Comments of the Independent Regulatory Review Commission

on

Department of Health Regulation No. 10-160

Managed Care Organizations

February 17, 2000

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The Department of Health (DOH) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered by January 18, 2002, the regulation will be deemed withdrawn.

During our review of this proposed rulemaking, the Commission has received considerable legislative comment. Legislative commentators include Senators Michael A. O'Pake, Democratic Caucus Chairman, and Jay Costa, Jr., Democratic Chairman of the Banking and Insurance Committee, and the following members of the House of Representatives: William F. Adolph, Jr., Vice Chairman of the Insurance Committee; Robert E. Belfanti, Jr., Democratic Chairman of the Labor Relations Committee; Dennis M. O'Brien, Chairman of the Health and Human Services Committee; Patricia H. Vance, Vice Chairman of the Professional Licensure Committee; Frank L. Oliver, Democratic Chairman of the Health and Human Services Committee; Leo Trich, Democratic Sub-Committee Chair on Health of the Health and Human Services Committee; H. William DeWeese, Democratic Leader; Michael R. Veon, Democratic Whip; and Anthony M. DeLuca, Democratic Chairman of the Insurance Committee.

Many of the above Members were actively involved in the passage of Act 68. A number of their comments and concerns are included in the Commission's Comments. We suggest the DOH carefully review the comments from Members of the Legislature.

Subchapter F. GENERAL

1. Section 9.602. Definitions. – Consistency with the statute; Clarity.

This subsection contains 39 definitions, which come from Act 68 of 1998 (Act 68) and the Health Maintenance Organization Act (HMO Act). Some of the definitions are identical; some are not. We object to the reiteration of the statutory definitions. Instead, DOH should reference the definitions in Section 2102 of Act 68 or Section 1553 of the HMO Act.

We further object to the following terms, which differ from the definitions contained in Act 68. If DOH does not reference the statutory definitions of these terms in the final regulation, it should justify any changes made to these definitions.

Complaint

The definition of "complaint" mirrors the statutory definition in Section 2102 of Act 68, except that it adds the phrases "by an enrollee" and "including contract exclusions and noncovered benefits."

Emergency service

The definition of " emergency service" differs from the statutory definition in Section 2102 of Act 68. Subsection (ii) deletes the word "emergency," substitutes the word "care" for "service," and adds the phrase "if the condition is as described in subparagraph (i)."

Service area

In the definition of "service area" DOH adds the phrase "**has received approval to operate from the Department**" (Emphasis added) to the definition.

Finally, there are definitions of three terms used in both the Insurance Department final Regulation #11-195 and this proposal that are different. To reduce confusion, definitions of "Gatekeeper," "Gatekeeper PPO," and "Integrated delivery system" should be the same in both regulations. Additionally, we recommend you review the Insurance Department final regulation #11-195 for other terminology inconsistencies.

2. Section 9.603. Technical advisories. – Clarity.

This section provides that "The Department may issue technical advisories to assist plans in complying with..." this regulation, the HMO Act and Act 68. However, the regulation does not address how DOH will notify interested parties that a technical advisory has been issued. DOH should consider publishing in the *Pennsylvania Bulletin* either the advisories or notice of the advisories and instructions for obtaining copies.

3. Section 9.604. Plan reporting requirements. – Clarity.

Subsection (a) Annual Reporting Requirements for Managed Care Plans

Paragraph (a)(2) requires plans to report "Health care services utilization data." This requirement is vague because it does not list the specific type of data that is required.

Paragraph (a)(3) requires plans to submit "Data relating to complaints and grievances." Again, this vague requirement leaves plans without clear direction regarding what information is required. Without targeted reporting requirements, how can DOH determine compliance with this regulation, Act 68 and the HMO Act? In the final regulation, DOH should clarify these reporting requirements.

Paragraph (a)(11) provides that DOH may request other information upon advance notice. This provision is vague because it does not specify the type of information that may be required, or the length of the advance notice period. DOH should either clarify this provision or delete it.

Subsection (b) Quarterly Reports

This subsection requires plans to submit quarterly reports that contain "key utilization, enrollment, and complaint and grievance system data." To improve clarity, DOH should amend the final regulation to specify the data that is required in the quarterly reports.

Penalties for late reporting

This section of the regulation is silent on what penalties, if any, apply to plans which fail to comply with these reporting requirements or to meet the timing deadlines in Subsections (a) and (b). For clarity, DOH should add a cross-reference to Section 9.606. *Penalties and sanctions.*

4. Section 9.605. Department investigations. – Clarity.

Subsection (a) appears to apply to all managed care plans, while Subsections (b) through (e) apply specifically to HMOs. Why are DOH's investigatory powers in Subsections (b) through (e) not applicable to other managed care plans?

5. Section 9.606. Penalties and sanctions. – Clarity.

Subsection (a)(2) references an "injunction to prohibit the activity that violates the provisions." To improve clarity, DOH should specify a violation of the provisions "of Act 68."

Under Subsection (a)(4), DOH may require a plan which has violated Act 68 or this regulation to adhere to a "plan of correction" approved by DOH. A "plan of correction" is also referenced in Section 2182(e) of Act 68. Act 68 does not specify what is to be included in the plan. To improve the clarity of the final regulation, DOH should specify the information that is to be included in a "plan of correction," and define this phrase.

Subchapter G. HMOs

6. Section 9.631. Content of an application for an HMO certificate of authority. – Reasonableness; Clarity.

This section outlines the information that must accompany an application for a certificate of authority under the HMO Act. According to the Preamble, DOH intended to eliminate the following two requirements:

- A description of the manner by which subscribers will be selected and appointed to the board of directors; and
- A detailed description of the HMO's incentives and mechanisms for cost control.

However, these requirements are contained in Paragraphs (1) and (16) of the proposed regulation. Section 1557 of the HMO Act addresses election of board members. Section 1558(a) of the HMO Act address incentives and mechanisms for costs control and directs DOH to review HMO contracts to determine that reasonable cost control measures are included. Consequently, DOH should retain Paragraphs (1) and (16) in the final regulation, and resolve the discrepancies between the Preamble and the text of the regulation.

DOH is also proposing to eliminate the following existing requirements:

- A job description for the medical director (28 Pa. Code § 9.52(16));
- A procedure for referral of subscribers to non-participating specialists (28 Pa. Code § 9.52(17)); and
- Written procedures for payment of emergency services provided by other than a participating provider (28 Pa. Code § 9.52(18)).

According to the Preamble, DOH is removing these requirements because ". . . they have been superceded by requirements in Act 68, or the Department believes they are no longer critical to the review of an applicant." We disagree. These requirements are significant in determining an applicant's ability to operate in accordance with Act 68 and the HMO Act. We request DOH either reinsert them, or explain why they are no longer relevant and provide citations to the sections of Act 68 which superceded these requirements.

7. Section 9.632. HMO certificate of authority review by the Department. – Reasonableness; Clarity.

Subsection (e) states that DOH "may" visit a site to determine its ability to comply with the HMO Act, Act 68 and this regulation. Under what circumstances would DOH determine a site visit is necessary?

