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THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

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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.

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.564.9200 Phone
717.561.5334 Fax
http://www.hap2000.org

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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.

- **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

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. 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.

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.

❺ <u>Other Operational Requirements</u>

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 <u>may</u> determine on-going compliance. *HAP recommends that the regulations regarding oversight be strengthened. This section should clearly demonstrate that the department <u>will</u> 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

HEALTHSOUTH
Rehabilitation Hospital of York

January 14, 2000

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

Dear Ms. Mitchell:

As the Chief Executive Officer of a 90-bed freestanding rehabilitation hospital in York, Pennsylvania, I would like to emphasize the importance of Act 68 regulations upon hospital systems and the patients whom we serve.

Hospitals faced with declining reimbursement coupled with inappropriate or unreasonable denials of payment are finding increasing difficulty in maintaining quality of care for those patients whom we serve in the communities in which we live. It is of vital importance to implement regulations which increase managed care accountability. Effective implementation of Act 68 can benefit patients by fostering greater coordination and cooperation among health plans and health care providers.

The Department of Health should be commended 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 practices;
- Requiring that all definitions of medical necessity by a health plan be the same across all documents (e.g., marketing literature, patient handbook, provider contracts, etc.) to ensure uniformity and consistency of medical decision making; and
- Enabling managed care plans to create mechanisms for routine procedural errors and denials to be addressed between the plan and the provider without the need for enrollee consent.

Please consider the following comments:

- The definition of inpatient services as defined for a hospital should not include skilled nursing facilities. Care provided in a skilled nursing facility is entirely different from inpatient services and should be defined as such. Skilled nursing care is not substitutable for inpatient acute or rehabilitation.
- The regulations should more broadly define PPOs, gatekeeper and passive (silent) PPOs.

1850 Normandie Drive • York, PA 17404 • 717 767-6941 • Fax 717 764-1341

Mitchell, Stacy

From: comerr@chplink.chp.edu
Sent: Tuesday, January 18, 2000 4:24 PM
To: samitche@health.state.pa.us
Subject: Comments on Proposed Regulations for Act 68

January 18, 2000

Ms. Stacy Mitchell
Director
Bureau of Managed Care
Pennsylvania Department of Health
Room 802
Health and Welfare Building
Harrisburg, PA 17120

Re: Comments on Proposed Regulations for Act 68

Dear Ms. Mitchell:

Please accept on behalf of Children's Hospital of Pittsburgh the following comments concerning the proposed regulations for Act 68 .

As you may recall, I contacted you some months ago to express concern that certain Managed Care Organizations ("MCOs") are using Act 68 to avoid paying for medically necessary services provided to their subscribers. These MCO's refuse to recognize a patient consent signed at the time of treatment for a provider initiated grievance. Act 68 comments made it clear that the provider-initiated grievance was created to allow providers access to the grievance process, yet, some MCOs use it to establish roadblocks for providers to receive deserved reimbursements. Even before Act 68, Children's Hospital was able to work with the MCO's in order to provide additional information or clarification that often resulted in overturning initial denials. However, after Act 68, a number of MCOs have taken the position that they will not accept any additional information for reconsideration of denied claims unless a beneficiary consent is dated after the denial. In order to comply with Act 68, we have had patients sign consent forms at the time of in-patient treatment. Treatment was not contingent upon the patient signing the form. When we try to obtain consents after the MCOs refuse to accept the consent we had obtained at the time of treatment, we experience difficulty in locating patients and having the forms returned in time to meet the appeal deadline. These MCOs also will not recognize an appeal as being filed unless the post-denial consent from was attached. As we can not get the form

returned within the thirty day time period, we are effectively precluded from pursuing the grievance and obtaining reimbursement. This inequity is clearly not intended by Act 68.

The proposed section 9.703 implies that the necessary consent may be obtained at the time of treatment. However, unless the regulations specifically state that the "consent may be obtained at the time of treatment" I am certain we will once again waste time and resources with certain MCO's because of their perceived lack of clarity in the regulations. I recall during our telephone conversation that you were concerned about protecting the patients if the provider, after obtaining consent at the time of treatment, chose not to pursue the grievance. You obviously addressed these concerns in the proposed regulations by including requirements that the provider must pursue the grievance to the second level, that the patient may withdraw consent at any time, and that treatment cannot be conditioned upon consent.

The proposed regulations also need to define more specifically the information a MCO must provide as the basis of its denial. Many MCOs refuse to provide the medical criteria that is used in making the utilization review decisions. When asked, they respond that this information is "proprietary". The MCO should specifically provide the criteria that is used to deny the service or the level of service. The regulations should also specifically state that such criteria may be used as tools in decision making but they should not be used as the sole basis for decisions. Further, it is very difficult for patients and the providers when each has provided information to a MCO for prior approval of a procedure received the approval and then, after the treatment is received, be faced with a retrospective denial. MCOs should not be permitted to retrospectively deny previously approved treatments unless the information provided was incorrect or fraudulent.

Also, proposed section 9.602 entitled Inpatient Services includes "skilled nursing" facilities within the meaning of in-patient services. We disagree with the inclusion of the skilled nursing, as such facilities are vastly different from acute hospital in-patient care. Skilled nursing facilities should be defined separately.

Finally, I want to commend the Department for including provisions which should ensure more accountability for managed care such as that all definitions of medical necessity by a health plan be the same. I also want to thank

you for
your time and consideration in this very important matter.

Very Truly Yours,

RHONDA L. COMER
General Counsel
Children's Hospital of Pittsburgh

PENNSYLVANIA HEALTH LAW PROJECT

650 SMITHFIELD STREET, SUITE 2330
PITTSBURGH, PA 15222
TELEPHONE: (412) 434-5779
FAX: (412) 232-6240

801 ARCH STREET, SUITE 610A
PHILADELPHIA, PA 19107
TELEPHONE: (215) 625-3663
FAX: (215) 625-3879
HELP LINE 1-800-274-3258

931 N. FRONT STREET, SUITE 87
HARRISBURG, PA 17102
TELEPHONE: (717)236-6310
FAX: (717) 236-6311

January 18, 2000

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

ORIGINAL: 2079/BUSH
COPIES: Harris
Jewett
Markham
Smith
Wilmarth
Sandusky
Wyatte

Dear Ms. Mitchell:

Attached please find comments to Proposed rulemaking at 28 PA Code Chapter 9, Managed Care Organizations, published in the December 18, 1999 Pennsylvania Bulletin. These comments are submitted on behalf of the Consumer Subcommittee of the Pennsylvania Medical Assistance Advisory Committee, the Philadelphia Welfare Rights Organization, the Consumer Health Coalition, and the Pennsylvania Coalition of Citizens with Disabilities.

If you have any need for clarification or additional information, we can be reached at the numbers above.

Sincerely,

Ann S. Torregrossa
David Gates
Michael J. Campbell
Francesca Chervenak
Alissa Eden Halperin

Comments on the Department of Health Act 68 Regulations filed by the Pennsylvania Health Law Project on behalf of the Consumer Subcommittee of the Medical Assistance Advisory Committee, the Philadelphia Welfare Rights Organization, the Consumer Health Coalition, and Pennsylvania Coalition of Citizens with Disabilities.

Subchapter F. GENERAL

1. 9.602 Definitions

a. **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.**

b. **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. At a minimum, the DOH regulations must maintain the existing standard. They should also establish minimum levels of experience and schooling. 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.

c. 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.**

d. 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.

e. **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.

The two definitions must be reconciled to prevent inconsistencies in licensing, monitoring, enforcement, etc.

f. **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~~**M** manage the utilization of health care services; ~~(B) I~~**I**ntegrates 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.

g. 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.**

h. **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.

2. 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."

3. 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.

4. 9.604 Department investigations.

The Department must be able to investigate information contained in enrollee grievances (whether initaited 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 the 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~~.

5. 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.

SUBCHAPTER G: HMOS

Subchapter G sets forth the criteria that new and foreign HMOs must meet in order to be able to obtain a Certificate of Authority and enroll and provide health care services to Pennsylvania citizens. However, since this Section also sets forth the conditions for ongoing entitlement of a Certificate Authority, many of the provisions impact all managed care organizations in Pennsylvania and give the Department the regulatory basis (or lack thereof) to require corrective action of a plan or threaten a plan with loss of its certificate of authority to operate in the Commonwealth.

DOH Regulatory Changes That Result in Inappropriate Loss of Consumer Protections

The DOH comments to the proposed regulations acknowledge that they revoke many current regulations that are critical to protect consumers and that are consistent with current Pennsylvania law.

A. The proposed regulations eliminate review by DOH of the process of Board selection. This DOH review is important to assure that the Board is composed of individuals capable of reviewing the managed care plan's policies and ensuring its compliance with laws and regulations. In explaining this change, which is not required by Act 68, the Department states, "The Department is proposing to eliminate the requirement that the applicant provide a description of the manner in which subscribers would be selected to the HMO's board. The HMO Act requires that at least one-third of the board be subscribers. The Department is concerned with the outcome of the selection procedure, and not the procedure itself."

