problems with the CRE application.**

a. The regulations do not specify what must be included in the application for all CRE applicants, only for those that would perform internal and external review. Section 9.744 requires more specific information of applicants for internal and external grievance review than section 9.743 does for applicants for initial review. § 9.744 requires, for example, applicants provide that "name, title, address and telephone number of a primary and at least one backup designee with whom the Department may communicate . . " whereas, §9.743 requires nothing more than the "name, address and telephone number of the entity . . ". The Department should be consistent and require the same specificity of all CREs, in recognition of the fact that the initial decisions are an important point at which a individual's health and the health care process can be significantly thwarted.

b. The regulations require an applicant to state where it has been denied accreditation. The applicant is not, however, required to provide an explanation of rejection for accreditation Perhaps there are some grounds that should not be determinative for whether the URE can become a CRE.

c. The regulations fail to inquire into the licensure and good standing of the applicant. Section 9.745 lists many factors that the Department may consider of the officers, directors, or management personnel of an applicant. The Department should also look to current licensure and standing in the medical profession.

d No UREs not existing at the time of the regulations may become CREs because applicant is required to list three clients for which it has conducted UR. How can a new company start up if it must be certified to do UR work but may not become so certified without having done such work before? If a company can meet the requirements, there must be another way

6. **Does not require CREs to actively comply with the Act.** The CRE provisions discuss at great length what must be queried in an application for a prospective CRE. The regulations, however, wholly fail to articulate that CREs are required to comply with standards established in the Act. The regulations fail to set forth that without the ability to meet certain requirement and the affirmation that the applicant will meet the requirements, a certificate will not be granted. This must be added to the regulations. CREs must not merely be interrogated about whether they could comply, they must be instructed that they are required to comply and they must be held to the requirement.

7. **Does not establish uniform standards for utilization review by CREs thus breeding inconsistent decisionmaking by the CREs.** Work group recommended that DOH require that utilization standards be applied consistently and equitably, require that the member's specific individual health status be considered, be based on sound clinical and scientific evidence, be made under the direction of the plan medical director, clinical standards for utilization review be required to be

current, subject to input from plan providers and made known to plan providers, not have financial or other incentives that adversely affect the quality of care, comply with Act 68 prior authorization requirements and include standards and time frames for PA procedures of plans, and include a review of the plans' medical necessity definitions

Subchapter L: Credentialling

This Subchapter does not establish uniform standards for credentialling, nor does it prohibit recredentialling based on non-risk adjusted utilization data. These are terribly important features that have been excluded. It disturbs any health care recipient to think that their providers may have been selected by random standards or criteria that differ from the ones their friends or family members' providers may have had to meet. The Standards work group recommended that DOH require minimum credentialling and recredentialling standards, based on current industry standards. The work group also recommended that plans be prohibited from basing their recredentialling decisions solely on economics. Recredentialling should be based on the initial factors that determined credentialing plus performance factors that include member complaints and satisfaction information, preventive and health maintenance information, on site review and utilization but, not economics.

1 **No enforcement mechanisms.** Section 9.761 requires plans to establish and maintain credentialing systems. This section and subchapter fail to require plans to comply with their credentialing systems. According to the language, plans may establish and maintain but need not follow their systems. Additionally, there is no DOH oversight of the credentialing systems or process. This is especially true in light of the fact that providers who are denied credentialing are given no administrative means or mechanism through which to seek DOH review of the plan decisions.

2. **Credentialing is not defined and no basics of what credentialing includes are provided.** There is no definition of credentialing provided in the regulations. Additionally, the regulations do not even set forth the most minimum of factors that should be included in any conceptualization of "credentialing", such as a providers current licensure, malpractice insurance, education, hospital privileges, etc. Standards must be ascribed. At the least, these bare minimums must be included.

3. **The regulations violate the intent of the General Assembly by interfering with direct access to OB/GYN care.** Enrollees are provided with direct access to OB/GYNs without impediment by plans In §9.761(a)(8), the Department purports to provide plans with the ability to limit the providers to whom enrollees may directly access by allowing them to evaluate providers who may be directly accessed for OB/GYN care. The Department has no authority for this.

4. **The regulations require a provider or prospective provider to request, in writing, the credentialing requirements.** If a plan can hold providers and applicants to standards, these standards must be provided to providers and applicants without request Applicants should receive them with their application packets. Providers should receive them when the requirements change and when they are being recredentialed.