8. Section 9.633. HMO board requirements. – Clarity.

Subsection (a) addresses the membership of an HMO's board of directors. However, the requirements contain the following vague phrases related to selection of board members: "undue influence" and "diverse representation of broad segments." These phrases could be open to interpretation, making compliance difficult for HMOs. DOH should clarify the meaning of these two phrases.

9. Section 9.634. Location of HMO activities, staff and materials. – Reasonableness; Clarity.

Paragraph (1) Documents

This paragraph addresses the accessibility of certain HMO documents for DOH review. The documents do not need to be permanently maintained in Pennsylvania, but must be made available in Pennsylvania within 48 hours. We request DOH explain how the 48-hour time period was determined. In addition, did DOH consider using a business day time period, rather than a time period based on hours?

Paragraph (2) Medical Director Licensure

This paragraph requires Pennsylvania licensure for an HMO's medical director when the director is responsible for overseeing utilization review and quality assurance activities for services provided to enrollees who are residents of Pennsylvania. We have not identified any statutory provisions which require Pennsylvania licensure. Some HMOs may have operations in other states as well as Pennsylvania and, consequently, may employ physicians who are licensed in other states. What other factors "qualify" a physician to oversee delivery of health care services? Why is Pennsylvania licensure required?

Also, the proposed regulation references ". . . services provided to enrollees who are residents of this Commonwealth . . . ." It is possible that an HMO could serve enrollees who work in Pennsylvania but reside in a neighboring state. Is it DOH's intent that a separate medical director, with separate licensure requirements, oversee services related to those enrollees? If not, the phrase "who are residents of this Commonwealth" is unnecessary.

Paragraph (3) Quality Assurance/Improvement Committee

This paragraph states, "The HMO's quality assurance/improvement committee shall **include** health care providers licensed in this Commonwealth." (Emphasis added.) It is unclear how many of the health care providers on the committee must to be licensed in Pennsylvania. DOH should clarify its intent in the final regulation.

10. Section 9.635. Delegation of HMO operations. – Clarity.

Commentators have noted that a broad interpretation of the term "HMO operations" could result in a burdensome reporting requirement which could include contracts that are not directly related to the health services provided. If DOH retains this provision, it should define "HMO operations" in the final regulation. Also, DOH should clarify which contracts it will review under the HMO Act (40 P.S. § 1558(a)).

11. Section 9.636. Issuance of a certificate of authority to a foreign HMO. – Clarity.

Subsection (a) Certification of Authority – Foreign HMOs

Under this subsection, DOH may grant a certificate of authority to a foreign HMO if DOH "is satisfied that it is fully and legally organized and approved and regulated under the laws of its state and that it complies with the requirements for HMOs organized within and certified by the Commonwealth." The regulation, however, does not specify what documentation the foreign HMO must provide to "satisfy" DOH. This information should be included in the final regulation.

Subsection (c) Waivers

DOH can waive or modify the requirements under the HMO Act if ". . . the waiver or modification will be consistent with the purposes of the HMO Act, and . . . would not result in

unfair discrimination in favor of the HMO of another state." The proposed regulation, however, gives no detail on how DOH will make this determination. DOH should clarify this provision in the final regulation.

Reciprocity

Section 1556.1(c) of the HMO Act (40 P.S. § 1556.1(c)) authorizes DOH to develop reciprocal licensing agreements with other states ". . . which permit the commissioner and the secretary to accept audits, inspections and reviews of agencies from other states to determine whether health maintenance organizations in other states meet Commonwealth requirements." The proposed regulation is silent on how DOH intends to administer the provision in Section 1556.1(c) of the HMO Act. DOH should include regulatory standards related to this provision in the final regulation.

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

Subsection (a) Provider Networks

This subsection refers to an "adequate network of health care providers . . ." and ". . . basic health services to enrollees as medically necessary and appropriate without unreasonable limitations as to frequency and cost." The terms "adequate," "appropriate" and "unreasonable" are vague. Without more specific standards, how will DOH enforce this provision and ensure compliance with the HMO Act and Act 68?

Subsection (b) Excluded Services

This subsection references services which are "customarily excluded by indemnity insurers." It is unclear what types of services fall into this category and who determines what is "customarily excluded." DOH should clarify this issue in the final regulation.

Subsection (c) Basic Health Services

An HMO must offer certain basic health services according to the HMO's definition of "medical necessity." There are no parameters in the regulation for defining this term. An HMOs definition should be consistent with directives of Act 68, such as medically necessary and appropriate follow-up obstetrical and gynecological care and referrals. DOH should consider identifying the basic components required in the definition of "medical necessity" to ensure an HMO's definition meets the requirements of Act 68.

Subsection (c)(3) requires that an HMO provide inpatient services as a basic health service. The existing regulations at 28 Pa. Code § 9.54(a)(3) require ". . . a minimum of 90 days per contract or calendar year." Although the proposed regulation defines "inpatient care" in Section 9.602. *Definitions.*, it does not include the 90-day standard. Why was this standard removed?

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

Paragraph (1) refers to "reasonable" access. To improve clarity, DOH should define what constitutes "reasonable" access.

14. Section 9.653. Use of co-payments and co-insurances in HMOs. – Statutory Authority; Need; Clarity.

According to this subsection, DOH will review an HMO's request to use co-payments and co-insurances in the HMO's benefit structure, at the request of the Insurance Department. Specifically, DOH will review the HMO's request to see if it would "detract from availability, accessibility or continuity of services and to ensure that the request constructively advances the purposes of quality assurance, cost-effectiveness and access."

We have several concerns with this provision. First, why is it necessary for DOH to state in its regulation that it may perform an inter-agency review on this particular issue? Are there other aspects of an HMO's operations that DOH would review at the Insurance Department's request? If so, what are they and how will these reviews be accomplished?

Second, does DOH have approval authority over an HMO's request to use co-payments and co-insurances in its benefit structure?

Finally, the regulation does not list the criteria DOH will use to determine the impact on "availability, accessibility or continuity of services" or how it will "ensure that the request constructively advances the purposes of quality assurance, cost-effectiveness and access." If DOH is going to review HMO requests in this area, it should alert the regulated community to the standards it will use to make these determinations. These standards should be included in the regulation.

15. Section 9.654. HMO provision of limited networks to select enrollees. – Clarity.

Subsection (a) Limited Subnetworks

To improve clarity, DOH should define this term in Section 9.602. *Definitions.*

Also, throughout Subsections (a) and (b), DOH refers to both "limited subnetworks" and "limited networks." DOH should use a single, defined term consistently in this section.

Subsection (b) Disclosure of Information

In (b)(1) and (b)(3), DOH uses the term "adequate" to describe disclosure of participating provider information to enrollees and the number and distribution of network providers. This term is vague. DOH should provide more specific parameters relating to these provisions. Additionally, DOH should ensure that the disclosure to enrollees in (b)(1) is consistent with the disclosure requirements in the Insurance Department's final Regulation #11-195.