Without DOH review of the process or the requirement that managed care plans be balanced and diverse, their Boards can be stacked to represent interests inconsistent with enrollees' basic health care needs. The Board of Directors is ultimately responsible for the policies which guide the plan's operation, including approval of the quality assurance plan, etc. There will not be a good outcome for Board composition, if the process for selection is not an appropriate one.

Furthermore, the DOH regulations should prohibit plan employees from constituting the enrollee Board membership. Plans have done this on numerous occasions to avoid true independent subscriber board composition.

B. The proposed elimination by DOH of a detailed description of the incentives for cost control or a requirement that they be reasonable. If these regulations are approved, managed care plans seeking approval to operate in this state would no longer be required to submit for Department review, "a detailed description of reasonable incentives for cost control within the structure and function of the proposed health maintenance organization." The rationale for this elimination is that " the Department has eliminated these requirements because they have been superseded by requirements in Act 68, or the Department believes they are no longer critical to the review of an applicant." Clearly, the intention of Act 68 was to increase the Department's review of inappropriate financial incentives or disincentives to control costs, not eliminate them. Review of financial arrangements between plans and health care providers to limit utilization were deemed by the General Assembly to be needed more now than ever and are mandated by Act 68.

C. Elimination of the requirement that the HMO provide a detailed description for the position of medical director. The proposed regulations eliminate the requirement that the HMO provide a detailed description for the position of medical director. Instead, the proposed regulations require that the HMO's medical director responsible for overseeing UR and quality assurance activities would be licensed to practice in this Commonwealth, and qualified to oversee the delivery of health care services here. However, it is impossible for the Department to determine if a person in the Medical Director's position has authority to oversee UR and quality assurance operations, without reviewing the job description. Also, the proposed regulations only require that the managed care plan **assure** that the Medical Director is qualified to oversee the delivery of health care services in Pennsylvania. There is no required DOH review of whether this assurance is being put into practice. The justification for this change is that "the Department has eliminated these requirements because they have been superseded by requirements in Act 68, or the Department believes they are no longer critical to the review of an applicant." Act 68 does not require these changes. In fact, the contrary is true. Act 68 mandates greater HMO scrutiny and review. Although it may be preferable to have a Medical Director licensed to practice in this Commonwealth to oversee quality assurance and utilization review activities, it is more preferable that the person: (1) be qualified or have experience in performing these functions; (2) presently live in the Commonwealth or has lived here in recent memory; (3) have a job description which requires him/her to perform these activities; (4) utilize appropriate review criteria for that purpose; (5) is employed for more than 1 hour a year for that

purpose; (6) not have financial incentive bonuses based on decreased utilization; (7) report directly to the Board of Directors, etc. Given the life and death decisions that Medical Director's must make daily, it is critical that there be clear regulatory standards to ensure that physicians filling this position are well qualified, devote appropriate time, utilize appropriate criteria and do not have inappropriate financial incentives.

D. Elimination of the requirement that HMOs provide a procedure for referral of subscribers to non participating specialists. The present HMO regulations require that before a certificate of authority is to be issued by the Department, it must review and approve the procedure for referral of subscribers to non participating specialists. This is critical for consumers, particularly those experiencing health care problems. This is particularly critical given the proposed DOH standard for approval of a network: a plan must have "a network of participating health care providers sufficient to provide reasonable access to and availability of the contracted non-basic health services to enrollees." §9.652(1). This definition is deficient in so many ways. It does not specify (1) what providers and specialists must be available; (2) whether they must include adult and pediatric providers for each specialty; (3) what appointment access standards apply (is it okay to wait a year for an appointment?); (4) how far one must travel for a referral (is it okay to require an enrollee to travel 400 miles across the state for an appointment?); etc.

The justification for this change is that "the Department has eliminated these requirements because they have been superseded by requirements in Act 68, or the Department believes they are no longer critical to the review of an applicant." Clearly, Act 68 does not require this change. Access to appropriate specialty care during a time of need can mean the difference between life and death. Clearly, policies for referrals to specialists not available in plan networks are critical to consumers in Pennsylvania. The elimination of this regulation is unwarranted.

E. Elimination of objective standards for network staffing ratios and qualifications. The Department of Health proposes to eliminate in its entirety, Section 9.76 of the present DOH regulations relating to professional staff standards. This important section includes the PCP/enrollee staffing ratio, overall physician/ enrollee staffing ratios, qualifications necessary for primary care practitioners and Medical Director standards. The rationale given for this is "specific staffing ratios contained in that section are obsolete. Staff model HMOs are no longer prevalent in the industry. Staffing

requirements are dealt with at the individual HMO level through credentialing requirements, and provider network recruiting. The requirements for primary care physicians and health care providers would be incorporated into proposed §§ 9.678 and 9.681 (relating to primary care providers and health care providers). So long as the HMO provides accessibility and access to personnel and facilities in a way that enhances the availability and accessibility of services, and provides for quality assurance mechanisms to ensure the safety of the enrollees, the Department would have no need to dictate staffing in this detail."

To the contrary proposed Sections §§9.678 and 9.681 do not provide the same objective criteria for staffing ratios and qualifications that the present regulations contain. There is a need to establish network/enrollee ratios and standards for all HMO models. More specifically:

i. The present regulations set forth minimum PCP/enrollee ratios that DOH must use to determine network adequacy. The proposed regulations contain no standards. This will lead to wide plan variation, lack of basis for DOH disapproval of network adequacy and a regulatory climate that "anything goes".

ii. The present regulations set forth minimum overall physician/enrollee ratios that DOH must use to determine network adequacy. The proposed regulations contain no standards. This, too, will lead to wide plan variation, lack of basis for DOH disapproval of network adequacy and a regulatory climate that "anything goes".

iii. The present regulations set forth qualifications for a primary care physician, including a requirement that such person practice 50% of his/her time as a PCP and that the person has practiced in this area for the last two years. The proposed regulations contain no such standards.

iv. The present regulations (§9.76(b) set forth standards for the Medical Director, but the proposed regulations are silent on this point, requiring only the name of said person and that s/he be licensed to practice in Pennsylvania. Without such standards, managed care plans can have token Pennsylvania Medical Directors without authority to direct the medical affairs of the plan. Instead these medical affairs can be the responsibility of entrepreneurs, not physicians.

Without some standards for professional staffing, DOH will be unable to direct plan staffing when it is inadequate and will be unable to point to its legal authority to require improvements in plan staffing.

F. Permitting Foreign HMOs to obtain secret waivers of Pennsylvania managed care requirements and to submit a copy of the application submitted in its state in lieu of Pennsylvania's application. The present DOH regulations do not permit any managed care plan, foreign or otherwise to operate in the Commonwealth without a certificate of authority. The proposed regulations continue this, but permit the Department to waive Pennsylvania state requirements without notice in the Pennsylvania Bulletin, opportunity for public comment or a public hearing. It would therefore be impossible to determine if the Department had properly applied the criteria for waiver, because of the secrecy of the process. The regulations should clearly indicate what provisions are not subject to waiver and should include all of the consumer protections, including disclosure requirements, grievance and appeal procedures, emergency services, right to a standing referral, etc. Act 68 does not authorize waivers of the consumer protections and unless the regulations clearly state what cannot be waived, then anything may, with variations from administration to administration. Without clearer standards for non waiver, no waiver should be permissible.

G. Elimination of the requirement that applications to DOH contain a copy of the most current financial statement and the proposed subscriber literature. The rationale for the elimination of this requirement is that this information is to be submitted to the Insurance Department. There are several problems with this. First, the Department of Health has the expertise in reviewing subscriber literature to determine if it complies with Department of Health policies. Second, DOH cannot determine if there is consistency between what the plan says it will be doing for purposes of obtaining a Certificate of Authority and what it is telling its enrollees in enrollee literature. Third, the Department of Health will not have the needed financial statements to determine what the plan has in place with respect to personnel, equipment, offices, etc. as opposed to what needs to be put in place.

H. Section 9.651. HMO provision and coverage of basic health services to enrollees. There are numerous concerns with the proposed changes in regulations.

i. The proposed regulation permits the HMO to exclude coverage for services as are customarily excluded by indemnity insurers (§9.651(b). This is a new provision unsupported by Act 68. Consumers give up access to providers available under indemnity insurance in order to obtain the more comprehensive and preventative service provided by managed care.

ii. the proposed regulations eliminate inpatient physician care and ambulatory physician care as a defined required basic health service. Although the outpatient services mentions medical services, the inpatient services makes no mention of physician care.

iii. the present regulations require that inpatient treatment be available for a minimum of 90 days per contract period or calendar year. The proposed regulations have removed this requirement without statutory justification.