Subchapter G., HMOs

9.621 Applicability
Just applies to HMOs

9.622 Prohibition against uncertified HMOs.
Includes foreign HMOs. **No requirement for recertification every 3 yrs. as recommended by the workgroup. §1.5**

9.623 Pre-application development activities.
A network is required for a certificate of authority.

9.631 Content of application for HMO certif. of authority.
Includes required submission of standard form provider and IDS contract. Including K between IDS and providers? Yes. 9.724 Including a detailed description of the types of financial incentives the HMO may utilize. How detailed? Includes a detailed description of the applicant's incentives and mechanisms for cost-control within the structure and function of the applicant What does this mean?
Requires detailed description of incentives and mechanisms for cost control. **However, no specific authority for the DOH to question plan assumptions and incentive factors utilized for reasonableness and potential risk transfer to providers as recommended by workgroup §2.11. Note proposed § 9.605, restricting DOH inquiry into the financial business of the plan. No license application fee to fund review by DOH staff per workgroup recommendation §3.1.2.**

9.632 HMO certificate of authority review by the Department.
Within 90 days, but no automatic approval if not acted upon.

9.633 HMO board requirements.
1/3 members, and the selection process shall be structured to obtain diverse representation of enrollees.

9.634 Location of HMO activities, staff and materials.

9.635 Delegation of HMO operations.
Appears to have no limits except that medical management delegation must be in accordance with 9.675.

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

Operational Standards

9.651 HMO provision and coverage of basic health services to enrollees.
HMO shall maintain an adequate network of providers. **Fails to develop, monitor and enforce standards to be used to evaluate network capacity, including PCPs, specialists, hospitals, ancillary practitioners and other frequently utilized services, per workgroup recommendation §3.2.3.** May exclude coverage of services customarily excluded by indemnity insurers. Enrollee may not be required to go out of network for emergency services, and a plan can't require a provider to advise an enrollee to stay in plan for emergency services.

9.652 HMO provision of other than basic health services to enrollees.
HMOs may provide other than basic coverage so long as the network is adequate, contracts meet the requirements of 9.722, and grievance and complaint procedures apply. **Ignores workgroup recommendation § 3.9.1., which would require disclosure of basic services to members.**

9.653 Use of copayments and coinsurances in HMOs
DOH will review on request of Ins. Scope of review limited to access, continuity, quality and cost effectiveness. **Ignores workgroup recommendation to DOH to review and monitor copayments, to set maximum limits, and to periodically update and publish these so that they do not become barriers to care. § 3.2.1. Ignores workgroup recommendation § 3.9.1., which would require disclosure of copayments to members.**

9.654 HMO provision of limited networks to select enrollees.
Offering limited subnetworks is OK only with adequate disclosure to potential enrollees (what is adequate? **workgroup recommended disclosure in provider directory and/or in the marketing and enrollment materials §2.14). Consistent with workgroup recommendation § 3.9.1.** what about notice to current enrollees?), and if the network is adequate, within reasonable traveling distance, and the enrollee can go out of limited network if needed.

9.655 HMO external quality assurance assessment
Required within 18 mo. of certif of authority, and every 3 yrs. thereafter. Can be combined with an accreditation review. **Fails to implement workgroup recommendation that within 6 to 12 months of licensure, DOH staff conduct an onsight visit to review the plan's quality improvement plan, per recommendation § 3.7.1.** It shall study the quality of care being provided, and the effectiveness of the quality assurance program. **Fails to require that DOH develop, monitor and enforce standards relating to quality improvement and health outcomes, which are to be the basis for external reviews, per workgroup recommendation § 3.7.2.**

9.656 Standards for approval of point-of-service options by HMOs
Requires a formal product filing with DOH, and must periodically inform the PCP of self-referrals, investigate PCP practices with higher than average self referrals, provide disclosure of costs, and does not encourage self referral. Why does DOH care if there are high self referrals?