Subsection (b)(4) limits enrollment in a limited network to "enrollees within a reasonable traveling distance to limited network providers." DOH should explain the criteria it will use to

determine what qualifies as a "reasonable traveling distance." Does DOH intend to apply the same traveling distance requirements found in Section 9.679(e)?

16. Section 9.655. HMO external quality assurance assessment. – Clarity.

Subsection (a) External Quality Assessment

HMOs must have an external quality assessment within 18 months of receiving a certificate of authority, and every three years thereafter. According to the Preamble, this time frame was selected to be consistent with " . . . standards of Nationally recognized accrediting bodies." We request DOH identify the "Nationally recognized accrediting bodies."

The assessment must be conducted by an "external quality review organization acceptable to the Department." DOH should publish a list of acceptable organizations or instructions for obtaining a list in the *Pennsylvania Bulletin.*

Subsection (c) External Quality Assessment and Accreditation Review

This subsection permits an HMO to combine the external quality assessment with an accreditation review, " . . . if the review adequately incorporates assessment factors required by the Department. . . ." However, the assessment factors are not contained in the regulation. In the final regulation, DOH should list the specific factors that must be considered as part of the external quality assessment, such as review of a statistically significant sample of medical records.

Penalties

Subsection (e) requires the HMO to file a copy of all interim and final reports on the assessment with DOH. However, there is no indication that penalties may be imposed if reviews disclose deficiencies or violations of Act 68, the HMO Act and these regulations. To improve clarity, DOH should add a subsection which provides that the results of a review may be used for enforcement purposes and cross-references Section 9.606. *Penalties and sanctions.*

17. Section 9.656. Standards for approval of point-of-service options by HMOs. – Need; Clarity.

Subsection (a) Formal Product Filing

This subsection requires an HMO to ". . . submit a formal product filing for a point of service (POS) product to the Department and the Insurance Department." For clarity, DOH should include a cross-reference to the relevant section of the Insurance Department's regulations relating to formal product filings.

Subsection (b)(1) Point of Service Options

Subsection (b)(1)(i) requires an HMO, which offers POS options, to "periodically" inform primary care providers of enrollee self-referrals. Commentators have raised concerns that this

requirement would violate the confidentiality rights of the enrollee. Why is this provision necessary? Also, what is the time frame required by "periodically"?

Subsection (b)(1)(ii) requires an HMO to "promptly" investigate any primary care provider (PCP) practice where enrollees utilize "substantially higher levels of non-PCP referred care than average . . . ." For clarity, DOH should define "promptly."

Also, the standard of "substantially higher levels of non-PCP referred care than average" is vague and could be open to broad interpretations among HMOs. The final regulation should include a more precise standard for HMO investigations of PCP practices relating to non-PCP referred care.

Subsection (b)(2) Disclosure to Enrollees

This subsection requires "clear disclosure to enrollees of out-of-pocket expenses." DOH should clarify what it means by "clear disclosure." Also, the disclosure requirements should be coordinated with the corresponding requirements in the Insurance Department's final Regulation #11-195.

Subchapter H. AVAILABILITY AND ACCESS

18. Section 9.672. Emergency Services. – Consistency; Reasonableness; Clarity.

Inconsistency with Insurance Department Regulations

There are a number of provisions in this section that were not addressed or were inconsistent with the Insurance Department's final Regulation #11-195. Subsection (c) in DOH's regulations states, "A plan shall apply the prudent layperson standard to the enrollee's presenting symptoms and services provided in adjudicating related claims for emergency services." The Insurance Department's regulations require the plan to "pay all reasonably necessary costs...including evaluation, testing, and if necessary, the stabilization of the condition of the enrollee." The DOH regulations, when compared to the Insurance Department's rulemaking, are not as comprehensive. For consistency, DOH should reference Section 2116 of Act 68 in this section to include coverage for all emergency services.

Additionally, Sections 154.14(e) and (f) of the Insurance Department's final Regulation #11-195 are not included, paraphrased or referenced in DOH's regulations. These sections relate to notification to an enrollee's plan of provided emergency services and provide information concerning emergency services to prospective enrollees and health care providers upon written request). Why were these sections not included in the regulation?

Subsection (c) Claims for emergency services

This subsection includes the phrase "adjudicating related claims." This phrase is vague. DOH should explain what are the claims related to.

19. Section 9.673. Plan provision of prescription drug benefits to enrollees. – Protection of the public health; Reasonableness; Clarity.

Subsection (b) Time Period for Written Inquiries

This subsection allows a plan 30 days to respond to a written inquiry from an enrollee regarding whether or not a specific drug is in the plan's formulary. Many commentators assert that a 30-day response period is too long. Why did DOH select 30 days, rather than a shorter response time?

Subsection (d) Distribution of Prescription Drug Benefit Policy and Process

Subsection (d) requires a plan to distribute its policy and process (relating to prescription drug benefits) to participating health care providers. However, Section 2136(b)(6) of Act 68 requires plans to disclose this information to both enrollees and prospective enrollees upon written request. The DOH should add "and enrollees and prospective enrollees upon written request" to this subsection.

Subsection (e) Prescription Drug Benefit Exception

This subsection provides that if a plan does not approve an exception, the enrollee (or health care provider) can file a grievance. Is a grievance always appropriate in this instance? How does this situation qualify as a grievance instead of a complaint?

20. Section 9.674. Quality assurance standards. – Statutory authority; Reasonableness; Clarity.

Standards and Measurements

This section requires all plans to have a quality assurance program. However, the standards of the program, structures, processes, personnel, and measurements are either unclear or absent.

Subsection (b)(4) requires that "[T]he plan's quality assurance structures and processes shall be clearly defined with responsibility assigned to appropriate individuals." This paragraph is unclear. DOH should specify who the appropriate individuals are, what their responsibilities will be, and how those responsibilities are will assigned.

Finally, this section does not include specific measurements to determine whether the quality assurance program has been effective. Plans are only required to have a program in place; they do not need to demonstrate that the program has been effective. We question the lack of any performance standards in this section, and we ask DOH to explain this omission.

Subsection (b)(3) Active Clinical Practice

This subsection includes the phrase "active clinical practice." "Active clinical practice" is defined in Section 2102 of Act 68. For improved clarity, DOH should reference the statutory cite of the term in this paragraph.

Subsections (b)(9) and *(b)(10)*

Subsection (b)(9) requires the plan to provide DOH with "a description of the annual quality assurance work plan, or schedule of activities...for the year." Subsection (b)(10) states "[T]he plan shall present a report of the plan's quality assurance activities annually to the plan's board of directors, and shall provide a copy to the Department." Because the substance of these two paragraphs are very similar, DOH should consider combining Subsections (b)(9) and (b)(10) in the final regulation.

21. Section 9.675. Delegation of medical management. – Statutory authority; Clarity.

Subsection (a) allows the plan to contract with an entity to manage health care services to enrollees, provided "[T]he plan shall submit the medical management contract to the Department for review and approval prior to implementation." We have two concerns with this subsection.

First, the regulation contains no time limit for DOH to review and approve these contracts. For clarity, DOH should include a time frame for their review and action.