I. Permitting utilization of limited networks for selected enrollees. Section 9.654 of the proposed regulation creates a process for plans to provide limited networks to selected enrollees, without statutory basis. Although such limitation would require DOH approval and would set some conditions, the process is inadequate to protect consumers:

i. The process requires disclosure to enrollees of the limited network. Because approximately 50% of all employees have a choice of only one plan, this notice provision, does not help these consumers avoid unnecessarily restrictive networks.

ii. If the covered service is not available within the limited network, the HMO must provide or arrange for the provision of the service. The wording of this proposed regulation makes it clear that DOH would approve networks without a single provider for a covered service! This proposed regulation would permit the plan to arrange this service without giving the enrollee any choice of provider. The plan could find the lowest price from an ad hoc non credentialed provider and force the consumer to receive services there. Under this proposed regulation if an enrolled child needed cardiac surgery for which their was no network provider, the plan could arrange for the surgery with an adult cardiac surgeon with higher than usual mortality outcomes, and it would have met the requirements of the proposed regulation. The proposed regulation sets no time or distance requirements in arranging this out of network care.

iii. The proposed regulation requires that enrollment is limited to enrollees within a reasonable traveling distance to the limited network providers, but there is no definition of "reasonable traveling distance". HMOs have the lowest penetration in rural areas and could use this limited network to require enrollees to travel long distances in areas with limited public transportation.

iv. The proposed regulation permits plans to allow their network providers to discriminate on the basis of race or payment source. Plans can bid on Medicaid managed care contracts, shield their mainstream providers from serving this population, provide lower provider capitations for higher risk enrollees, etc. This proposed regulation sanctions this behavior.

Through these proposed regulations, DOH not only wants to remove whatever objective standards there are defining adequacy of plan networks necessary for granting of a certificate of authority, but also permit the plan to further restrict access to health care providers by limiting some enrollees to a network that is potentially less than is required to obtain a certificate of authority. DOH is using the passage of Act 68, "the Managed Care Accountability Act" as an excuse to sanction, without statutory authority, procedures which are adverse to consumers. Instead of sanctioning this additional limitation on access, DOH should be prohibiting it.

J. Adverse changes in the plans' external quality assurance assessment. Without statutory authority, DOH has proposed to change the timing and nature of the external quality assurance assessment required of all HMOs in the following manner:

i. Extending the first external review from one year to 18 months. Under the present regulations, each plan must undergo an external quality assurance review within 1 year of obtaining a certificate of authority. DOH proposes to change this to 18 months, because it often takes that long for plans to have the systems in place to obtain any national accreditation. This proposed extension may be a convenience to the plans, but leaves consumers in new, untested plans without any outside scrutiny. In order to receive a certificate of authority, the plans must describe in their application to DOH what they plan to do for quality assurance, grievance, complaints, credentialing, etc. DOH may not do a site visit to determine if the plans has done what it says it planned to do in order to obtain a certificate of authority. There is no readiness review by the

Department. The first assured external review may be the external review entity hired by the plan under this proposed regulation. Instead of the proposed extension of time, DOH should be requiring external reviews sooner.

ii. Reducing the scope of the external reviews for quality assurance assessment The present regulations (Section 9.93(c)(5) require the external reviewer to review a statistically significant sample of medical records. The proposed regulations eliminate this requirement and permit the plan to hire the reviewer, pay the reviewer, and determine the scope and nature of the review. We have seen what can happen if this is permitted to happen. The CHIP contractors were permitted to hire their own external reviewers and determine the scope of review. So few records were examined, that the review had no statistical validity whatsoever.

iii. No uniform review of plans to assure compliance with Act 68, the HMO Act or their supporting regulations. Plans are required to have an external assessment conducted on the "quality of care being provided to enrollees and the effectiveness of the quality assurance program". No further guidance is provided by the regulations on the scope of review. No mention is made of review for compliance with Act 68 or the HMO Act and supporting regulations. The proposed regulations should set forth in detail the scope of the external review. If plans are not reviewed on an ongoing basis for their compliance with Act 68 compliance, some will not comply.

iv. Eliminating the requirement that the report of the assessment go to the plan board of directors. The present regulations require that a copy of the assessment report be issued by the expert in writing to the plan's board of directors. The proposed regulations require that it go to the plan's senior management. It is the Board that is ultimately responsible for HMO policy and it is the Board that should be given the report.

v. No requirement of corrective action, etc. if external review finds serious problems. The proposed regulation requires plans to provide a copy of the external review to DOH within 15 days of receipt. However, it does not require the plan to file a corrective action plan if deficiencies are found.

vi. No public access to external review. There is no requirement that the outcome of the external review be available to the public. To the contrary, DOH does not permit the public access to these assessments. Other health care providers, such as

nursing facilities are required to post deficiencies at the facility in public places and review outcomes are available to anyone on the web. DOH is permitting private entities under contract to the plan instead of state reviewers do external assessment and permitting them to keep the findings secret. There is no assurance that DOH staff will even attend the review.

vii. No assured further external review for 3 years even if serious problems are identified. DOH may in its discretion require a second review before three years, however, there is no regulatory process identifying when this will happen or the process to compel correction. Plans are not required to file corrective action plans. DOH may or may not schedule a site visit to determine if the violations have been corrected. DOH may or may not require another external review earlier than the next scheduled three year review.

With no assured follow-up when problems are identified, limited scope of review and no public disclosure, the external quality assurance assessment provides little protection to consumers. The proposed regulatory changes further weaken an already inadequate external review system.

Other Needed Changes

The following are other shortcomings in proposed language that DOH is seeking:

A. Mandatory site visits prior to granting the Certificate of Authority. Section 9.632(e) states that the Department may visit or inspect the site or proposed site in order to ascertain its capability to comply with the HMO Act and Act 68. Managed care plans need not show any prior experience, proven capacity, etc. as a criterion to receive a certificate authority. Most of the regulatory requirements only ask the entity to describe what they plan to do. It is critical that before a certificate of authority is issued that the Department do a readiness review to determine if the managed care plan has actually done what it planned to do and is in fact ready and capable of managing Pennsylvania citizens' health care. This is all the more critical because the draft regulations propose to extend the time before any external entity visits a plan from one year to eighteen months and the Board of Directors need not be fully in place for one full year.

B. Full Board of Directors in place before enrollments. Although the Department's comments indicate that the Department is proposing to remove the requirement that the board be composed of one-third enrollees within 1 year from the date of receipt of

the certificate of authority, since this is an artificial deadline. The HMO is required to have a board made up of one-third enrollees by the HMO Act (40 P. S. § 1557). The board must reflect the requirements of the act as soon as an HMO has enrollees. However, Section 9.633 of the proposed regulations is inconsistent with the comments. It requires such a Board to be in place within one year of the plan's receipt of the certificate of authority. Because policies (quality assurance, grievance, etc.) which will guide the plan's operation for years are determined when the plan first begins operation, it is critical that the enrollee board members be in place to influence that process. The regulations should make it clear that employees of the plan may not qualify as enrollee board members.

C. No requirement of appropriate medical necessity definitions The Department of Health permits plans to refuse to cover services prescribed by a licensed health care provider based on grounds of medical necessity. However, unlike the Department's previous draft regulations, the Department does not require that that denial be based on accepted medical practice. Section 9.651 permits plans to have unfettered discretion in defining the medical necessity criteria and to have unfettered discretion in applying it. Theoretically, a plan could have a medical necessity definition requiring the service or procedure to be necessary to save the person's life. In that case, the plan could legally deny on medical necessity grounds virtually all of the basic health services listed in Section 9.651.

DOH Proposed Language that Represents Improved Safeguards for Consumers
The following proposed regulatory changes are supported because they constitute an improvement for consumers:

A. Adequate time for DOH to determine what additional information is needed. Section 9.632(c) provides The Department of Health with the additional time to determine what additional information is needed from a managed care plan. The present regulation (Section 9.53(b) only gives the Department 10 days to determine what additional information is needed.

B. Elimination of the practice of deeming applications complete even though the applicant has not provided all necessary relevant information relating to provider

networks (§9.632(d). Obviously, it is critical that the Department have all required information before it issues a Certificate of Authority.

C. Authority for the DOH to require renegotiation of subcontracts between the HMO and subcontractors for delegated duties. As the DOH's comments indicate, " The Secretary has the authority to require renegotiation of provider contracts when they are inconsistent with the purposes of the HMO Act). Subsection (a) would ensure that the Department is able to carry out its responsibilities under the HMO Act. "

D. Elimination of confusing copayment language. The proposed elimination of the confusing copayment language is positive. However, the proposed language in Section 9.653 permits consideration of not only copayment but coinsurance. Approval of coinsurance is not authorized by statute. Language should be added that DOH's consideration of whether the requests to charge copayments would detract from availability, accessibility or continuity of services, the Department will be from the economic position of the lowest wage enrollee in the plan.

E. Review by the DOH of point-of-service options. Section 9.656. sets forth DOH standards for approval of point-of-service options by HMOs. DOH's comments state that " the Department has a responsibility to monitor POSs to ensure access and availability of provider networks to enrollees" and recognizes that "the issues that could arise with POS plans would be the same as those that could arise from limited networks. There is the possibility that the primary care provider would perform an inadequate job of gatekeeping, so that enrollees would be forced to choose the higher-out-of pocket option. This situation would defeat the purpose of managed care, and would raise questions of violations of the HMO Act. " However, the proposed regulation solely sets forth the assurances that plans need to make to obtain approval for a new point of service product. They do not establish a monitoring mechanism to determine if such access problems exist or if plans are complying with the required procedures and taking corrective action if there appears to be access problems.