Subchapter J. Health Care Provider Contracts

9.712 Applicability.
Applies to all managed care plans

9.722 Plan and health care provider contracts.
Standard form K to be submitted for DOH approval prior to use, and any change 10 days prior to use. (What happens if not acted upon?) **Does not contain an explicit 45 day deemer provision, as recommended by the workgroup. Does not explicitly allow negotiations to result in customized contracts as to other provisions. §2.9**

The K may not contain a provision allowing a plan to sanction, terminate or fail to renew for: advocacy, helping with grievance, protesting a plan decision, policy or practice, or taking § 2133 permitted actions.) (Comment: Suppose indirectly, referrals, etc. are factored into rates, bonus, etc.? Is DOH going to look at this? Should at least say: directly or indirectly.) **Workgroup § 2.10 g**

Confidentiality protection language must be in the K, with DOH, DOI and DPW access to the records for QA, investigation of complaints, and other compliance. **Workgroup § 2.10 b and c.**

Must require the provider to participate and abide by decisions of plan's QA, UR and Grievance systems. **Workgroup § 2.10 d** (Why and how UR and grievance, or was the provider referenced here meant to include IDSs?)

Language concerning: prompt payment of claims, adherence to federal and state laws, **(Workgroup § 2.10 g,)** requiring the provider to give 60 days advance written notice of termination of the provider K (Comment: what about refusal to renew? Is there any provision in the regs for notice to enrollee of failure to renew?) **No provision for immediate termination of provider who is harming patients, or had license suspended per Workgroup § 2.10 f.**

Plan must describe the bonus and withhold factors.

Cannot weigh utilization higher than quality, enrollee services, and other factors collectively. (Confusing. Are they lumping quality, enrollee services and other factors together? Also, how define enrollee services?)

9.723 Integrated delivery systems. (IDS).
Ks between IDS and plan, and IDS and providers must meet the requirements of the previous reg.

9.724 HMO-IDS contract.
DOH must approve the K. The IDS doesn't need its own license. The IDS cannot delay, reduce or deny services because of the relationship between the HMO and the IDS or its providers. IDS providers must meet the HMO's credentials. The HMO remains directly accountable to DOH, and the IDS must cooperate with the HMO and DOH regarding access to records, on-site reviews. IDS agrees that any delegated functions are subject to HMO and DOH review and validation. IDS agrees to provide required data to the HMO and DOH. IDS must be certified if performing UR. IDS must agree that it and providers will hold members harmless. Must provide for Act 68 continuity of care if IDS K is terminated. **Consistent with workgroup recommendation § 5.3.7.** Must safeguard against significant disruption of continuity if the IDS K is suspended, terminated or unexpectedly not renewed. (Enforcement?) Either party can terminate upon 60 days notice for no reason. (Why is this a reg.?)
Delegation of medical management must meet § 9.675.

9.725 IDS-Provider Ks.
Nothing in the agreement shall limit the HMO's ensurance of QA, Utilization management, (why?) enrollee complaint and grievance systems. DOH can monitor HMO systems, and HMO has authority over providers. Must include an acceptable hold harmless clause.

Subchapter K. Utilization Review Units.

9.741 Applicability.
To UR entities needing certification.

9.742 Certified Utilization review entities (CREs).
Entities must be licensed, and renewed every 3 yrs. DOH may renew, suspend or revoke if CRE fails to comply with Act 68 or this chapter. A licensed insurer or plan need not get a separate certification.

9.743 Content of an application for certification as a utilization review entity. Includes list of each plan for which UR is currently performed. (Any requirement for updating?) Description of: selection and credentialing procedures, ability to arrange for a wide range of providers to review, confidentiality, prompt response to calls, ability to verify ID of plan, capacity to maintain a written record of UR decisions, including a detailed justification of all required notifications for 3 yrs. **Does not set forth the specific standards for timeliness or confidentiality of records, per workgroup recommendations §3.5.4, and .5 but instead references the Act. The regs should set out the statutory requirements. No credentialing**

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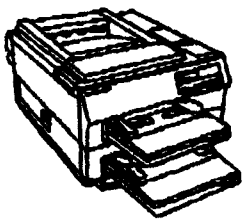

Date: 1/18/2000

TO: CMNR John R McGinley

Fax Number: (717) 783-2664

FROM: David Wilderman

Department: _____

Comments: _____

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MEMORANDUM

TO: Stacy Mitchell, Director
Bureau of Managed Care
Pennsylvania Department of Health

FROM: Christine Klejbuk, Vice President/Public Policy
chris@panpha.org

DATE: January 18, 2000

SUBJECT: PANPHA's Comments on the Department of Health's Proposed Regulations to Implement Act 68 of 1998, the Managed Care Accountability Act.