Second, this subsection doesn't indicate whether enrollees and providers will be notified when medical management decision-making is delegated. Do medical management companies have a direct impact on the availability, access or quality of an enrollee's care? If so, it would be reasonable to alert an enrollee when medical management decision-making has been subcontracted. DOH should consider adding language requiring plans to notify enrollees and providers to the delegation of medical management.

22. Section 9.676. Standards for enrollee rights and responsibilities. – Consistency with statute; Clarity.

Paragraph (4) requires a plan to adopt policies and procedures to assure implementation of enrollee's rights and responsibilities, including "[O]ther rights and responsibilities mandated by State and Federal law." This phrase is vague. For clarity, DOH should cite any applicable state laws that clearly delineate other rights and responsibilities a plan should adopt and implement.

23. Section 9.678. Primary care providers. – Statutory authority; Protection of the public health; Reasonableness; Clarity.

Primary care provider training and experience

This section establishes criteria for primary care providers and allows plans to consider Certified Registered Nurse Practitioners (CRNP) as a primary care provider. Act 68's definition of a primary care provider includes the term "health care provider." Act 68's definition of a health care provider includes, "a physician, podiatrist, optometrist, psychologist, physical therapist, certified nurse practitioner, registered nurse, nurse midwife, physician's assistant, chiropractor, dentist, pharmacist or an individual accredited or certified to provide behavioral health services." Is this section designed to allow any health care practitioner to be designated as a primary care provider? DOH should clarify in this section which health care providers are able to be primary care providers.

Subsection (d) Primary Care Provider - CRNP

Subsection (d) allows a plan to consider a CRNP a primary care provider if the CRNP meets the plan's credentialing criteria and practices in accordance with State law. We have a number of concerns regarding this subsection.

First, the definition of "primary care provider" in Act 68 does not exclude CRNPs from performing acts of medical diagnosis or prescription of medical therapeutic or corrective measures. However, 63 P.S. Section 422.15(a) states that "[A] CRNP shall act in accordance with regulations authorized by this section." Regulations authorized by this statute are contained in 49 Pa Code, Section 21.251, which contains the definition of CRNP. It requires CRNPs that perform the aforementioned duties do so "in collaboration with and under the direction of a physician licensed to practice medicine in this Commonwealth."

For consistency with existing statutes and regulations, DOH should: add language clarifying that a CRNP may be considered a primary care provider as long as the CRNP collaborates with or is supervised by, a licensed physician; or include a cross reference to Section 21.251.

Second, DOH should consider requiring written notice that alerts the enrollee that their primary care provider is a CRNP – not a physician. This written notice should also identify the physician with whom the CRNP has a written agreement to provide such services.

Finally, Subsection (d) includes the phrase, "in accordance with State law." This phrase is unnecessary, and should be deleted.

Subsection (f) Change of Designated PCP

This subsection allows enrollees to change a primary care provider "with appropriate advance notice to the plan." The term "advance notice" is vague. For clarity, DOH should provide a specific time frame during which an enrollee must give a plan notice of their intention to change a primary care provider.

24. Section 9.679. Access requirements in service areas. – Reasonableness; Clarity.

Subsection (e) requires plans to "ensure that services for hospitalization, primary care and frequently utilized specialty services shall be available to enrollees within 20 minutes or 20 miles in urban areas, and 30 miles or 30 minutes in rural areas." We have three concerns with this subsection.

First, this subsection should include the criteria that will be used to determine network adequacy, or provide a cross-reference to Section 9.654(b). *HMO provision of limited networks to select enrollees.* Additionally, for some specialty areas, network adequacy should be determined on a case-by-case basis. DOH should consider including this in the final regulation.

Second, how will the 20/20, 30/30 "rule" be enforced? DOH should include methods for ensuring that enrollees are able to access services within their 20/20 or 30/30 radiuses.

Finally, we understand that access standards for the Department of Public Welfare's (DPW) HealthChoices HMO program are 30 miles / 30 minutes urban, 60 miles / 60 minutes rural. Did DOH consider adopting the standards from the DPW Program? How will DOH's access standards impact upon DPW's program? DOH should explain.

25. Section 9.681. Health Care Providers. – Reasonableness; Clarity.

Subsection (a) Provider Directory

Subsection (a) requires a plan to furnish a provider directory to enrollees. Section 2136(a)(14) of Act 68 requires plans to update this directory at least annually. For clarity, DOH should add the phrase "updated annually" to this subsection. Additionally, DOH should indicate whether a plan is required to distribute an entire provider directory to enrollees annually, simply send the updated entries, or make updates available upon request.

Subsection (c) Services from Nonparticipating Providers

This subsection allows plans with no available, participating health care providers to arrange for services to be provided by nonparticipating providers. The criteria for determining whether a health care provider exists, is available, or is participating are unclear. This subsection should further define "no available, participating health care providers," or give criteria to determine whether a health care provider is "available" or "participating."

26. Section 9.682. Direct access for obstetrical and gynecological care. – Statutory authority; Clarity.

Inconsistency with Insurance Department Regulations

There are a number of provisions in the Insurance Department's final Regulation #11-195 that are either inconsistent with, or absent from, DOH's regulations. Section 154.12(b) of the Insurance Department regulations state, "[A]...plan **may require** a provider of obstetrical and gynecological services to obtain prior authorization for selected services such as diagnostic testing...." Subsection (b) of DOH's regulations state, "[A] plan **may not require** prior authorization for these services, or any aspect of services...including related laboratory or diagnostic services." These two subsections are inconsistent. DOH should be consistent with the Insurance Department's final Regulation #11-195.

Additionally, the Insurance Department's rulemaking applies the term "routine" to obstetrical services in Section 154.12(c), but not to gynecological services. DOH uses the same term for both obstetrical and gynecological services in Section 9.682(b) of its proposed regulations. Again, DOH should explain why "routine" is used for both classifications of service.

Subsection (b) and *(c)*

We have two questions about these subsections. First, Subsection (b) provides that plans may not require prior authorization for services considered as a "routine part of obstetrical and gynecological care." Additionally, Subsection (c) states "[A] plan may require that directly accessed participating health care providers seek prior plan authorization for **nonroutine**

services." (Emphasis added.) DOH should explain what "routine" and "nonroutine" services entail, and why the terms were included.

Second, the phrase "related laboratory or diagnostic procedures" in Subsection (c) is unclear. DOH should provide examples of these procedures in the final regulation.

Subsection (d)

This subsection states, "The plan shall have these policies and procedures (relating to obstetrical and gynecological care) approved by its quality assurance committee." Section 9.674(a) states, "[A] plan shall have an ongoing quality assurance program that includes review, analysis and assessment of the access, availability and provisions of health care services." However, no other policies or procedures in the proposed rulemaking are required to be approved by a plan's quality assurance committee. Additionally, Act 68 does not require a plan's quality assurance committee to approve these policies and procedures. DOH should explain why obstetrical and gynecological care policies are being singled out for approval.

27. Section 9.683. Standing referrals or specialists as primary care providers. – Statutory authority; Reasonableness; Clarity.