Subchapter H: Availability and Access

1. §9.672 Emergency services

Generally, the revisions to §9.672 Emergency services are positive. Among the good parts of this section are §9.672(b) which prohibits denial of claims for lack of prior authorization of emergency services, §9.672(d) which includes ambulance services as emergency services, and §9.762(e) which prohibits a plan from requiring the use of a particular ambulance service in an emergency. These are all areas in which the proposed regulations should be supported.

Section 9.762(c), states that "a plan shall apply the prudent layperson standard...in adjudication related claims for emergency services." This should read "in adjudicating" instead of "in adjudication" and, additionally, the term "related" in the regulation is unclear. "Related" to what? The term should be eliminated.

2. §9.673 - Prescription drugs

The disclosure of the effect of a formulary provision and the provisions relating to the exceptions process in §9.673 "Prescription drugs" are positive aspects of the regulations that benefit the enrollees and embody the intent of the General Assembly. However, the 30 day time period for a plan to respond to enrollee requests regarding coverage of a specific drug found in §9.673(b) is too long. While a time limit is new and positive for enforcement purposes, 30 days seems a long time to give the HMO to respond to a simple question. This is especially true in light of the effect so long a wait could have on an enrollee's health should their treatment have to be delayed 30 days while they await the plan's reponse. The present rule in most HealthChoices Contracts is that plans must respond to providers' prior authorization requests within 24 hours. A similar time frame is appropriate for plans to respond to enrollees, especially where the question involves no review of requests, etc. and merely a phone call with information the plan should have easily accessible.

3. § 9.674 - Quality Assurance Standards

The quality assurance standards of § 9.674 are weak and ineffective. According to the regulations, health plans are required to have a QA process. However, the regulations establish no specific standards or outcome measurements. They do not even suggest a rough framework from which plans can craft quality assurance outcome measurements. The regulations indicate that so long as the plans have a process in place and follow that process, the Department will not look to see if the process actually results in quality care. The Department is held to insure that the requirements of the

Act are met. Quality Assurance is imperative to insuring quality health care delivery to all enrollees. The delivery of quality health care was the purpose of Act 68 and the General Assembly intended the Department lay the foundation for insuring the delivery of quality health care.

Specifically, plans must have a QA plan and these quality assurance plans must be reviewed and accepted by the Department as satisfying standards that will insurance quality health care. The Department must establish QA standards with which the plans QA plans must comply. Each plans' 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, mechanisms to inform providers and enrollees of updates and changes, participation of providers and members in the QA process, 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, and fair utilization standards that will be applied consistently, equitably, but yet with attention to the needs and health of the individual. Another important factor is that the Quality Assurance plan must 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. Also the QA plan must include a focus on the delivery of services to special populations. The Department must evaluate each plan's quality improvement efforts for effectiveness on an annual basis and make the results of that evaluation public.

Accordingly, the proposed section should be changed as follows:

§ 9.674. Quality Assurance Standards

The quality assurance plan must include regularly updated standards for health promotion, early detection of disease and injury prevention for all ages and 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.

(a) 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.

(b) 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.

(c) 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.

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

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

a. Be applied consistently and equitably;
b. require that the member's specific individual health status be taken into account;
c. be based on sound clinical and scientific evidence;
d. be made under the direction of the plan medical director;
e. be current, subject to input from plan providers and made known to plan providers;
f. not have financial or other incentives that adversely affect quality of care;
g. 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 and provides for q quality health care for enrollees of all ages, including those with chronic health care conditions.

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

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

(n) Include coordination requirements to behavioral health care and 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.

4. § 9.675. The delegation of medical management

The delegation of medical management provisions at § 9.675 must be revised. Section 9.675(a) has been revised to require that the plan get approval from the Department for any contract to delegate medical management. Additionally, §9.675(c) has been revised to prohibit compensation to contractors performing medical management from including incentives to deny payment for services. These are valuable revisions to the regulations.

Section 9.675(d), however, has not been revised from the first draft and must be revised before the regulations are finalized. This section lists the requirements for plan oversight of any medical management contractor. The list of requirements fails to insure oversight or compliance with the Act by failing to require the contractor to report to the plan on a monthly basis, rather than quarterly, and by failing to require the random sampling that the plan must perform to occur annually or to include enough people to have validity.

5. §9.676 Enrollee Rights and Responsibilities.

The standards for enrollee rights and responsibilities in § 9.676 do not meet the requirements of the Act. Section 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 Department proposes to require that plans provide: "(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 providing instructions to non-English speaking enrollees on how they can obtain the information "in an alternative format." We also believe that federal law requires more.

The Department appears to have eliminated most of the specifics regarding disclosure of information to enrollees and prospective enrollees because these matters are to be covered in the Insurance Department regulations. The disclosures are a crucial part of the Act. It is important that the Departments work together to insure that between the two of them, regulations governing and detailing all the disclosures mandated by the Act are promulgated. Additionally, with respect to the rights of non-english speaking enrollees, the Insurance Department's most recent incarnation of regulations indicated that it also did not intend to require plans to provide information to non-english speaking individuals. The DOI based this on the grounds that most plans usually have some mechanism in place for dealing with the non-english speaking population and thus, regulations were not necessary. This is a prime example of why it

is essential for the Health & Insurance regulations to be promulgated and considered by the IRRC at the same time.

6. §9.677. Medical Necessity

The Medical Necessity provision of Section § 9.677 has been negatively revised since the prior draft of the regulations and must be returned to the original proposed language. 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! The language provided a level of fairness and uniformity that must be added to the proposed regulations.

Additionally, the Department must revise the regulations so that plans are required to 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 in making their medical necessity determinations.

7. § 9.678 Primary care providers

Section § 9.678 is unduly confusing and must be clarified. Section 9.678(c) states that a plan "MAY consider a physician in a nonprimary care specialty as a primary care provider". This provision fails to mention that under the Act plans are required to allow specialists to serve as PCP for certain enrollees (§2111(6)(II) of the Act). This requirement is mentioned elsewhere in the regulations at §9.683 but the failure to include it here renders these provisions unnecessarily confusing. Plans **must** consider a physician in a nonprimary care specialty as a PCP for certain enrollees. At a minimum, a reference to §9.683 would be useful.

8. §9.679 - Access requirements in service areas

The access requirements in service areas of § 9.679 are too vague. The initial draft of the Department's regulations required plans to "ascertain participating providers', ... ability to provide ...care" as part of provider recredentialing. Now the regulations require plans to "demonstrate at all times that it has an adequate number and range of health care providers....". The initial draft was vague to begin with and the revised version is worse. The Department must establish standards for access requirements and specify the access requirements that may differ with the circumstances. For example, the Department has failed to address issues surrounding urgent care access. Urgent care appointments must be available within 24 hours.

Appointments for prenatal care should not have waiting times in excess of 30 days. In no case should other appointments have waiting times greater than 45 days.

9. §9.680 Access for Persons with Disabilities

We urge the Department to make it clear in the regulations that it will review "the policies, plans, and procedures" mandated by the Act and the proposed regulations, to determine the adequacy of these policies, plans and procedures and that the department shall impose sanctions upon those plans whose policies, plans and procedures are inadequate or are not followed.

10. §9.681 Health Care Providers.

Section 9.681(d) states that a "plan shall have written procedures governing the availability and accessibility of frequently utilized health care services..." The services listed are basic services that every HMO is required to provide such as well patient exams and emergency care. The purpose of this section, which did not appear in the initial draft of the regulations, is puzzling. If this provision implies that plans may impose some limits on the availability and accessibility of these services, it is extremely troubling. The provision must be clarified and availability and access to such basic services must be assured.

11. § 9.682. Direct access for obstetrical and gynecological care

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

The proposed regulation contradicts the Act to the extent that it, like the DOI proposed regulations seek to limit the direct access to ob/gyn services called for in Act 68. Act 68 does not place any limits on the direct access, whether for "routine" or other

care. The General Assembly sought to provide and assure insureds unobstructed access to this important service. If it had wished limits to be placed on this access, if would have so indicated.

12. §9.683 - Standing referrals or specialists a primary care providers

Section 9.683 on standing referrals or specialists as primary care providers contradicts the Insurance Department's proposed regulations which were recently withdrawn. DoH's regulations 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 proposed regulation is far more detailed than that of Insurance regarding the process for deciding whether an enrollee can get a standing referral or specialist as PCP. Once again, an example of why the DoH and Insurance regulations should be considered at the same time.

13. § 9.684 - Continuity of Care

Here again, in addressing continuity of care, DoH has issued regulations that are in conflict with regulations proposed by Insurance. DoH's regulations require the plan to notify patients of the right to continuity of care, or even just the fact of termination when plans terminate a provider; Insurance's do not. The Department of Health has recognized the importance of insuring that enrollees are notified when their providers are being terminated. The regulations must be consistent. Yet another example of why the DoH and Insurance regulations should be considered at the same time.

Subchapter I. Complaints and Grievances

The Subchapter establishes a two tiered internal review process for complaints and grievances and imposes requirements governing the internal process, the external review process and alternative provider dispute resolution. In some areas, the proposed regulations represent a step backwards from pre-Act 68 requirements in protecting the rights of enrollees to a fair internal review. In some areas, the regulations simply need to be strengthened to meet the remedial intent of the Act. In others, the regulations must be amended because they conflict with Act 68.