The Pennsylvania Association of Non-Profit Homes for the Aging (PANPHA) represents 369 nonprofit providers of housing, health care and services to over 68,774 elderly and disabled persons in the State. Our members employ over 50,638 persons. We appreciate the opportunity to comment on several aspects of the proposed Department of Health (DOH) regulations.

1. Lack of Definitions in the Proposed Regulation

Act 68 requires that DOH promulgate "such regulations as may be necessary to carry out the provisions of this article." (Section 2181) Under the section of Managed Care Plan Requirements (Section 2111), it is required that a managed care plan shall "assure availability and accessibility of adequate health care providers in a timely manner, which enables enrollees to have access to quality care and continuity of health care services." It is our belief that the regulatory oversight of DOH requires the Department to assure that managed care plans comply with Section 2111.

It is difficult for us to understand how DOH can determine compliance by a plan in the absence of definitions for this section. Whether one uses the saying, "reasonable men can differ", "it's in the eyes of the beholder", or "the devil is in the details", the lack of regulatory definitions to give guidance to the Department as it assesses compliance with this requirement is a serious concern. It is not in the best interests of the consumers of the Commonwealth to leave the interpretation of "availability", "adequate", "timely manner", "quality care" up to the managed care plans to define. While we can appreciate the challenge in defining these critical elements, someone will define them and it should be the regulatory department rather than individual managed care organizations.

We are also concerned about the lack of any standard definition for "medical necessity". It appears from these proposed regulations, that the Department will not provide even basic parameters for what is expected in the definition of medical necessity. Earlier drafts of this regulation included language from DOH which, at least, put some parameters to the definition. (The earlier draft required that "(a) A plan shall adopt and maintain a definition of medical necessity which is consistent with national and industry standard definitions of medical necessity, is not unduly restrictive and does not rely on the sole interpretations of the plan or the plan's medical director.")

Under Section 9.655(c) of the proposed regulation, what are the "assessment factors required by the Department"?

2. Technical Advisories

While PANPHA is supportive of departments to issue interpretive guidelines on regulations, it does seem to us as we have worked with departments (including DOH), that not all interested/affected constituencies have access to these advisories. Proposed Section 9.603 should include language that the issuance of a technical advisory will be noted in the *Pennsylvania Bulletin*, with information on how to obtain a copy.

3. Consistency Needed

Managed Care Organizations have the joint oversight of the Departments of Health and Insurance. It is in everyone's best interest if there is consistency between the regulations from the two departments. We hope that the staff of the IRRC would be most mindful of the importance of comparable language in both sets of regulations.

Thank you, again, for the opportunity to comment.

cc: Harold F. Mowery, Jr., Majority Chair, Senate Health and Welfare Committee
Vincent Hughes, Minority Chair, Senate Health and Welfare Committee
Dennis O'Brien, Majority Chair, House Health & Human Services Committee
Frank Oliver, Minority Chair, House Health and Human Services Committee
Rich Sandusky, IRRC

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FAX COVER SHEET

DATE: 1-18-00

TO: Rich Sandusky, IRRC

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FROM: Chris Kleiber

PHONE: 717-763-5724
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Number of pages including cover sheet: 3

Message

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January 18, 2000

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Ms. Stacy Mitchell, Director
Bureau of Managed Care
Department of Health
PO Box 90
Harrisburg, PA 17108-0090

Re: Department of Health Proposed Rulemaking – Managed Care Organizations – Pennsylvania Bulletin, Vol. 29, No. 51, December 18, 1999.

Dear Ms. Mitchell:

I am writing as President of the Pennsylvania Medical Society to offer comments on the above captioned proposed rulemaking relative to the Quality Health Care Accountability and Protection Act (Act 68 of 1998). I am aware of and appreciate the effort the Department has put forth in seeking input from affected parties, including the Medical Society, in drafting these regulations.

I must begin my comments by expressing dismay over the handling of the definition of "medical necessity" in the proposed regulations. By reading the Department's comments, which precede the proposed regulations, it is clear that you recognize that health plans may have multiple definitions of medical necessity. In the proposed regulations you have addressed the medical necessity issue regarding health plans with multiple products and multiple operating procedures within products. These regulations only require consistency of medical necessity definitions within a plan's products. It doesn't remove the inconsistency of definitions between plans.

