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

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,

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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~~ manage the utilization of health care services; ~~(B) I~~ integrates the financing and delivery of health care services to enrollees by arrangements with health care providers selected to participate on the basis of specific standards; ~~(C) P~~ **and** provides financial incentives for enrollees to use the participating health care providers in accordance with procedures established by the plan.

(ii) a managed care plan includes, etc.

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. <u>9.604 Department investigations.</u>

The Department must be able to investigate information contained in enrollee <u>grievances</u> (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. <u>§9.745 - Responsible Applicant</u>

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.

Gelnett, Wanda B.

From: Jewett, John H.
Sent: Friday, January 28, 2000 8:27 AM
To: IRRC
Subject: FW: Act 68

DOH comments 1.4.00.doc

DOH bullets.doc

Please add to the file for #2079.

Thanks!

-----Original Message-----
From: Alissa Halperin [mailto:aehalperin@yahoo.com]
Sent: Friday, January 28, 2000 8:17 AM
To: jjewett@IRRC.STATE.PA.US
Cc: atorregro@aol.com
Subject: Act 68

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Not sure whether you have received a copy of the comments we filed on behalf of several clients to the DOH Act 68 regs. Attached is a copy of the comments as well as a summary of our comments.

As they are quite lengthy, we would welcome the opportunity to and would be more than happy to meet with you and discuss them with you at your earliest convenience.

Sincerely,

Alissa Halperin
(215)625-3897

Pennsylvania
Psychiatric Society

The Pennsylvania
District Branch of the
American Psychiatric Association

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January 17, 2000

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

Re: Proposed Rulemaking - Managed Care Organizations - Pennsylvania Bulletin, Vol. 29, No. 51, December 18, 1999

Dear Ms. Mitchell:

I am writing on behalf of Lee C. Miller, MD, President of the Pennsylvania Psychiatric Society, in order to comment on the Department of Health's proposed regulations for managed care organizations.

The proposed regulations reflect a commitment to consumer and patient protection which we applaud. Several of our concerns with the earlier, draft document have been satisfactorily addressed in the proposal, such as the definition of "gatekeeper." Likewise, much of the new material, such as § 9.675 (Delegation of medical management), and the CRE application requirements in § 9.743 (Content of an application for certification as a CRE), should make a significant contribution toward the Department's goals.

We would like to make a few suggestions for further improvement of the proposed regulations, as follows:

Definition of managed care plan: the Department's proposal to define ancillary service plans, which are referenced in the definition of "managed care plan," is a good one. We believe the potential for confusion still exists, however, in regard to the phrase " or an indemnity arrangement which is primarily fee for service." We recommend adding language to clarify that when a primarily fee for service plan nevertheless requires management for the broad range of conditions treated by a particular medical specialty, such as treatment for mental health diagnoses, that portion of the plan will be subject to Act 68 regulations if it would qualify were it a free-standing plan.

Medical necessity: References to medical necessity in several places, including § 9.651 (c) and § 9.677, allow plans to determine their own definitions of medical necessity. Although we appreciate the requirement in § 9.677 that a plan's definition must be the same wherever it appears or is applied under a plan, we do have some concern about the degree of latitude which a plan appears to have in determining its definition. This concern is heightened by the requirement that the external grievance process make its determination based on the plan's definition. What are the safeguards against a plan's use of clinically unreasonable definitions? Does the Department have the right to disapprove an HMO plan whose definition of medical necessity, in its judgment, is inappropriately narrow, not allowing for sufficient flexibility in the application of clinical judgment, or not consistent with community standards?

We appreciate the opportunity to comment on the proposed regulations, and hope that they are helpful to you.

Sincerely yours,

Gwen Yackee Lehman/dnl

Gwen Yackee Lehman
Executive Director

LAUREL
HEALTH SYSTEM

Laurel Health System
15 Meade Street
Wellsboro, Pennsylvania 16901-1813

January 17, 2000

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The Honorable Matthew E. Baker
House of Representatives of Pennsylvania
P.O. Box 202020
Harrisburg, PA 17120-2020

Dear Representative Baker:

I am sending this letter to inform you of the importance and the impact of Act 68, The Quality Health Care Accountability and Protection Act, enacted January 1, 1999, on our hospitals and health systems.