Of particular concern is the failure of the regulations to grant consumers the right to access information within the plan's possession in cases involving denial or reduction of services. This would include: i) identifying and specifying the credentials of whomever made the decision; ii) identifying the documents or discussions considered in reaching the decision; and iii) allowing the enrollee to review and obtain copies of the documents, in preparation for a complaint or grievance review.

Within the review process, certain fundamental protections are lacking, including: i) a requirement that plans clearly articulate the reasoning behind decisions to reduce or deny services (we continue to see "not medically necessary," with no explanation of what was considered, accepted or rejected); ii) a prohibition against a plan changing its reasons after the review process has begun (leaving the enrollee unable to respond to a moving target); and iii) a requirement at the second level review that plans make available (in person or by telephone) those persons involved in the decision.

Comments not specifically addressed to the language of a proposed regulation below (because they address matters not in the proposed regulations) are:

There should be provision for an expedited review process for matters which do not involve issues of medical necessity, but which, if not resolved more quickly than under the review process outlined in this Subchapter, would jeopardize the enrollee's life, health or ability to regain maximum function. Our reading of the regulations is that it limits expedited review to grievances. A current case in our office demonstrates the problem with this approach. Our client is quadriplegic, on a respirator and in need of significant nursing assistance. After providing nearly two years of in home nursing, his HMO notified him that his services are considered custodial, and will be discontinued. The issue is one of coverage not medical necessity. Similar cases have involved denials of care because the treatment was considered "experimental."

Under the pre-Act 68 DOH Operation Standards, disputes regarding denials of care which was alleged to be necessary and pressing were required to be decided by the

plan in 48 hours, regardless of whether the issue was one of medical necessity. This enrollee protection needs to be included in the DOH regulations. We do not view Act 68's specific inclusion of an expedited grievance process as precluding the Department from imposing a similar expedited complaint process in limited circumstances, consistent with its responsibilities for quality and oversight of the complaint and grievance process.

The regulations need to articulate clear requirements for accommodation of enrollees who do not communicate in English, who face other barriers to equally accessing the complaint/grievance process. This would include among other things, translation of all notices and the provision of trained interpretation services throughout the complaint/ grievance process.

1. **9.702 Complaints and Grievances**

a. §9.702(a)(2) prohibits administrative procedures, time frames, or tactics that discourage the enrollee from or disadvantage the enrollee in using the procedures. This is a positive general statement. However, certain specific protections are necessary and should be guaranteed by regulation.

We suggest adding the following to (2):

> Procedures must assure the enrollee's right to: i) the opportunity for timely advance review his or her plan file, and copies of plan records or documents relating to the matter in dispute, whether or not they were relied upon by the plan in reaching its decision, ii) the identity and credentials of whomever participated in a decision to reduce or deny services, and iii) the opportunity to question plan employees or contractors whose actions or inactions are at issue at the second level review.

b. §9.702(a)(3) requires that copies of complaint and grievance procedures be submitted to DOH for review and approval. It is important that DOH review these procedures in advance, and this provision is therefore positive. However, there needs to be a mechanism for addressing the fairness of a plan's procedures as applied to an individual specific complaint or grievance in real time. Enrollees whose right to a fair internal review of their problem has been impeded by a plan's application of its procedures, have no process for addressing the problem in a timely manner. For example, an enrollee client who complained that her plan did not act in a timely manner on a request for services was refused access to information in her plan's possession (the plan's phone log of her calls) which she needed to prepare a second level grievance. Similarly, the plan refused to identify who made the decision to deny her wheelchair, or the credentials of that individual, despite her Act 68 right to have the decision rendered by a properly credentialed individual. She has no forum for raising this issue internally, nor is it clear that even the external review entity can or would address this issue.

c. We recommend adding the following:

> (4) Enrollees who believe that a plan's administrative procedures, time frames, or tactics are being applied in such a way as to discourage the enrollee from, or disadvantage the enrollee in using the procedures, may contact DOH at (insert phone #). DOH will immediately review the matter and issue a determination, binding on the plan, whether the procedure is noncompliant or creates unacceptable burdens.

d. §9.702(b) requires that a plan immediately correct procedures found noncompliant or creating unacceptable administrative burdens. This is positive and should be retained.

e. §9.702(c)(1) Requires that classification of an appeal as complaint or grievance cannot have intent to adversely affect or deny the enrollee's access to the process. The words "or result in," should be added after "intent to," the word "affect" should be changed to "affecting" and the word "deny" should be changed to "denying." Otherwise, the Department can move to correct situations only where there has been deliberate action by the plan.

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f. §9.702(c)(3) provides that as enrollee may contact the plan if there is a disagreement re: classification. The enrollee will not know of this right unless the plan informs him/her. Therefore, we recommend adding a sentence under § 9.704 (c) (1) (i) as noted below.

g. §9.702(c)(6) provides that DOH will monitor reporting of complaints and grievances, and <u>may</u> audit or survey to verify compliance. Auditing or surveying should be a regular part of the monitoring process rather than an option. If the option is retained, standards should be articulated as to when an audit or survey should occur.

2. 9.703 Health care provider initiated grievances.

a. This regulation imposes important protections, which need to be retained.

3. 9.704 Internal complaint process.

a. §9.704(a) provides that a plan's internal complaint process must comply with § 2141 of the Act and be acceptable to the Secretary, and (b) requires the plan to permit an oral or written complaint by enrollee. The right to complain should be extended to former and potential enrollees, who have contractual and legal rights for which there may be no other recourse but to file a complaint. (For example, a former member may seek payment for a service provided during a period of enrollment, which the plan

denied as not covered. Likewise, a potential enrollee might seek information about network limitations.)

b. §9.704(c)(1) sets out procedural requirements for the first level complaint review. There is frequent confusion about whether an enrollee's initial contact with a plan constitutes an inquiry, a complaint, or a grievance. Requiring acknowledgment from the plan would establish the date of receipt for purposes of monitoring compliance with the Act's timelines, clarify the plan's characterization of what it is reviewing for the enrollee, so that the enrollee can turn to DOH if a disagreement exists. We recommend the insertion of the following new section, with a renumbering of existing sections:

> (i) Upon receipt of a complaint, the plan must confirm its receipt in writing, and indicate the date received, the plan's understanding of the substance of the complaint or grievance, and the method of contacting DOH if the enrollee disagrees with the classification of the complaint or grievance, or believes that the administration of the process adversely affects or denies the enrollee's access to the process.

c. §9.704(c)(1)(ii) provides that an enrollee must be permitted to provide written data or other materials in support of a complaint, and can specify the remedy being sought. The enrollee is often in the dark as to what the plan has looked at or will look at, and has no idea what new materials would be responsive or complementary to what the plan has gathered. In the interests of fairness and sharing information in order to focus the issues and resolve them at an early point, we recommend adding a new section and renumbering:

> (ii) The enrollee must be permitted to review the file and records of the plan as they relate to the matter at issue, and the plan shall produce and provide copies of related documents, including documents kept electronically, at no cost to the member.

d. §9.704(c)(1)(iii) provides that the plan must complete its review and investigation within 30 days. However, the regulations leave a gap of indeterminate length between the completion of the investigation and the reaching of a decision. To address this problem, we suggest you add, after "complaint,": "and reach its decision..."

e. §9.704(c)(1)(iv) requires notification of a decision within 5 business days, including the basis for the decision and appeal procedures. We recommend the addition of a second and third sentence:

> The basis for the decision shall be detailed, and shall recite what information or documents were considered; what, if any arguments were accepted and rejected, relevant contract provisions, and the reasoning for accepting or rejecting the various arguments. The plan may not base a decision against the enrollee on any reason not raised in an initial decision.