Subsection (b) Plan Procedures

This subsection allows a plan a time period to issue a decision regarding an enrollee's request for a standing referral or the designation of a primary care provider. DOH should explain why "within 45 days" is an appropriate time period to reply to this type of request.

Subsection (b)(3) Treatment Plan

Paragraph (3) states, "(an enrollee) be under a treatment plan approved by the plan and provided in writing to the specialist." Section 2111 of Act 68 allows referrals and designations of specialists "shall be pursuant to a treatment plan approved by the managed care plan, **in consultation with the primary care provider, the enrollee and, as appropriate, the specialist.**" (Emphasis added.) For consistency with the statute, DOH should insert the phrase "in consultation with the primary care provider, the enrollee and, as appropriate, the specialist" in this paragraph.

28. Section 9.684. Continuity of care. – Consistency with Statute; Clarity.

Subsection (h) Continuation of Services

This subsection states, "[A] plan shall use best efforts to ascertain the health care provider's willingness to continue to provide health care services." The phrase "best efforts" is vague. DOH should provide examples of "best efforts" in the final regulation.

Subsection (k) Termination of Providers for Cause

Subsection (k) describes the responsibility of the plan if a participating health care provider is terminated for "cause." The term "cause" is unclear. Section 2117(b) of Act 68 describes the

reasons a participating health care provider could be terminated for cause. For improved clarity, DOH should reference Section 2117(b) of Act 68 in this subsection.

Subchapter I. COMPLAINTS AND GRIEVANCES.

29. Transition to Act 68 complaint and grievance process - Implementation Procedures; Reasonableness.

It is our understanding that prior to Act 68 DOH has used a guidance document relating to operational standards for fundamental fairness of the complaint and grievance process. Commentators have stated protections in this guidance document have not been carried forward into the regulation. DOH should explain the following:

- Why provisions in the guidance document, consistent with Act 68 and the HMO Act, are not codified.
- Whether the complaint and grievance procedures established in the guidance document will change upon implementation of these regulations.
- Whether the changes in the procedures will diminish the rights of enrollees.
- How areas in the guidance document that are not addressed in the regulation will be interpreted and enforced.

30. Section 9.702. Complaints and grievances. – Duplication; Clarity.

Subsection (a) General.

Paragraph (1) ends with the phrase "and is satisfactory to the Secretary." Complaint and grievance procedures must meet the processes specified in Act 68 and this subchapter. DOH should explain what additional requirements the Secretary intends to impose or delete this phrase.

Paragraph (2) is limited to the enrollee. Under Section 9.703, health care providers can also initiate grievances with the consent of the enrollee. DOH should consider whether these protections should include health care providers.

Paragraph (3) is unclear because it does not provide any specific requirements for approval of procedures. A reference to Section 9.710, which provides the specific requirements for approval of complaint and grievance procedures, should be added to Paragraph (3).

Two requirements of Section 2136 of Act 68 are not included in the general requirements of Section 9.702. First, the requirement to have "a toll free telephone number to obtain information regarding the filing and status of a complaint or grievance" as required by Section 2136(8)(i) of Act 68 should be added.

Second, "the enrollee's right to designate a representative to participate in the complaint or grievance process" is required by Section 2136(8)(iii) of Act 68. Although this is mentioned in specific sections such as Section 9.705(h), this right is for the entire process and should be included in Subsection (a).

Subsection (b) Correction of plan.

Section 2182(e) of Act 68 gives DOH the authority to require a managed care plan to develop and adhere to a plan of correction approved by DOH. Subsection (b) should be amended to clearly reflect the authority in Section 2182(e) of Act 68 to require a managed care plan to develop and adhere to a plan of correction.

What is the difference between a noncompliant plan and a plan that creates unacceptable administrative burdens on the enrollee? It would appear that a plan that placed unacceptable administrative burdens on an enrollee would not be in compliance with Section 9.702(a)(2), and therefore would be noncompliant. DOH should delete the phrase "and a plan that creates unacceptable administrative burdens on the enrollee."

Subsection (c) Complaints versus grievances.

While this subsection provides mechanisms to resolve errors in classification of complaints and grievances, it does not provide guidance on how to distinguish between complaints and grievances. The Insurance Department's final regulation #11-195, Section 154.17(a), includes examples of complaints that can be filed with the Insurance Department. DOH should consider adding language to this section that explains the difference between a complaint and a grievance, along with examples. Further, DOH should review the final Insurance Department regulation to ensure there are no conflicts in the classification of complaints and grievances.

Paragraphs (1), (2) and (3) use the term "appeal." This term is vague and conflicts with how "appeal" is used in Section 9.705. *Appeal of a complaint decision.* DOH should use another term in Subsection (c).

Paragraph (1) ends with the term "process." For consistency with Subsections (a) and (b), Paragraph (1) should use the term "procedures."

Paragraph (2) only requires the plan to "consult" with DOH or the Insurance Department. It is unclear whether a determination made by DOH is binding. The regulation should state whether the determination is binding or nonbinding.

Paragraph (4) mentions waiving filing fees if a grievance is improperly filed as a complaint. Why doesn't Paragraph (5) require refund of a fee charged if a complaint was improperly filed as a grievance?

Subsection (d) Time Frames

Paragraph (d)(1) states a plan may not impose "unreasonable time limitations on an enrollee's ability to file an appeal or grievance." We have two concerns with this requirement. First, as it applies to grievances, Paragraph (1) duplicates the requirements in Paragraphs (2) and (3). Second, the term "unreasonable" is unclear. DOH should either delete Paragraph (1) or amend it to provide the specific 15-day requirement to file appeals.

Paragraph (2) uses a time limit of "30 *calendar* days" whereas Paragraph (3) requires "45 days." Time limits expressed in days are interpreted as calendar days. For clarity, the word "calendar" should be deleted from Paragraph (2).

31. Section 9.703. Health care provider initiated grievances. – Economic Impact Clarity.

General

Health care provider grievances would be filed under Sections 9.706 to 9.708. For clarity, this section should be in sequence with those sections.

Subsections (f), (g) and (h) provide broad requirements for the content of a consent form. The written consent is between a health care provider and an enrollee. A health care provider may have patients in different plans. Without guidance from DOH, each plan could place its own requirements on consent forms. DOH should consider use of a universal consent form so that health care providers and plans do not waste time and resources resolving conflicts over enrollee consent.

Subsection (b) Consent to File Grievance

Commentators have raised questions over whether consent can be obtained at the time of treatment. Subsection (b) only prohibits a health care provider from making consent a condition of treatment. DOH should clarify in the regulation whether consent can be obtained at the time of treatment provided it is not a condition of treatment.

Subsection (d) Billing of Services Subject to Grievance

Subsection (d) prohibits a health care provider from billing the enrollee until an external grievance is completed. Commentators questioned whether billing can occur if the grievance is filed by an enrollee. DOH should clarify whether Subsection (d) applies to all grievances, regardless of whether the enrollee or the provider initiates the grievance.