Act 68 has proven, thus far, to be an effective starting point in creating accountability in managed care organizations and has taken strides in improving health insurance practices. There are, however, some needed modifications to the Act to ensure a high quality of care to our patients. They are as follows:

1. The Department of Health has defined emergency services differently from the Insurance Department; they need to be similar. In reference to inpatient services, skilled nursing services need to be defined on their own and not included as inpatient time.

2. The section on co-payments and co-insurance is too vague and needs to be clarified to ensure patient access to care.

3. Insurance regulations do not coincide with the definition of emergency services. This definition needs to include evaluation, stabilization and treatment.

4. The definition of medical necessity needs to be similar at all Departments to ensure access to care, and a process of periodic evaluation for determining such medical necessity is needed.

-continued-

5. The term "access" needs to be clarified, as it implies the use of motor vehicles but does not address inaccessible or unaffordable transport.

6. The Department of Health has differentiated between routine and non-routine obstetric and gynecologic care, while the Act has not. This also needs to be similar to avoid conflict in the future.

7. The Department of Health and the Insurance Department differ on continuity of care. It is important that these also be similar.

8. There is a lack of clarity in regard to grievance issues. Denial letters have lacked, in the past, a clinical rationale; and at times, services which were pre-approved have been denied once submitted for billing.

9. In regard to internal complaints, the consumer needs additional time to file such complaints. Thirty days is recommended.

10. The dispute resolution needs to be simplified, such as not requiring written consent from the patient to allow the provider to seek a resolution in procedural errors and administrative denials.

11. It should be required that any changes to contract terms be mutually agreed upon and communicated to providers with thirty days notice.

12. The regulations need to include how monitoring of all those involved will take place to ensure compliance with state laws and regulations.

It is imperative that these issues be addressed and the needed corrections be made to the regulations of Act 68 so that the Laurel Health System, and hospitals and health systems across the state, may continue to provide the best possible care to our communities.

Thank you for your consideration.

Sincerely,

Ron

Ronald J. Butler
President and CEO

HOUSE OF REPRESENTATIVES
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

DATE: 2/3

SENDING TO:
Telecopy Number: 3-2664

Department/Company: LDRC

Name: John Jewett

Number Of Pages Including Cover Sheet: 3

Message: Per our discussion

SENT FROM:
Name: Amanda Johnson

Department: Ins Cmte

Telecopy Number: 717-783-2322

Phone: 7-7978

HIGHMARK

January 17, 2000

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

Re: Proposed Managed Care Organization Regulations

Dear Ms. Mitchell:

We appreciate the opportunity to provide comments on the Department of Health's (the Department's) proposed regulations for managed care plans. These comments are provided on behalf of Highmark Inc., Keystone Health Plan West, Keystone Health Plan Central and Healthguard.

First, we wish to commend you on the caliber of work as presented. The proposed regulations reflect thorough and thoughtful work by the Department, are in an easily accessible format, and effectively combine many previously issued policy statements and regulations. The statements in the preamble were helpful in assisting us in our review and understanding of the proposed regulations. We appreciate that the task before the Department was a significant challenge, and are pleased to acknowledge how well the Department has risen to the task.

We are highlighting comments in this memorandum that represent our most significant concerns. Note that we've provided an attachment that highlights some other potential clarifications or corrections that may be required, depending on the form the final regulation takes:

9.602. Definitions. - Medical Management. In the Department's definition of medical management, is the phrase "providing effective and efficient health care services". This language is a concern because it could be presumed that any managed care plan that performs medical management functions, and all do, also provides care. That is not true of most managed care plans - only the limited number of staff model HMOs do so. The whole issue of health plan liability turns on the question of whether the managed care plan is providing care. We maintain that we provide for the provision of such care through our contracts with providers, but are not in the business of medicine ourselves. Providers are responsible for providing care - for making the determination of diagnostic procedures and treatment plans - not managed care plans. Thus, we strongly urge you consider the following change to the proposed language:

> Medical Management – a function that includes any aspect of UR, quality assurance, case management and disease management and other activities for the purposes of

determining, arranging FOR THE PROVISION OF, OR monitoring ~~or providing~~ effective and efficient health care services.