This forces the plan to evidence having done more than rubber stamp its previous decision, and it prevents the unfair situation in which the enrollee has successfully addressed the plan's rational for taking an adverse action, as articulated in the initial determination, but loses because the plan has developed a new, previously unarticulated reason for denial. This approach is fundamental to an honest process.

f. §9.704(c)(2) sets forth the second level review process. §9.704(c)(2)(i) establishes the composition of the committee as 3 or more individuals who were not involved in the first level review. The language of the proposed regulation tracks the statute. However, this sets a minimum standard which the department can and should exceed. As written, the regulation would allow the same persons(s) who made the initial decision to make the second level review decision. We suggest that you change "in the first level review" to "with the initial matter being complained of..."

g. §9.704(c)(2)(i) also provides that one third of the membership must not be employees of the plan. Fundamental fairness standards formerly adhered to by the plans required that the non-employee also be an enrollee. We recommend that you reimpose this minimal fairness requirement by inserting after "shall" "be enrollees who are..."

h. §9.704(c)(2)(ii) requires the plan to notify the enrollee in writing of the right to appear. The requirement does not specify an advance notice requirement. Members need sufficient advance notice to arrange work schedules, assure availability of witnesses and representatives, etc. This is particularly important since under the regulations as written, a member has no mechanism for raising an objection with DOH if a plan is not flexible or accommodating in its scheduling. We recommend imposing the 15 day advance notice requirement recommended by the DOH workgroup, by inserting after "writing'" ", at least fifteen days prior to the review hearing."

i. §9.704(c)(2)(ii)(A) requires the plan to provide reasonable flexibility in time and travel distance. DOH needs to set standards for travel time. Otherwise, DOH has no basis for determining the reasonableness of the travel distance. The 20/20 and 30/30 rule that applies to access to PCPs seems appropriate, with exceptions if the enrollee's condition or other factors warrant a shorter time or distance.

j. §9.704(c)(2)(ii)(C) states that attendance at second level is limited to enrollee, representatives, witnesses, appropriate plan representatives, and members of the committee. An enrollee should be able to bring other individuals to the second level review so long as the process is not disrupted. Enrollees often wish to bring a friend or relative, or need to bring an attendant.

k. §9.704(c)(2)(ii) leaves out a host of provisions necessary to assure that the enrollee has a full and fair chance to present his or her issue. We recommend the addition of the following provisions:

> (D) The plan shall permit the member to review the file and records of the plan as they relate to the matter at issue, and the plan shall produce and provide copies of related documents, including documents kept electronically, at no cost to the member.
>
> (E) The plan shall identify, state the position, if any, relative to the plan, and provide the qualifications of any individual who rendered the decision, if any, under review.
>
> (F) The plan shall permit the member to request the presence of plan employees, and the plan shall assure the presence of plan employees at the review for questioning by the member.

l. §9.704(c)(2)(iv) provides that deliberations, including the enrollee's comments must be transcribed or summarized. It is not just the deliberations, but the entire hearing which needs to be transcribed. This is the only record which DOH or DOI will have to review if the matter is appealed, and testimony of the enrollee and witnesses will not otherwise be recorded. Furthermore, transcription is necessary, since otherwise, the mischaracterization of the events to the advantage of the plan (even if unintentional) is inevitable. The member should also be guaranteed the right to personally record or have the hearing transcribed. (One health plan explicitly forbids members from recording the second level review.) Otherwise, the member has no ability to rebut the plan's characterization of the testimony. We suggest that you change the language to:

> (iv) The second level hearing, including the deliberations of the second level review committee, shall be transcribed verbatim. The enrollee shall have the right to record or transcribe the hearing. All documents and other physical evidence submitted by the member shall be maintained as part of the appeal record.

m. §9.704(c)(2)(v) requires the plan to complete the second level review within 45 days of receipt of request. We suggest that after "review," add "and reach a

decision..." Otherwise, there is an undetermined period between the completion of the review and the issuance of the decision.

n. §9.704(c)(2)(vi) requires notification to the enrollee within 5 days. We recommend that you add, after "enrollee," and the enrollee's representative, if any... Notification frequently goes out to one or the other but not both, even at different times in the same case. The addition would represent a minor imposition on the plan which is especially necessary for enrollees who depend on others for assistance in the process.

o. §9.704(c)(2)(vii) requires the plan to include the basis for the decision, and the appeal process, and send it in such a manner as to document the enrollee's receipt. We recommend that you add a second and third sentence: "The basis for the decision shall be detailed, and shall recite what information or documents were considered; what, if any arguments were accepted and rejected, relevant contract provisions, and the reasoning for accepting or rejecting the various arguments. The plan may not base a decision against the enrollee on any reason not specifically raised in the first level review decision." This forces the plan to evidence having done more than rubber stamp the previous decision, and it prevents the situation where the enrollee has successfully rebutted the plan's reasoning for taking an adverse action as articulated at the first level review, only to lose again based on a new denial theory that the plan has developed.

p. If an enrollee fails to observe the timelines imposed by the regulations or the statute, he or she is without a method of redress. However, a plan may disregard time frames with impunity under these regulations. We recommend the addition of a new provision:

> (d) If the plan fails to act within the time frames established herein, the relief sought by the member shall be granted automatically by the plan.

q. The currently proposed §9.704(d) gives the DOH address for purposes of this section. DOH should devote toll free telephone, fax and TDD numbers for the taking of such appeals.

4. 9.705 Appeal of a complaint decision.

a. §9.705(a) provides that an enrollee has 15 days from receipt of second level decision to appeal in writing to DOH or DOI. Consistent with the previous comment, accommodation must be made pursuant to the ADA.

b. §9.705(b) sets forth requirements for a proper appeal of a complaint. We recommend that you change the word "shall" to "should." Minor omissions are bound to occur, and the effect of the regulation should not be to penalize the enrollee by throwing out the appeal when this happens.

c. We recommend that you also add the following provision to the introduction: The Department will assist enrollees to identify and gather any of this information and material as is necessary to proceed with the appeal. The list of mandatory items to be included with the appeal (particularly copies of all correspondence from the plan) is too burdensome, especially for enrollees who are frail or have some level of cognitive impairment. The department should provide guidance for such individuals in the absence of an ombudsman.

d. §9.705(d) provides that upon verification that the appeal is timely, DOH will request the complaint file, which shall be forwarded within five days. There is no indication of what the complaint file is supposed to contain. The minimum contents should be listed. Also, there should be a requirement that the plan provide the case file to DOH, with a copy to the enrollee, without a request.

e. §9.705(e) provides that the plan and enrollee may provide additional information for review as appropriate. We recommend the addition of a requirement that both the plan and member provide simultaneous copies of any additional information to one another.

f. §9.705(f) requires that both the DOI and DOH will determine the appropriate agency for review. There should be a process, with time frames, for reaching the determination and communicating it to the parties. We are aware of one case under the HMO Act in which a matter went undecided for months while the two departments decided which should take jurisdiction.

5. 9.706 Enrollee and provider grievance system.

9.706 Sets forth regulatory requirements for the grievance process.

a. §9.706(b) establishes that the enrollee or provider, with written consent, may file a written grievance. We recommend a requirement that the plan accept oral grievances and reduce them to writing. Federal Law requires reasonable accommodation for enrollees for whom the requirement of a writing poses a barrier. Beyond this, however, many enrollees cannot read or write. We believe that the Act 68 requirement of a writing is met, and enrollees are best served, if the plan reduces an oral grievance to writing.

b. §9.706 (c)(1) establishes the process for the first level review. It generally follows the first level complaint process, except that decision can go to enrollee or provider, and must include the clinical rational for the decision. The comments here will repeat many of the comments made above. We recommend the insertion of the following new section, with a renumbering of existing sections:

> (i) Upon receipt of a grievance, the plan must confirm its receipt in writing, and indicate the date received, the plan's understanding of the substance of the grievance, and the method of contacting DOH if the enrollee disagrees with the classification, or believes that the administration of the process adversely affects or denies the enrollee's access to the process.

c. §9.706 (c)(ii) provides that an enrollee must be permitted to provide written data or other materials in support of a complaint, and can specify the remedy being sought. The enrollee is often in the dark as to what the plan has looked at or will look at, and has no idea what new materials would be responsive or complementary to what the plan has gathered. In the interests of fairness and sharing information in order to focus the issues and resolve them at an early point, we recommend adding a new section and renumbering:

> (ii) The enrollee must be permitted to review the file and records of the plan as they relate to the matter at issue, and the plan shall produce and provide copies of related documents, including documents kept electronically, at no cost to the member.

d. §9.706 (c)(1)(iii) provides that the plan must complete its review and investigation within 30 days. However, the regulations leave a gap of indeterminate length between the completion of the investigation and the reaching of a decision. To address this problem, we suggest you add, after "grievance,": "and reach its decision..."

e. §9.706(c)(1)(iv) requires notification of a decision within 5 business days, including the basis for the decision and appeal procedures. We recommend the addition of a second and third sentence:

> The basis for the decision shall be detailed, and shall recite what information or documents were considered; what, if any arguments were accepted and rejected, the relevant contract provisions, and the reasoning for accepting or rejecting the various arguments. The plan may not base a decision against the enrollee on any reason not raised in an initial decision.

This forces the plan to evidence having done more than rubber stamp its previous decision, and it prevents the unfair situation in which the enrollee has successfully addressed the plan's rational for taking an adverse action, as articulated in the initial determination, but loses because the plan has developed a new denial theory. This approach is fundamental to an honest process.

f. Act 68 appropriately requires notice to the provider and (rather than or, as stated in proposed §9.706(c)(1)(iv)) the enrollee.
§9.706(c)(2) governs the second level grievance review. §9.706(c)(i) sets forth the Committee makeup. We recommend adding the requirement that at least one member be a non-employee plan member This is consistent with previous guidelines, and at least places one person on the panel who may share the enrollee's perspective.

g. §9.706(c)(2)(ii) requires the plan to notify the enrollee in writing of the right to appear. The requirement does not specify an advance notice requirement. Members need sufficient advance notice to arrange work schedules, assure availability of witnesses and representatives, etc. This is particularly important since under the regulations as written, a member has no mechanism for raising an objection with DOH if a plan is not flexible or accommodating in its scheduling. We recommend imposing the 15 day advance notice requirement recommended by the DOH workgroup, by inserting after "writing'" ", at least fifteen days prior to the review hearing."

h. §9.706(c)(2)(ii)(A) requires the plan to provide reasonable flexibility in time and travel distance. DOH needs to set standards for travel time. Otherwise, DOH has no basis for determining the reasonableness of the travel distance. The 20/20 and 30/30 rule that applies to access to PCPs seems appropriate, with exceptions if the enrollee's condition or other factors warrant a shorter time or distance.

i. §9.706(c)(2)(ii)(C) states that attendance at second level is limited to enrollee, representatives, witnesses, appropriate plan representatives, and members of the committee. An enrollee should be able to bring other individuals to the second level review so long as the process is not disrupted. Enrollees often wish to bring a friend or relative, or need to bring an attendant.

j. §9.706(c)(2)(ii) leaves out a host of provisions necessary to assure that the enrollee has a full and fair chance to present his or her issue. We recommend the addition of the following provisions:

> (D) The plan shall permit the member to review the file and records of the plan as they relate to the grievance, and the plan shall produce and provide copies of related documents, including documents kept electronically, at no cost to the member.
>
> (E) The plan shall identify, state the position, if any, relative to the plan, and provide the qualifications of any individual who rendered the decision, if any, under review.