32. Section 9.704. Internal complaint process. – Clarity.

Subsection (a) Requirements

Subsection (a) contains the phrase "and is acceptable to the Secretary." The internal complaint process must meet Act 68 and this subchapter. DOH should either explain what additional requirements the Secretary intends to impose or delete this phrase.

The second sentence of Subsection (a) lacks clarity. The parallel Section 2141(a) of Act 68 states "an enrollee shall be able to file a complaint regarding a participating health care provider or the coverage, operation or management policies of the managed care plan." Subsection (a) should be rephrased to follow Act 68.

Subsection (b) Complaints

Subsection (b) would allow written or oral complaints for both initial and second level review. However, Section 2141(b)(2) of Act 68 only addresses oral complaints for an initial review.

Section 2141(b)(5) requires the plan to include the procedure "to *file* a request" for a second level review. The regulation should state that a written request is required to initiate a second level review.

Subsection (c) Paragraph (1) First level review.

For clarity, Subsection (c)(1)(i) should state ". . . one or more employes *of the plan*" to better reflect Section 2141(b)(1) of Act 68.

Subsection (c)(1)(iii) states review and investigation must be completed in 30 days, but does not specifically state when a *decision* is required by the plan. For clarity, DOH should state the required time frame for plan decisions.

Subsection (c)(1)(iv) should reference Section 9.702(d)(3) which requires the plan to give the enrollee a minimum of 45 days to file a second level complaint.

In Sections (c)(1)(iv) and (c)(2)(vii), commentators state the phrase "basis for decision" is unclear. Use of this phrase could result in a denial of a complaint that the enrollee may not be able to understand. It is unclear how much detail is required of the plan in the basis for the decision. For example, would the basis for the decision require contract citations? DOH should provide further guidance on how detailed the information from the plan regarding the decision.

Subsection (c)(1) does not state whether a first level decision is binding unless appealed. Under Subsection (c)(2)(iii), a second level decision is binding unless appealed. Is a first level decision binding unless appealed?

Subsection (c) Paragraph (2) Second level review.

Subsection (c)(2)(i) is unclear because there are two requirements in one sentence. The regulation would be clearer if one sentence describes the minimum size of the committee and a second sentence states the prohibition on members who participated in prior decisions.

In Subsection (c)(2)(ii)(A) the phrase "reasonable flexibility in terms of time and distance" is unclear. DOH should provide more specific requirements for scheduling reviews similar to the requirements in Section 9.679(e).

In Subsection (c)(2)(ii)(C), the word "or" causes confusion in the phrase "...the enrollee's provider or applicable witnesses . . . ." As written, it would allow either the provider to attend or applicable witnesses, not both. Both could be needed in certain circumstances and should be allowed. The word "and" should be substituted.

Subsection (c)(2)(iv) allows the deliberation of the second level review committee, including the enrollee's comments to be "transcribed verbatim or summarized." Would a summary be sufficient for appeals under Section 9.705?

Subsection (c)(2)(v) states the second level review must be completed in 45 days, but does not specifically state when the plan is required to issue a *decision*. For clarity, DOH should specifically state when a decision must be issued by the plan.

Subsection (c)(2)(vii) requires a notice to include "the procedures and time frame" to file an appeal. The procedures are specified in Section 9.705 and the time frame is 15 days as specified in Section 2142 of Act 68. For clarity, Subsection (c)(2)(vii) should reference the procedures in Section 9.705 and state the specific 15-day time period.

Since an enrollee can have a representative, Subsections (c)(2)(vi) and (vii) should also require notice to the enrollee's representative, if known.

33. Section 9.705. Appeal of a complaint decision. – Statutory Authority; Clarity.

Subsection (a)

This subsection requires an enrollee to appeal within 15 days of receipt of the second level decision. How is receipt of the decision determined?

Subsection (a) contains the phrase "or the Insurance Department." This phrase should be deleted since DOH has no authority over the Insurance Department.

Subsection (b)

Paragraph (b)(3) requires "The enrollee's plan ID number." Does this mean the ID number assigned to the enrollee by the plan, or some other number, such as an NAIC number assigned to the plan? Also, "ID" should be replaced with "identification."

Subsection (c)

Subsection (c) requires notice to the plan. The regulation should also require notice to the enrollee of the status of the filing (i.e., a timely filing or a late filing).

Subsection (d)

For clarity, the two sentences in Subsection (d) should be combined to state that upon confirmation of a timely filing, the plan shall forward the file within five business days.

Subsection (f)

This Section ends without any time constraint on DOH to rule on the appeal. The plan has 30 days to complete an initial review and 45 days to complete a second level review. DOH should consider adding a time period within which it will rule on an appeal.

Subsection (f) should state that the time requirements for review will not be affected by a decision to change the department reviewing the appeal.

34. Section 9.706. Enrollee and provider grievance system. – Clarity.

Subsection (a)

Subsection (a) contains the phrase "and is acceptable to the Secretary." The internal complaint process must meet the requirements of Act 68 and this subchapter. DOH should either delete this phrase or explain what additional requirements the Secretary intends to impose.

Subsection (c) Paragraph (1) First level review.

Subsection (c)(1)(iii) states the first level review must be completed in 30 days, but does not specifically state when the plan is required to issue a *decision*. For clarity, DOH should state when a decision is required to be issued by the plan.

Subsection (c)(1)(iv) does not reference Section 9.702(d)(3) which requires the plan to give the enrollee a minimum of 45 days to file a second level grievance. DOH should reference the requirement of Section 9.702(d)(3).

Subsection (c)(1)(iv) should require notice to both the enrollee *and* the health care provider to be consistent with Section 2161(b)(3) of Act 68.

Subsection (c)(1) should indicate whether the initial decision is binding unless appealed.

Subsection (c) Paragraph (2) Second level review.

The phrase "reviewing a grievance appealed to the second level of review" in Subsection (c)(2)(i) is not needed and should be deleted.

Subsection (c)(2)(ii) actually encompasses two separate requirements. It should be split into two separate paragraphs for clarity.

Subsection (c)(2)(ii)(A) requires the plan to provide "reasonable flexibility in terms of time and distance" when scheduling a review. The phrase "reasonable flexibility in terms of time and distance" is unclear. DOH should provide more specific requirements for scheduling reviews similar to the requirements in Section 9.679(e).

Subsection (c)(2)(iii) allows the deliberation of the second level review committee, including the enrollee's comments to be "transcribed verbatim or summarized." Would a summary be sufficient for appeals under Section 9.708?

Subsection (c)(2)(vi) requires a notice to include "the procedures and time frame" to file an appeal. The procedures are specified in Section 9.707 and the time frame is 15 days as specified in Section 2162 of Act 68. For clarity, Subsection (c)(2)(vi) should reference the procedures in Section 9.707 or state the specific 15-day time period.

Since an enrollee can have a representative, Subsection (c)(2)(vi) should also require notice to the enrollee's representative, if known.

Subsection (c)(2)(v) should require notice to both the enrollee *and* the health care provider to be consistent with Section 2161(c)(4) of Act 68.

Subsection (c) Paragraph (3) Same or similar specialty.