9.604. Plan reporting requirements. (a) Annual Reports - Currently the Department preserves the confidentiality of provider-specific reimbursement arrangements. The language in item (8), however, appears to discontinue that practice. This is a concern to plans. It could severely jeopardize competitive contracting. We thus urge consideration of clarifying language, as follows:

(8) Copies of currently utilized generic or standard form health care provider contracts including copies of any deviations from the standard contracts and reimbursement methodologies. PLANS MAY SUBMIT SUCH DEVIATIONS OF REIMBURSEMENT METHODOLOGIES AS CONFIDENTIAL AND PROPRIETARY, PROVIDED THAT THEY ARE CLEARLY MARKED AS SUCH AND SUBMITTED IN A SEPARATE DOCUMENT ALONG WITH THE ANNUAL REPORT DOCUMENT.

9.635. Delegation of HMO operations. - The Department has not defined "HMO operations" anywhere in the regulations. A broad interpretation of the term would result in HMOs having to file every vendor or outsource contract, whether for advertising, printing, marketing, etc. with the Department. We believe this would result in an excessive administrative burden for both plans and the Department. The intent - preserving the integrity of the HMO's responsibility for, and Department monitoring of, HMO functions - can be maintained with our proposed, revised language:

(a) AN HMO may contract with any individual, partnership, association, corporation, or organization ~~for the performance of HMO operations~~. A contract for delegation of HMO operations ~~shall be filed with the Commissioner and~~ does not diminish the authority or responsibility of the board of directors of the HMO, or the ability of the Department to monitor quality of care and require prompt corrective action of the HMO when necessary.

9.675 Delegation of medical management - The Department includes new requirements for managed care plans in this section. It seeks to extend its oversight to contractors performing medical management functions for plans. It requires the filing of medical management contracts for review and approval prior to implementation. Many plans already have such contracts in place, without previously having to obtain the Department's approval. Is it the Department's intent to grandfather such existing contracts? We believe this provision should only apply to contracts entered into or renewed after the effective date of the regulation, and strongly urge that this be noted. Recommended language is provided in the attachment to this letter.

An additional concern relates to the process for review and approval of such contracts. We note the lack of a timeline for review, and any deemer provision, should the Department fail to act in a timely manner. We have this concern also with respect to the provider contracts Sections 9.722, 9.724, and 9.725. We recommend similar language be added to all of those sections of the regulations requiring prior approval of contracts, as follows:

1) IF THE DEPARTMENT DOES NOT TAKE SPECIFIC ACTION IN THE FORM OF AN APPROVAL OR REQUEST FOR ADDITIONAL INFORMATION OR CLARIFICATION WITHIN 45 DAYS OF RECEIPT OF THE FILING, THE FILED CONTRACT(S) SHALL BE DEEMED APPROVED.

THE DEPARTMENT SHALL USE REASONABLE EFFORTS TO MAKE ITS REQUEST FOR ALL ADDITIONAL INFORMATION OR CLARIFICATIONS AT ONE TIME. AFTER A REQUEST FOR ADDITIONAL INFORMATION OR CLARIFICATION HAS BEEN MADE, IF THE DEPARTMENT DOES NOT TAKE ANY ADDITIONAL SPECIFIC ACTION IN THE FORM OF AN APPROVAL OR DISAPPROVAL WITHIN THIRTY (30) DAYS OF THE RECEIPT OF THE ADDITIONAL INFORMATION OR CLARIFICATION, THE FILED PROVIDER CONTRACT(S) SHALL BE DEEMED APPROVED.