> (F) The plan shall permit the member to request the presence of plan employees, and the plan shall assure the presence of plan employees at the review for questioning by the member.

k. §9.706(c)(2)(iii) provides that deliberations, including the enrollee's comments must be transcribed or summarized. It is not just the deliberations, but the entire hearing which needs to be transcribed. This is the only record which DOH or DOI will have to review if the matter is appealed, and testimony of the enrollee and witnesses will not otherwise be recorded. Furthermore, transcription is necessary, since otherwise, the mischaracterization of the events to the advantage of the plan (even if unintentional) is inevitable. The member should also be guaranteed the right to personally record or have the hearing transcribed. (One health plan explicitly forbids members from recording the second level review.) Otherwise, the member has no ability to rebut the plan's characterization of the testimony. We suggest that you change the language to:

> (iv) The second level hearing, including the deliberations of the second level review committee, shall be transcribed verbatim. The enrollee shall have the right to record or transcribe the hearing. All documents and other physical evidence submitted by the member shall be maintained as part of the appeal record.

l. §9.706(c)(2)(iv) requires the plan to complete the second level review within 45 days of receipt of request. We suggest that after "review," add "and reach a decision..." Otherwise, there is an undetermined period between the completion of the review and the issuance of the decision.

m. §9.706(c)(2)(v) requires notification to the enrollee within 5 days. We recommend that you add, after "enrollee," and the enrollee's representative, if any... Notification frequently goes out to one or the other but not both, even at different times in the same case. The addition would represent a minor imposition on the plan which is especially necessary for enrollees who depend on others for assistance in the process.

n. §9.706(c)(2)(vi) requires the plan to include the basis for the decision, and the appeal process, and send it in such a manner as to document the enrollee's receipt. We recommend that you add a second and third sentence: "The basis for the decision shall be detailed, and shall recite what information or documents were considered; what, if any arguments were accepted and rejected, the relevant contract provisions, and the reasoning for accepting or rejecting the various arguments. The plan may not base a decision against the enrollee on any reason not specifically raised in the first level review decision." This forces the plan to evidence having done more than rubber stamp the previous decision, and it prevents the situation where the enrollee has successfully

rebutted the plan's reasoning for taking an adverse action as articulated at the first level review, only to lose again based on a new denial theory that the plan has developed.

o. §9.706(c)(2)(vi) should require that the enrollee be notified of the decision in all cases, even if the provider is pursuing the grievance. Likewise, the prescribing provider should be notified of the review, even if he or she did not personally pursue the grievance. therefore, change "or" to "and" in the last line.

p. If an enrollee fails to observe the timelines imposed by the regulations or the statute, he or she is without a method of redress. However, a plan may disregard time frames with impunity under these regulations. We recommend the addition of a new provision:

> §9.706(d) (add below, although the recommendation comes here for continuity sake.) If the plan fails to act within the time frames established herein, the relief sought by the member shall be granted automatically by the plan.

q. §9.706(c)(3) governs the statutory requirements around reviewer qualifications. §9.706(c)(3)(ii) states that the expert need not attend, but may participate via report. This provision seriously erodes a protection introduced by Act 68, flies in the face of any concept of due process, and should be eliminated. Under the proposal, the expert is provided an opportunity to vote, without seeing or hearing the testimony and other evidence provided by the enrollee. If this recommendation is rejected, any report by an expert should automatically be shared with the enrollee and prescribing provider, without the necessity of a request, written or otherwise.

6. 9.707 External grievance process.

a. §9.707 governs the external review process. As a general comment, the entire process for external review appeal and notification is very convoluted, and should be simplified, wherever possible.

b. 9.707(b)(2) (3) (4) provide that within 5 business days, plan notifies DOH, enrollee or provider and the UR entity that conducted the review, that external grievance review has been filed, and asks DOH to assign a CRE. The plan provides DOH with name, address and phone number of a primary and alternate contact person. We recommend that you change the language to provide notice to the enrollee, and the provider, if the provider is pursuing the appeal. Although the statute establishes a minimum requirement that the provider or enrollee be notified (presumably whichever filed the appeal) it is essential for due process that the enrollee be given notice in any event.

c. 9.707(b)(5) sets out requirements for the request to DOH for assignment of a CRE. The Department should develop a simple form for these appeals, and require that

they be included by the plan with the second level grievance decision, if the decision is not fully favorable to the enrollee. Also, it should be made clear that the member should send along copies of correspondence that are readily available, but that the failure to do so will not be grounds for dismissal of the appeal. The requirement that the enrollee provide copies of any correspondence from the plan will be burdensome for many consumers. The plan is in a better position to provide the correspondence.

d. 9.707(b)(6)(i) - (iv) requires that within 15 days of receipt of external review request, the plan or UR entity that conducted the internal review shall forward to the CRE: the decision, all reasonably necessary supporting information, a summary of applicable issues, and contract language supporting the medical necessity definition. Copies of these documents should be provided to the enrollee, and if applicable, to the provider. The member should know what the plan considered in reaching its decision.

e. 9.707(b)(7) provides that within the same 15 days, the plan must provide the enrollee or provider with a list of items including the remedy being sought by the enrollee. We recommend that you delete the provision requiring the plan to describe the remedy being sought by the enrollee. The enrollee is the one who knows what he/she wants.

f. 9.707(b)(7) provides that within the same 15 days, the plan must provide the enrollee or provider with a list of documents being forwarded to the CRE for external review. As previously noted, the enrollee and provider, if applicable, should get the documents rather than a list.

g. 9.707(b)(8) provides that within 15 days of receipt of a notice of appeal sent by the plan, the enrollee or provider may send additional information to the CRE through the plan. The plan must send it to the CRE expeditiously. The enrollee should be permitted to send the new information directly to the CRE, with copies to the plan. As written, i.e. with no specific time requirements for the plan to forward the information to the CRE, there is unnecessary delay and greater potential for loss of the documents.

h. 9.707(c) and (d) provide that within 2 business days, DOH assigns a CRE and notifies the plan and the CRE, and the plan notifies the enrollee or provider w/i 2 business days of notification. DOH should also notify the enrollee and the provider. As is the pattern here, the enrollee and provider are at the mercy of the plan to provide information.

i. 9.707(e) states that DOH will provide information about the CRE's accreditation upon request. Information about the CRE's accreditation should be automatically distributed, since the enrollee would not know that to request it.

j. 9.707(g) provides that either party has 3 business days from receipt of notice of assignment of CRE to object. A process needs to be defined for objecting, including grounds, and to whom directed?

k. 9.707(h) sets forth rules regarding fees. One provision of Act 68 is omitted. You should add: "If the enrollee files the external grievance and the plan prevails, the plan shall pay all fees and costs associated with the grievance."

7. **9.708 Grievance reviews by certified utilization review entities.**

§9.708 governs grievance reviews by CREs.

a. 9.708(c) provides that the CRE shall review all information considered by the plan, and any other information provided under the regs. You should add "submitted to or" before the word "considered." While a technical point, it is important that information submitted to the plan be made available to the CRE, even if the internal review committees refused to consider it.

b. 9.708(d) requires a CRE decision by 1 or more board certified MDs or DOs, or active physicians or approved licensed psychologists in active clinical practice or in same or similar practice.
The word "or" after "active clinical practice" appears to be a mistake in both the statute and proposed regulation.

c. 9.708(e) provides that CREs must use Act 68 emergency standards definition, and plan def. of medical necessity and emergency. We recommend that you delete "and emergency." The emergency standards definition in the statute contains a definition of emergency.

8. **9.709 Expedited review.**

§9.709 governs the Act 68 mandate for expedited review.

§9.709(a) requires a plan to make expedited review available at any stage of review. We recommend that you add a second sentence: The opinion of a physician or nurse PCP that the enrollee's life, health or ability to regain maximum function would be placed in jeopardy by delay occasioned by the review process in this subchapter, shall be conclusive. Insert, after the word "request" in the current second sentence, "and the plan shall grant..." There is no process for settling disputes over whether, in a given case, expedited review preconditions are met. We propose to follow the Medicare rule, which places this issue in the hands of an examining physician or nurse PCP.