Subsection (c)(3) uses the term "similar." The similarity of specialties could be broadly interpreted. DOH should define or specify the scope of a "similar specialty."

35. Section 9.707. External grievance process. – Statutory Authority; Clarity.

Subsection (b)

Paragraph (b)(1) requires an enrollee to appeal within 15 days of receipt of the second level decision. How is receipt of the decision determined?

Paragraph (b)(2) uses the word "or." This could be read to require notification to only one entity. For clarity, DOH should indicate whether notification should be given to the enrollee or provider, depending on who filed.

The reference to "subsection k" in Subsection (b)(4) appears to be in error. DOH should review this reference.

Paragraph (b)(4) mentions an "external grievance coordinator." This position is not defined or explained in the regulation. DOH should add a definition of "external grievance coordinator."

Paragraph (b)(5)(iv) requires "The enrollee's plan ID number." Does this mean the ID number assigned to the enrollee by the plan, or some other number, such as an NAIC number assigned to the plan? Also, "ID" should be replaced with "identification."

In Subparagraphs (b)(5)(viii) and (b)(6)(ii) it is unclear what "reasonably necessary" supporting documentation is. These provisions should specify the information required.

36. Section 9.708. Grievance reviews by CRE. – Clarity.

Since an enrollee can have a representative, Subsection (a) should also require notice to the enrollee's representative, if known.

37. Section 9.709. Expedited review. – Clarity.

Subsection (a)

Subsection (a) requires expedited review ". . . if the enrollee's life, health or ability to regain maximum function will be placed in jeopardy by delay . . . ." The intent of an expedited review could be negated by disagreement over the prognosis of the enrollee. The regulation should state who makes this determination.

Subsections (c) and *(f)*

Subsections (c) and (f) should specify "upon *receipt of* the enrollee's request."

Subsection (i)

Subsection (i) requires "receipt on the next business day." What constitutes "receipt on the next business day"?

Subsection (i) uses the term "response" and Subsection (j) uses the term "decision." For clarity, a single term should be used consistently.

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

Timeframes for approval

Section 9.710 does not have a timeframe or formal process for approval of the complaint and grievance systems or changes to them.

- Is approval required prior to implementation?
- How must changes initiated by the plan be approved?

DOH should add the specific requirements and timeframes for system approval.

Subsection (a)

Subsection (a) should require approval by DOH rather than use the phrase "satisfactory to the Secretary."

Subsection (b)

Subsection (b) should state how far in advance DOH expects these filings.

Subchapter J. HEALTH CARE PROVIDER CONTRACTS

39. Sections 9.722, 9.724 and 9.725. – Consistency with the statute; Reasonableness; Need; Clarity.

Timeframe for approval

Overall, the subchapter provides no time period for DOH review and approval. Plans, HMOs and Integrated Delivery Systems (IDSs) should be given notice as to the length of time DOH will need to review and approve the contract forms.

Fiscal Impact

The requirement in Section 9.722 mirrors existing regulations that cover HMOs but extends the requirements to other managed care plans that are not HMOs. For plans not covered by the HMO Act, DOH states in the Preamble that its statutory authority for this requirement is Section 2111(1) of Act 68 (40 P.S. § 991.2111(1)). This section of the statute states that a plan shall

"assure availability and accessibility of adequate health care providers in a timely manner, which enables enrollees to have access to quality care and continuity of health care services." Unlike the HMO Act, Act 68 does not contain any specific language addressing the review of contracts by DOH.

What fiscal impact will Subchapter J have? The Preamble and the Regulatory Analysis Form for this regulation do not contain any information regarding the cost of this requirement for the plans or DOH. This information should accompany the final-form regulation. In addition, DOH should consider whether there are less cumbersome and less expensive alternatives for implementing Act 68.

40. Section 9.722. Plan and health care provider contracts. – Consistency with the statute; Reasonableness; Need; Clarity.

Subsection (a) DOH Review

This subsection requires plans and HMOs to submit standard forms for each provider contract to DOH for review and approval. There are two concerns.

First, commentators indicated that many contracts simply require general compliance with state and federal regulations and laws, and a provider manual published by a plan. For some plans, the provisions of this section may be included in their provider manuals rather than in each contract form. Rather than require each contract form to be submitted, it may reduce paperwork requirements if DOH reviews and approves provider manuals that are referenced by contracts.

Second, the requirements of this section may be duplicative for HMOs participating in the Medical Assistance (MA) program. They are required to submit contracts to the Department of Public Welfare (DPW). If the MA requirements are similar, then DOH may be able to reduce paperwork costs by allowing HMOs to use the same documents that they submit to DPW, or DOH could accept DPW's notice of approval of the contracts rather than undertake a separate review.

Subsection (b) Contract Changes and Amendments

This subsection requires the plan to "submit any change or amendment" to a contract to DOH ten days "prior to implementation of the change or amendment." There are two concerns.

First, this requirement will be burdensome for plans handling and mailing paperwork to DOH. Is it necessary for DOH to review **every** change or amendment? DOH should consider limiting this subsection to avoid unnecessary filing and review costs.

Second, the regulation should specify whether DOH will review and approve the amendments or changes. In addition, the regulation needs to set a time period for DOH review.

Subsection (c) Provider Protection Provisions

Subsection 9.722(c) states that a provider contract cannot contain provisions allowing the plan to sanction, terminate or fail to renew a health care provider for certain reasons including taking an action specifically permitted by Section 2113 of Act 68. There are two concerns.

First, Subsection 2121(e) of Act 68 states "no managed care plan shall exclude or terminate a health care provider from participation in the plan due to" two activities not mentioned in Section 2113. They include:

(2) The health care provider has a practice that includes a substantial number of patients with expensive medical conditions.

(3) The health care provider objects to the provision of or refuses to provide a health care service on moral or religious grounds.

Therefore, Subsection 9.722(c)(4) should reference both Section 2113 and Subsection 2121(e).

Second, if a plan terminates, or fails to renew a contract with a provider, what is the mechanism to insure that Sections 2113 and 2121(e) of Act 68 were not violated?

Subsection (e) Consumer Protection Provisions

This subsection sets forth "consumer protection provisions" that contracts must contain. There are two concerns.

First, Subsection 9.722(e)(5) states that the contract will include "language requiring the health care provider to adhere to State and Federal laws and regulations." What is the purpose of the general reference to "State and Federal laws and regulations"? This regulation should reference the specific laws and regulations with which providers must comply.

Second, Subsection 9.722(e)(6) requires contracts to include "language concerning prompt payment of claims." What type of language is being required? Is this a reference to the prompt payment of claims provisions of Act 68 or 31 Pa. Code § 154.18 of Regulation #11-195 from the Insurance Department? If so, DOH should reference Act 68 or the pertinent regulatory provision.

Subsection (f) Health Care Provider Contract Requirements

This subsection requires the contract to include information concerning reimbursement systems for providers. There are two concerns.

First, Subsection 9.722(f)(1) requires the contract to describe the reimbursement methods, including systems and factors for the types of economic or bonus incentive systems used. What level of detail will DOH require? As a part of the reimbursement method description, the regulation should require details concerning the amounts and percentages used in the methods.