9.678 Primary Care Providers - The Department requests a form of disclosure be added to directories advising members that there is no guarantee that a given provider will always be available to the member. We agree with the intent of the notice, but are concerned that the language is too broad and could be interpreted as requiring directories to advise members of the implications of any referral change on a provider-by-provider basis. This would represent significant costs to the managed care plans. We believe a general notice would satisfactorily meet the disclosure requirement, and propose a change to the language to support that, as follows:

e) A plan shall include in its provider directory a clear and adequate ~~disclosure~~ NOTICE of the ~~applicable referral~~ POSSIBILITY OF limitations caused by the choice of a given provider as a primary care provider.

Subchapter I. Complaints and Grievances – We raise concerns related to the handling of complaints regarding excluded services. As noted in the regulation in 9.651 (b) "an HMO may exclude coverage for the services as are customarily excluded by indemnity insurers, except to the extent that a service is required to be covered by State or Federal law". Such excluded services are non-covered, even when medically appropriate or necessary. However, plans have noted that some appeals of non-covered services have, in fact, been handled as grievances, rather than as complaints. An example is provided in the Attachment – related to 9.673 and prescription drug benefits. Even when a plan offers prescription drug coverage, with closed or open formularies, there may be some drugs deemed non-covered, excluded services.

Also, in 9.683 (b)(7) the Department now notes they seek to make the appeal of a plan's determination of an enrollee's designation of a specialist as their primary care provider a grievance, rather than a complaint. Since these are based on the managed care plan's policies - which are operations and management decisions - they should be treated as complaints, not grievances. Additionally, we note that the current statement of policy, and the explanatory grid previously posted on the Department's website treats these appeals as complaints, not grievances. Therefore, we respectfully suggest that these continue to be treated appropriately as complaints, not grievances.

We urge the Department to exercise care in the determination of what constitutes a grievance. Including issues that are *not* related to questions of medical necessity or appropriateness, but are rather related to excluded services, or managed care plan's operational policies, will only increase the number of grievances, and costs of administration for managed care plans.

9.704 Internal complaint process. (c)(2)(vii) The Department has included a new requirement that is problematic. The last sentence notes that the decision shall be sent in a manner so that the plan can document receipt of the decision. We respectfully disagree with this recommendation. Our previous experience with such a process was that members found it burdensome, complained that it was an additional way in which the plan inconvenienced them, and that it caused an unnecessary delay in the timeliness of their receipt of the information. Certified mail – the most cost-effective way to document receipt - requires a signature for pick up. Most working members are not at home during the day to receive such mail, and thus must make a special effort to go to their post office during normal working hours. For commuters that often means a delay until the following Saturday. Previously, for example, Keystone Health Plan West experienced a high volume of member complaints regarding the practice of sending notices by Certified mail, and discontinued it. Finally, we note that the requirement imposes administrative costs at a time when plans are seeking ways to contain costs to avoid any additional premium rate increases.

This same new requirement is included in 9.706 Enrollee and provider grievance system (2) (vi). In both cases we recommend the deletion of the requirement.

Subchapter J - Health Care Provider Contracts - Sections 9.722, 9.724, and 9.725 all specify that plans shall submit a health care provider contract for review and approval prior to implementation. As noted previously, there is no information regarding the review period and approval process. This can be very detrimental to the development of networks and managed care products, thus we strongly urge the Department to codify through this rulemaking a review process and deemer provision. Suggested language for inclusion in each of those three sections is provided in the attachment to this letter.

9.722 Plan and Health Care Provider Contract - This section does not require prior approval, but requires filing of changes or amendments. We wish to clarify that such required filings do NOT include new rates of reimbursement -since a filing for every new rate or reimbursement change would cause a significant - and unnecessary - staffing and resource burden on the plans and the Department. Accordingly, we suggest the following change:

> 9.722.(b) The plan shall submit any change or amendment to a <u>STANDARD FORM OF</u> health care provider contract, <u>EXCEPT NEW RATES OF REIMBURSEMENT</u>, to the Department <u>NO LATER THAN 10</u> days prior to implementation of the change or amendment.