The Society contends, and so commented on to the draft regulations, that there is no justification to permit medical necessity to be defined differently between plans than within plans. A health care provider should not have to consider which plan the patient is covered under before determining whether the treatment needed by the patient will be determined to be medically necessary by the plan.

The Society has offered several definitions of "medical necessity" including one adopted by the American Medical Association. That definition is as follows:

"Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (1) in accordance with generally accepted standards of medical practice; (2) clinically appropriate in terms of type, frequency, extent, site, and duration; and (3) not primarily for the convenience of the patient, physician, or other health care provider."

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The paramount issue with respect to the definition and its use is consistency in its application and understanding between patients, health care providers, and the insurance industry.

We also strongly recommend that medical necessity definitions be required to reflect the presenting symptoms and condition of the patient at the time and place the services were recommended or provided. Subjecting the service to retrospective review on the basis of information not available at the time the service was provided is unfair to the patient and the health care provider.

The Department has recognized the legislature's intent by requiring application of a prudent layperson standard and the use of presenting symptoms for evaluating emergency situations. There should not be a dual standard for non-emergency care!

The Medical Society recommends that the Department define medical necessity using a prudent physician standard or at least define the standards the Department will require in approving a health plan's definition of medical necessity.

Attached are specific comments offered on behalf of the Society. These comments relate to specific sections and subsections of the proposed regulations. When referring to Society comments on the previous draft regulations, I will use the term "draft regulation."

If you have any questions concerning these comments or would like to discuss further, please contact Mr. Donald McCoy, the Society's Director of Policy and Regulatory Affairs.

On behalf of the Pennsylvania Medical Society, I appreciate this opportunity to offer comments on these important regulations.

Sincerely,

Donald H. Smith, MD
President

Cc: Chair, Senate Public Health & Welfare Committee
Chair, Senate Banking and Insurance Committee
Chair, House Health and Human Services Committee
Chair, House Insurance Committee
Independent Regulatory Review Commission
Secretary of Health
Commissioner of Insurance

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PENNSYLVANIA MEDICAL SOCIETY
Comments
Department of Health
Proposed Rulemaking
Managed Care Organizations
PA Bulletin, Vol. 29, No. 51, December 18, 1999

9.602. Definitions

Gatekeeper PPO – The definition of Gatekeeper PPO in the draft regulation included the statement "A gatekeeper PPO is a managed care plan." This statement provided clarification as to the application of Act 68 requirements to such entities.

The Medical Society recommends the insertion of the phrase "A gatekeeper PPO is a managed care plan." at the end of the definition of "Gatekeeper PPO."

Inpatient services – The definition in the draft regulation included reference to "medically necessary physician services." The services included in the proposed definition exclude any reference to treatment services and includes only facility services offered ancillary to treatment.

The Medical Society recommends the insertion of the phrase, "and all diagnostic and treatment services provided by health care practitioners" after "diagnostic testing."

POS plan – Point-of-service plan – The definition deletes previous language of the draft regulation designating point-of-service plans as managed care plans for the purposes of the Act. Again, it is important that all entities intended to fall under Act 68 requirements are clearly designated.

The Medical Society recommends that the phrase "A POS is a managed care plan." be inserted after the last line of the definition.

9.603. Technical advisories.

The Medical Society is concerned that the Department's intention to use technical advisories to convey additional information will not permit stakeholder input or allow for public notification of the promulgation of the advisories. An example of the Society's concern is the technical advisory on use of nurse practitioners as gatekeepers which was sent only to managed care plans in 1995. The advisory was promulgated to physicians, yet the Society had no opportunity for input prior to its publication and found out about it after the fact.

The Medical Society recommends that any technical advisories be proposed for board stakeholders' comment prior to publication. The Society further recommends that notice of the publication of technical advisories be given through the *Pennsylvania Bulletin*.

9.633. HMO Board requirements.

The Medical Society had raised in its previous comments, the issue of the qualifications of the plan's medical director and members of the plan's quality assurance/improvement committee. As required by the Act, individuals rendering decisions as to the medical necessity of services rendered or proposed are to be licensed and, depending on the level of review, have added qualifications including active clinical practice and specialty certification. The proposed regulation addresses the issue of licensure but not the added qualifications.