Second, Subsection 9.722(f)(2) sets forth specific proportions for incentive reimbursement systems. It states that no system can weigh utilization performance as a single component more highly than the other factors collectively. These other factors include quality of care and enrollee

services. This would allow low utilization to equal almost one half of the incentive. How did DOH determine these proportions? In addition, DOH should consider standards promulgated by the Health Care Financing Administration at 42 CFR § 417.479.

41. Section 9.723. IDS. and Section 9.724. HMO-IDS provider contract. – Reasonableness; Clarity.

These two sections relate to contracts between an IDS and HMO, and contracts between the IDS and health care providers. There are two concerns.

First, Subsection 9.723(b) requires an HMO and IDS to notify DOH in writing at least 60 days in advance of any proposed action that would stop the IDS's providers from treating enrollees, including institution of litigation, termination or nonrenewal. Commentators noted that an HMO or IDS may not always receive 60 days advance notice of litigation. DOH should consider revising this subsection to allow for flexibility when an HMO or IDS does not receive 60 days advance notice of litigation.

Second, both sections are confusing because they intermix requirements for contracts between an IDS and HMO, and requirements for contracts between an IDS and health care providers. For example, Subsection 9.724(c) includes the requirement that the HMO provide DOH with copies of the contracts between an IDS and health care providers, and sets forth a list of 14 detailed standards for contracts between IDSs and HMOs. To clarify the requirements for these two different types of contracts, they should be set forth in separate sections.

42. Sections 9.723, 9.724 and 9.725. – Consistency; Reasonableness; Clarity.

These sections establish standards and requirements for IDSs and HMOs. The definition of an IDS in Section 9.602 of this regulation defines an IDS as a partnership or other legal entity that "[e]nters in to a contractual arrangement with a plan." Why is the term "HMO" used in these sections rather than plan or managed care plan?

Subchapter K. CREs

43. Section 9.742. CREs. – Clarity.

Subsection 9.742(c) states that a licensed insurer or plan with a certificate of authority shall comply with the requirements of Act 68 but is not required to obtain certification as a CRE. However, the requirements for a certificate of authority include assessment by an external quality review organization. It is our understanding that this assessment would include a review of the plan's utilization review component that is equivalent to certification of a CRE. For this reason, this subsection should reference Section 9.655 relating to HMO external quality assurance assessment.

44. Section 9.743. Content of an application for certification as a CRE. – Consistency with the statute; Reasonableness; Need; Clarity.

Subsection (b)

Subsection 9.743(b) allows DOH to change the application form by publishing notice of the changes in the *Pennsylvania Bulletin*. Any changes to the application form must be non-substantive in nature. Substantive changes must be made via a new rulemaking. This subsection should include language that any changes would be in accordance with this regulation or consistent with the content requirements in this section.

Subsection (c)

This subsection sets forth content requirements for the CRE application form. There are five concerns.

First, Subsection 2151(c) of Act 68 states that DOH "may adopt a nationally recognized accrediting body's standards to certify utilization review entities to the extent the standards meet or exceed the standards set forth in this article." Subsection 9.743(c)(5)(vii) requires a CRE's application to include: "Evidence of approval, certification or accreditation received by a Nationally recognized accrediting body in the area of UR [utilization review], if it has secured the approval, certification or accreditation."

What accrediting bodies meet the standards set forth in this regulation and Act 68? DOH should designate these organizations in the regulation or publish a list of accrediting bodies that is available to the public.

Second, Subsections 2152(a)(4)(i) - (iii) of Act 68 set forth specific "turnaround" time requirements for UR decisions. There are two issues related to these statutory requirements. The first concern is that the specific statutory time requirements for UR decisions should be referenced or included in the regulation. Second, how will DOH determine whether a CRE has the ability or capacity to meet these "turnaround" time requirements?

Third, Subsection 9.743(c)(5)(ii) states that the application should include a description of the applicant's "acceptable selection and credentialing procedures and criteria for physician and psychologist clinical peer reviewers." What is meant by "acceptable"? Do these procedures and criteria include the requirement in Section 2152(a)(5) of Act 68? What is included in "other required credentials"? DOH should clarify.

Fourth, Subsection 9.743(c)(5)(ix) will limit applicants to those who are already in the business of CREs. This subsection requires that the application include a list of three clients for which the applicant conducted UR. Is it the intent of DOH to prevent entry into this market by new CREs? If not, this subsection needs to be revised.

Subsection (d)

Subsection 9.743(d)(3) asks the applicant to certify that a plan is not providing compensation to a CRE employee or other person performing UR on its behalf that contain direct or indirect

incentives to approve or deny payment for health care services. However, Subsection 2152(b) of Act 68 simply states: "Compensation to any person or entity performing utilization review may not contain incentives, direct or indirect, for the person or entity to approve or deny payment for delivery of any health care services." The regulation should not limit the application of the statutory language to plans. The subsection should reference the language of Act 68.

45. Section 9.744. CREs participating in internal and external grievance reviews. – Reasonableness; Clarity.

Subsection 9.744(a)(3) requires disclosure of any potential conflict of interest. Why isn't this requirement a part of the application in Section 9.743? A CRE may avoid this disclosure requirement if it uses the application procedures in Section 9.743. Since DOH needs to identify CREs that meet the requirements of Section 2162 of Act 68, wouldn't it be useful to have this information for all CREs?

46. Section 9.748. Maintenance and renewal of CRE certification. – Clarity.

This section should contain specific language providing DOH with access to the same records and other information concerning a CRE as described in Subsection 9.747(b). In addition, this subsection should state that DOH will have access to and review UR decisions developed by the CRE. This is necessary to allow DOH to monitor CREs for compliance with Act 68 and this subchapter.

Subchapter L. CREDENTIALING

47. Section 9.761. Provider credentialing. – Clarity.

Subsection (b) should require DOH approval to be consistent with Section 2121(a) of Act 68. In addition this subsection should provide the process and time frame for approval of the provider's credentialing plan.

48. Miscellaneous Clarity Issues.

Section 9.702. Complaints and grievances.

Paragraph (a)(1) uses the singular word "procedure." For clarity, we suggest using the plural word "procedures" to emphasize that complaints and grievances are separate procedures.

Section 9.711. Alternative provider dispute resolution systems.

The title of this Section could imply there is an alternative provider rather than an alternative dispute resolution system. Since this system is an agreement between the provider and the plan, the word "provider" should be deleted from the title.

Section 9.711. Alternative provider dispute resolution systems.

There is a typographical error in Subsection (e). It should state "...alternative dispute resolution system...."

Subsections 9.721. Applicability.

In this section, why are the terms "health care providers" and "IDSs" repeated twice?

Subsections 9.722(a), 9.722(b), 9.724(b) and 9.743(b).

On its page 44, the *Pennsylvania Code and Bulletin Style Manual* recommends the use of the word "before" instead of the word "prior." In these three subsections, DOH should replace the words "prior to" with "before."