9.761. Provider Credentialing - provision (a)(3) of this section extends aspects of credentialing currently only performed routinely for primary care providers to all providers. We note that NCQA has removed specialists from such specific credentialing requirements as cited in (a) (3), and thus recommend the following change:

> 9.761. Provider Credentialing.
> (a)(3) Include in the initial credentialing and recredentialing process FOR CREDENTIALING PRIMARY CARE PROVIDERS, a plan assessment of the participating.....

The Department *should* accept a credentialing system that meets the requirements of an accrediting body acceptable to the Department, thus the term "may" should change to "shall", as follows:

> 9.761 (c) A plan ~~may~~ SHALL meet the requirements of this section by establishing a credentialing system that meets or exceeds standards of a Nationally recognized accrediting body acceptable to the Department. The Department will publish a list of these bodies annually in the *Pennsylvania Bulletin*.

As previously noted, we appreciate the opportunity to provide these comments. I can be reached at (717) 975-7426, via fax at (717) 731-2337, or via e-mail at candy.gallaher@highmark.com. if you have any questions.

On behalf of Highmark Inc. and its subsidiary and affiliated HMOs, thank you, again.

Sincerely,

C. M. (Candy) Gallaher
Regulatory Affairs Director

CMG:cjp

Attachment

cc: Carey Vinson, MD, Keystone Health Plan West
Laurie McGowan, Esq., Keystone Health Plan Central
Mary Barninger, HealthGuard
Geoff Dunaway, Pennsylvania Insurance Department
Bruce Hironimus, Highmark Inc.

Department of Health PROPOSED REGULATIONS Additional comments - Preamble:	For Managed Care Organizations
Preamble Section 9.672 Emergency services. Paragraph 2: Subsection (f) would require the plan to pay for services provided by a nonparticipating provider at the same ~~rate~~ LEVEL OF BENEFIT as it pays to a participating provider....	Issue: The use of the term "rate" could be interpreted to permit the same rate of payment - or same dollar amount. In that case an enrollee would not be held harmless. We suggest a revision to be consistent with the regulation 9.672(f). which references "level of benefit" rather than "rate". Or, conversely, if it is the Department's intent to permit such balance-billing, to revise the regulation to reference "rate" rather than "level of benefit".
Regulations:	
9.602 Definitions. Outpatient Setting - A physician's office, PATIENT'S HOME, outpatient facility, ambulatory surgical facility or hospital when a patient is not admitted for inpatient services.	The definition fails to reference a patient's home as an outpatient setting. Yet providers make house calls; and home visits and therapeutic care are often approved and rendered in the enrollee's home. Thus, we recommend the inclusion of "patient's home" in the definition.
9.606 Penalties and sanctions. (a) (1) Impose a civil penalty of up to $5,000 per violation of Article XXI.	Issue: Clarify with appropriate reference.
9.673 Plan provision of prescription drug benefits to enrollees. (e) If the plan does not approve a health care provider's request for an exception TO A DRUG INCLUDED IN THE FORMULARY, the enrollee or the health care provider with the written consent of the enrollee, may file a grievance under SubChapter I (relating to complaints and grievances). APPEALS FOR COVERAGE OF EXCLUDED DRUGS ARE COMPLAINTS, NOT GRIEVANCES.	Issue: Prescription drug benefit coverage, even with formularies, can exclude certain services. For example, some policies exclude Rogaine and drugs intended to restore hair growth. The Department's language would have broad and unintended consequences, causing a Complaint related to an excluded service to be treated as a Grievance.
9.675(a) A plan may contract with an entity for the performance of medical management relating to the delivery of health care services to enrollees. The plan shall submit ~~the~~ medical management contractS ENTERED INTO OR RENEWED AFTER THE EFFECTIVE DATE OF THIS REGULATION to the	Issue: Plans with such contracts in place at the time of the effective date of the regulations could face sanctions if this proposed change is not made.