The Society also recommended that a provision be added to permit the medical director and the quality assurance/improvement committee to have direct access to the plan's board to discuss issues relative to quality and access to care provided through the plan's network. Plan policies and standards which adversely affect quality and/or access must be addressed appropriately and expeditiously as soon as the problem is identified.

The Medical Society recommends that Section 9.633, HMO Board requirements, be amended by the addition of qualifications for the medical director and members of the quality assurance/improvement committee of each plan. These requirements should address active clinical practice and certification. The Society further recommends that the health plan's board structure be required to include a mechanism for the medical director and the quality assurance/improvement committee to report problems affecting quality or access as soon as the problems are identified.

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

This section requires HMOs to provide and cover services "according to its definition of medical necessity." As stated in the Society's comment letter, we believe that the Department of Health must be active in the review for approval of the plans' definition of "medical necessity" prior to its use.

The Medical Society recommends that Subsection 9.651 (c) be amended by the insertion of the phrase ", approved by the Department" after the word "necessity."

Under subsection (c)(1) (Emergency services), the wording of the subsection has been changed from "the plan shall not require...to utilize a participating provider. . ." to "the plan may not. . ." Even though both words in context have the same result, the word "shall" denotes the intent in stronger terms. Additionally, added reference should be made to the prudent layperson standard to insure compliance with that standard.

The Medical Society recommends that Subsection 9.651 (c)(1) be amended by adding, "In considering emergency services, the plan shall provide coverage according to the prudent layperson standard." Also substitute the word "shall" for the word "may."

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

The draft regulations permitted the Department to establish maximum co-payments and co-insurance amounts and set specific maximums which could be applied. The proposed regulations permit the Department, upon request of the Insurance Department, to review a plans' benefit structure to determine whether the co-payment or co-insurance amounts might limit access to health care or otherwise affect accessibility of services. The regulations don't establish any criteria to be used to make any decision regarding availability or accessibility, leaving a lot of room for interpretation.

The Medical Society recommends that language be inserted in Section 9.653 establishing some standard for the test for availability and accessibility or some maximum threshold on the level of co-payment or co-insurance which may be requested.

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

The draft regulations contained a phrase limiting out-of-pocket expenses of enrollees who exercised a POS option which was intended to prevent use of such expenses to unfairly restrict POS services, especially out-of-network. The Society believes that the omitted provision provided a needed safeguard for patients.

The Medical Society recommends that Subsection 9.656 (b)(2) be amended by the insertion of the phrase "Such expenses shall be reasonable and not designed to unfairly restrict access to such services." to the end of that subsection.

9.672. Emergency services.

The Medical Society is pleased with the correction reported in the December 25, 1999, Pennsylvania Bulletin changing the language of subsection (c) to read that the plan shall apply the prudent layperson standard. . . emergency services.

The Society is also pleased with the addition of a new subsection (f) which requires that the plan shall cover emergency services at the same level of benefit for both network and non-participating health care providers.

9.673. Plan provision of prescription drug benefits to enrollees.

Subsection (a) discusses the plan's requirement for disclosure to enrollees that restrictions in drug availability may result from use of a formulary. There is no requirement for a listing of what those restrictions might be as there was in the draft regulations. Such information would be useful to the enrollee and their health care provider in considering changes in plan coverage.

The Medical Society recommends that Subsection 9.673 (a) be amended by substitution of the word "any" for the word "that" and the insertion of the word "which" after the word "availability" at the end of the sentence.

Subsection (d) requires the plan to distribute its policy and process for seeking exceptions to the plan's formulary to participating providers. The subsection should be amended to require disclosure to the enrollee and to a non-participating provider when appropriate for the provision of care utilizing the formulary.

The Medical Society recommends that Subsection 9.673 (d) be amended by the insertion of the phrase, "and to the enrollee or non-participating health care provider providing care to the enrollee, upon written request." after the word "prescriber."

9.674. Quality assurance standards.

Subsection (b)(1) requires a plan to maintain a written description of its quality assurance program and related activities and to make this information available upon request to the Department.

The Society would suggest that such information be submitted to the Department so that the Department and interested parties can review the program information.