SECTION J: HEALTH CARE PROVIDER CONTRACTS

Oversight of provider contracts by DOH is critical to ensure that (1) the patient/provider relationship is not corrupted by inappropriate financial arrangements which create conflicts of interest between the provider and the patient; (2) the contract does not place direct or indirect restrictions on communications which impair a patient's right to consent to or refuse health care services; and (3) the licensed HMO does not subcontract duties and financial risk down stream to unqualified, unlicensed entities out of reach of oversight by DOH.

Needed Improvements to DOH's Proposed Regulatory Language

1. Section 9.722(e)(2)(7) should be changed to so that plans cannot circumvent Act 68 protections by inappropriately deselecting health care providers at will at the end of the term.

Although the regulations prohibit HMO-provider contracts from containing language which 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 nor any opportunity for health care providers to appeal, if the HMO has sanctioned, terminated or failed to renew a contract for an impermissible reason. This is needed to actualize the consumer/provider protections against plan retaliation set forth in Act 68.

2. Section 9.722(f)(1) should be changed to require not just the method of reimbursement, but the amount and percentage of each method of reimbursement.

The method of reimbursement alone is not instructive. All plans could list "monthly capitation" and "bonus incentive systems" as their method of capitation, but the amounts and the degree to which it corrupted the physician/patient relationship could be very different.

3. Section 9.722(f)(2) should be changed because it permits plans to make inappropriately large payments to providers for low utilization rates.

This proposed regulation would permit plans to offer up to 49% of the total incentive reimbursement for low utilization rates. This permits plans to create an

unacceptable conflict of interest between the health care provider and the patient by sanctioning substantial financial incentives to providers by the HMO to limit care. Although gag clauses are banned by the regulation, these regulations permit substantial financial incentives which will in and of themselves make physicians feel constrained to limit communication with patients about treatment options to protect their own financial interests.

4. Section 9.722(f)(2) should be changed because it permits financial disincentive to serve and treat expensive patients by permitting plans to base economic incentives and disincentives on non-risk adjusted factors.

Financial incentives for utilization performance should be prohibited unless they are risk adjusted. Plans will use these incentives to drive providers who specialize in the treatment of patients with expensive conditions out of their plans for financial reasons. If able, the consumers will follow.

5. Section 9.722(f)(2) should be changed because it does not provide an 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.

DOH should propose an objective standard for public comment that would ensure that the protections in Act 68 and cited in the proposed language are realized and are applied uniformly. (For instance HCFA defines "substantial financial risk which could influence provider judgment" as 25% of potential payments for covered services.)

6. Section 9.724 (a) Permits licensed HMOs to subcontract almost all functions to anyone (and put that entity at risk for providing all health care services instead of the HMO) with the exception that soliciting and enrolling members and the grievance and complaint process can only be subcontracted to any unlicensed person, corporation or other entity.

DOH has no direct regulatory authority over these entities who are performing such important plan functions as credentialing providers, contracting with providers, quality assurance, provision of health services, etc.

Section 9.724(c)(2) permits the unlicensed person or entity to deliver prepaid basic health care services to enrollees and perform administrative services without being required to obtain a certificate of authority. Consumers will enroll with an HMO

unaware that their health care has been subcontracted at full risk to an unlicensed entity that is to provide their care.

There are no standards to determine staffing, adequacy of networks, or any of the other criteria necessary for a certificate of authority. This almost totally unregulated, wholesale transfer of responsibility to unlicensed, potentially unqualified entities should not be permitted and is without statutory authority.

7. Section 9.724(b) contains inadequate penalties for failing to obtain prior approval of an HMO-IDS contract.

This Section does not prohibit such contracts without DOH approval, but suggests that they may have to be renegotiated if prior approval is not obtained.

8. Section 9.724 requires inadequate reporting to the HMO and DOH to ensure that the HMO provides adequate oversight over the operations of the IDS.

If HMOs are no longer at financial risk for the health care services being provided, there is a good chance that they will not adequately monitor the health care being provided under the IDS contract. Similarly, if the IDS is totally at financial risk for the covered lives, it will not want the HMO interfering with utilization decisions, credentialing, etc. This proposed regulation contains inadequate contract reporting requirements. There must be adequate contract reporting with close DOH oversight to ensure that this occurs.

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.

Of great concern is the failure of the regulations to require CREs to actively comply with the Act. The CRE provisions of this subchapter 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 should clarify that without the ability to meet certain requirements and an affirmation that the applicant will meet the requirements, a certificate will not be granted. 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.

Although section 2152 of Act 68 requires that UREs conduct utilization reviews of the health care services being reviewed and provide notice of their decisions within set timeframes, the timeframes are not found in the regulations. 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. The General Assembly believed it important enough to legislate timeframes and they must be followed. **These timeframes are critical to ensure prompt access to health care services and specifying them in the regulations is necessary to ensure health plan compliance.**

1. §9.742 - Certified Utilization Review Entities (CREs).

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. The same must be true for

noncompliance with DOI regulations. Since the Department of Health has assumed the role of certifying CREs and governing their conduct, it must insure compliance with all parts of the Act and all regulations, to the extent that they apply to CREs.

Under this section, 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. Additionally, section 9.742(c) allows a licensed insurer or plan to be a CRE without having to be certified as a CRE. According to the regulations, all a licensed insurer must do is comply with the standards and procedures of §2152. The Act says a licensed insurer must comply with §2151. At a minimum, licensed insurers must be required to comply with §2151 and §2152. What better way to insure compliance than by requiring the licensed insurer to go through the certification process? Insurance companies should be required to get a CRE certification.

2. **§9.743 - Content of an application for certification as a Utilization Review Entity and 9.744 - CREs Participating in Internal and External Grievance Reviews**

§9.744 requires information regarding potential conflicts of interest from applicants who seek to do internal and external grievance reviews but no such information is required under §9.743 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. The regulations do not go far enough to implement the intent of the General Assembly and protect against conflicts of interest in only limited circumstances. Logic dictates that when a truly independent entity renders the initial decision of medical necessity and appropriateness, that decision is more credible and more supportable. All parties face a fair judge and the issue of bias need not be addressed on appeal. Additionally, the enrollee has the right to object to a CRE on the grounds of conflict of interest. The right is meaningless unless the enrollee can access information that reveals conflicts of interest.

Section 9.743 CRE application requires a 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.

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. These terms must be clarified. For example, it must be made clear

that no entity that is participating as a reviewer for DPW fair hearings process, etc can be certified as a CRE.

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 information 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.

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. Such information would be useful to determine whether the URE can become a CRE.

UREs not existing at the time of the regulations cannot become CREs because an 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.

3. **§9.745 - Responsible Applicant**

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 as well as to whether they have been the subject of violations of this Act as set forth in §9.606.

A most troubling aspect of this section is that it fails to establish uniform standards for utilization review by CREs thus breeding inconsistent decisionmaking by the CREs. The Department's Work group recommended that it require 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 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; include standards and

time frames for prior authorization procedures of plans, and include a review of the plans' medical necessity definitions.

4. §9.747 - Department review and approval of certification request and §9.748 - Maintenance and Renewal of CRE Certification

This section does not allow the Department to access the information it needs to determine and insure compliance with the Act and the regulations. 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.**

Act 68 requires the Department to implement the requirement of the Act and thus, the Department must exercise its obligation to oversee the CREs and not dispose of this obligation by substituting accreditation for oversight. 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 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 supply that the applicant or CRE is accredited, but that it complies with the Act. Accordingly, the Department should freely consider that a CRE is accredited in conducting its oversight activities, however, accreditation should not be considered a substitute for the oversight activities. The maintenance and renewal of certification must include on-site inspection.

The Department's review of compliance with the Act and the regulations must include a review of decisions rendered by the CRE. Arguably, in having access to the books, records, staff, facilities, etc., it could be implied that the Department will have access to and will review the CRE's decisions 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 insure compliance with Act 68 and the regulations.

Subchapter L: Credentialling

This Subchapter does not establish uniform standards for credentialling, nor does it prohibit recredentialling based on non-risk adjusted utilization data. Consumers must be able to know what minimal standards providers must meet to be in their network and expect some common criteria from one plan to the next. 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. It must be specified that economics not be a factor.

1. **§9.761 - Provider Credentialing**

No enforcement mechanisms. Section 9.761 requires plans to establish and maintain credentialing systems but does not require plans comply with their credentialing systems. Additionally, there is no DOH oversight of the credentialing systems or process. This is especially troubling in light of the fact that providers denied credentialing are given no administrative mechanism through which to seek DOH review of the plan decisions.

Credentialing is not defined and no minimum elements of credentialing are provided. There is no definition of, or standards for, 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 provider's current licensure, malpractice insurance, education, hospital privileges, etc. Standards must be ascribed. At the least, these bare minimums must be included.

The regulations violate the intent of the General Assembly by deleting the guarantee of direct access to OB/GYN care. In §2111 of the Act, enrollees are to be provided with direct access to OB/GYNs without impediment by plans. In §9.761(a)(8), the Department provides 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. This is contrary to the Act.

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.