Department for review and approval prior to implementation.	
9.675(d)(5) A requirement that the contractor submit written reports of activities and accomplishments to the plan's quality assurance OR OTHER APPROPRIATE committee on at least ~~a quarterly~~ AN ANNUAL basis.	Issue: (d)(5) seems very similar to (d)(2). If the Department were looking for more, such as an analysis of the effectiveness of the program, it would be more appropriate to do so on an annual basis. It is too difficult to assess effectiveness quarterly. Also, depending on the functions being delegated, the report may be more appropriately sent to another committee.
9.681. Health Care Providers (b) A plan shall include a clear disclaimer in the provider directories it provides to enrollees that the plan cannot guarantee continued access during the term of the enrollee's enrollment to a particular health care provider, and that if a participating health care provider used by the enrollee ceases participating, the plan will MAKE EVERY EFFORT TO provide access to ~~alternative~~ ALTERNATE providers with ~~equivalent training and experience~~ THE SAME OR SIMILAR EXPERTISE.	Issue: The language sets forth a standard not always achievable. Thus we recommend the language "make every effort to". Alternative has certain meanings regarding scope of licensure that is not intended here, thus the recommended change. Finally, providers would never have equivalent training or experience, as each has different educational and clinical history. The Department's standard use of the phrase "same or similar" is preferred. (See regulation's use in 9.706).
9.683 Standing referrals or specialists as primary care providers. (b) (5) Ensure that a standing referral to, or the designation of a primary care provider as, a specialist will be made to participating ~~specialists~~ PROVIDERS when possible. Nonparticipating ~~specialists~~ PROVIDERS may be utilized ~~as appropriate.~~ IF NO PARITICPATING PROVIDER IS AVAILABLE.	Issue: The language is not exactly correct, since primary care providers can also be designated specialists.. Thus we recommend the change of "specialist" to "provider".
9.683 (b)(7) Ensure the written decision denying the request provides information about the right to appeal the decision through the ~~grievance~~ COMPLAINT process.	Issue: The appeal is regarding the managed care plan's policies and procedures, thus a complaint. We note the Department's comment in the preamble that they wish to treat these as grievances, but respectfully disagree, for reasons cited in our cover letter.

9.703 Health care provider initiated grievances. (a) A health care provider may, with the WRITTEN consent of the enrollee, file a written grievance with the plan.	Issue: The requirement for written consent is set forth elsewhere in the regulation.
9.703 (c) Once a health care provider assumes responsibility for filing a grievance, IF THE ENROLLEE REQUESTS, the health care provider may not refuse to grieve the issue through the second level grievance review.	Issue: Clarification. Many appeals by providers are where an enrollee is held harmless under the provider contract. If the provider wishes to drop the appeal after the first level, they should be permitted to do so, and only be required to go to the second level if the enrollee requests.
9.703 (e) If the health care provider elects to appeal an adverse decision of a CRE, the health care provider may not bill the enrollee for services provided that are the subject of the grievance until ~~it~~ THE ENROLLEE chooses not to appeal an adverse decision to a court of competent jurisdiction.	Issue: Clarification.
9.704(c)(1)(iii) The plan shall complete its review and investigation of the complaint within 30 days of the receipt of the complaint. THE ENROLLEE MAY BE CONTACTED, AND AT THE ENROLLEE'S REQUEST THE PERIOD MAY BE EXTENDED ANOTHER 30 DAYS IF THE PLAN HAS NOT RECEIVED NECESSARY INFORMATION TO REVIEW THE COMPLAINT.	Issue: Plans should be permitted to ask enrollees if they wish to extend the period for review when notifying them that despite using all diligence, the plan is unable to obtain the medical records needed to complete the review. Without such extensions, granted at the enrollee's discretion, we are forced to proceed without the necessary records - usually due to provider's delays in forwarding such information. This can force enrollees and plans into unnecessary second level reviews.
9.704 Internal complaint process (2)(i) ....The members of the second level review committee shall have the duty to be ~~unbiased~~ IMPARTIAL in their review and decision.	Issue: Terminology used in reviews and judgements is typically "impartial".
9.704 (c) (2) (iv) The ~~deliberation~~ PROCEEDINGS of the second level review committee, including the enrollees comments....	Issue: The use of the term "deliberations" implies more than a recording of the proceedings. Deliberations are the part where the committee votes. Just as in jury proceedings, or proceedings before the court, "deliberations" are off the record. Only the recorded, public proceedings are available.