The Medical Society recommends that Subsection 9.674 (b)(1) be amended by deletion of the phrase "and shall make . . . upon request." and the insertion of the phrase "and shall submit this information to the Department at the time of application for certificate of authority and when any changes to the program are made."

9.677. Requirements of definition of "medical necessity."

Addressed in cover letter from the Medical Society.

9.678. Primary care providers.

Subsection (d) permits plan to consider the use of a certified registered nurse practitioner (CRNP) as a primary care provider. There is currently no provision to require the plan to inform the enrollee concerning the appropriate scope of practice of the CRNP or of the required collaborative arrangement between the CRNP and the physician.

The Medical Society recommends that Subsection 9.678 (d) be amended to include a requirement for the plan to notify the enrollee that the CRNP is not a physician, to identify the physician with whom the CRNP has a written collaborative agreement, and to permit the enrollee to select another primary care provider.

9.679. Access requirements in service areas.

Subsection (c) requires plan to demonstrate the adequacy of its provider network by number and specialty. No standards for determination of network adequacy are included. Are the requirements of the original HMO statute still applicable? Do they still provide an adequate level of care?

The Medical Society recommends that Subsection 9.679 (c) be amended to address the issue of adequacy of provider network more completely by identifying what criteria will be used by the Department to determine network adequacy.

9.681. Health care providers.

Subsection (a) requires plans to provide a directory of network providers. There is no requirement of how the directory is to be structured; what information is to be included; what is the frequency of updating; and what guarantee there is of the accuracy of the information.

Enrollees and providers have criticized the plans for inaccurate listings that may affect the patient's ability to select a plan with the providers of the patient's choice.

The Medical Society recommends that Section 9.681 be amended to require health plans to publish the directory of health care providers annually, providing quarterly updates and an ability for telephone and/or on-line 24 hour verification of information on network providers. The Society also recommends that the format of the directory include the identity of all licensed health care providers who may be associated by practice, including the hospital privileges of each provider; and in the case of nurse practitioners, the identity of that practitioner's collaborating physician.

9.682. Direct access for obstetrical and gynecological care.

The Society commented on the use of the term "routine" in this section when describing access to obstetrical/gynecologic care. The term is undefined and open to misinterpretation. As pointed out in previous Society comments, use of the term could limit such services to annual examinations. Gynecologic problems and symptoms, by their nature, are not routine.

The Medical Society recommends that the word "routine" be deleted from Subsection 9.682 (b).

9.704. Internal complaint process.

Subsection (1)(iv) requires the plan to notify the enrollee in writing of the decision of the initial review committee. In situations where the complaint involves the performance of the health care provider, that provider should also be notified and given information of his right of appeal of any adverse decision.

The Medical Society recommends that Subsection 9.704 (1)(iv) be amended by the insertion of the following language after the first sentence: "If the complaint involves the performance of services by the health care provider, the provider shall also be notified in writing of the committee's decision.

9.706. Enrollee and provider grievance system.

Subsections (1)(iv), (2)(ii), and (2)(v) require plan notification of the party requesting the grievance of the decisions and the rights of appeal at each level of the grievance process. The Society believes that both the enrollee and provider should be notified simultaneously of the plan's decision. If both parties are notified, by virtue of the requirement for enrollee consent for the filing of the grievance, then both parties should be notified of the outcome of the process.

The Medical Society recommends that Section 9.706 be amended to require notification of the enrollee and the provider in all decisions related to the grievance filed.

Subsections (3)(i) - (iii) include reference to the use of licensed psychologists rendering decisions at the initial and second level grievance process. The statute permits psychologists to participate in reviews of services that are within the licensed psychologists' scope of practice. Psychologists shall not participate in reviews of care involving inpatient hospitalization and in the administration of drugs. Additionally, they would not be the equivalent of a psychiatrist and should therefore not be used to render medical necessity decisions concerning medical services rendered by physicians.

The Medical Society recommends that Subsections 9.706 (3)(i) – (iii) be amended to clarify the limitations on the use of psychologists initial and second level grievance reviews.

9.708. Grievance reviews by CRE.

Subsection (d)(2) describes the criteria for reviewers participating in the external grievance process. The criteria includes the term "active clinical practice". Although defined in statute, there may be misinterpretation since the definition is not included in the regulations.

The Medical Society recommends that the definition of "active clinical practice," as defined in the statute, be added to the definition section of the regulations.