9.706 (c)(1)(iii) The investigation and review of the grievance shall be completed within 30 days of receipt of the grievance. THE ENROLLEE MAY BE CONTACTED, AND AT THE ENROLLEE'S REQUEST THE PERIOD MAY BE EXTENDED ANOTHER 30 DAYS IF THE PLAN HAS NOT RECEIVED NECESSARY INFORMATION TO COMPLETE THE REVIEW AND INVESTIGATION	Issue: Same issue as in complaint 9.704(c)(1(iii). plans should be permitted to ask enrollees if they wish to extend the period for review when notifying them that despite using all diligence, the plan is unable to obtain the medical records needed to complete the review. Without such extensions, granted at the enrollee's discretion, we are forced to proceed without the necessary records - usually due to provider's delays in forwarding such information. This can force enrollees and plans into unnecessary second level reviews.
9.706 Enrollee and provider grievance process (2)(i) ....The members of the second level review committee shall have the duty to be ~~unbiased~~ IMPARTIAL in their review and decision.	Issue: Terminology used in reviews and judgements is typically "impartial".
9.706 (2) (iii) The ~~deliberation~~ PROCEEDINGS of the second level review committee, including the enrollees comments....	Issue: The use of the term "deliberations" implies more than a recording of the proceedings. Same issue as noted in 9.704 (c)(2)(iv).
9.706 (3) Same or similar specialty (i) Both the initial and second level grievance review committees shall include THE INPUT OF a licensed physician or an approved licensed psychologist, in the same or similar specialty as that which would typically manage or consult on the health care service in question.	Issue: The language of Act 68 allows for the INPUT OF such providers. It does not require that they be present at the committee, as noted in the preamble. Thus, we suggest this clarifying language.
9.708. Grievance reviews by CRE. (c) The assigned CRE shall review all information considered by the plan in reaching any prior decision to deny coverage for the health care service in questions, and information provided under 9.707 (relating to external grievance process). (1) THE CRE MAY NOT MAKE COVERAGE DECISIONS SUCH AS REQUIRING PLANS TO COVER SERVICES NOT COVERED UNDER THE POLICY, OR SPECIFICALLY EXCLUDED UNDER THE POLICY.	Issue: CRE's decisions should not be premised on a belief that a given service should be covered under an enrollee's policy. As noted previously, plans may exclude services. Nothing in the CRE's review should be deemed to authorize them to breach such contracts. Act 68 permits CREs to hear "grievances", which are statutorily defined in Section 2102 as "not including a complaint". A "complaint" is a dispute involving "coverage, operations or management policies". Therefore, a CRE is statutorily prohibited from

	making coverage decisions.
9.709(f) Within 1 business day of the enrollee request WHICH HAS BEEN DETEREMINED TO BE AN EXPEDITED APPEAL, the plan shall submit a request for an expedited external review to the Department by Fax transmission or telephone call....	Issue: Not every request from an enrollee for expedited review meets the plan determination of an expedited grievance.
9.710 (c) Complaint and grievance procedures for ~~*special populations, such as*~~ Medicaid and Medicare HMO enrollees, shall comply with Act 68 to the extent permitted by Federal law and regulation.	Issue: As the Department noted in the preamble, this is new subject matter. We are concerned that the term "special populations" is broad, and potentially problematic. We suggest clarification of the intent in the preamble, or removal of the term in the regulations.
9.722(a) INSERT NEW (1): (1) IF THE DEPARTMENT DOES NOT TAKE SPECIFIC ACTION IN THE FORM OF AN APPROVAL OR REQUEST FOR ADDITIONAL INFORMATION OR CLARIFICATION WITHIN 45 DAYS OF RECEIPT OF THE FILING, THE FILED PROVIDER CONTRACT(S) SHALL BE DEEMED APPROVED. THE DEPARTMENT SHALL USE REASONABLE EFFORTS TO MAKE ITS REQUEST FOR ALL ADDITIONAL INFORMATION OR CLARIFICATIONS AT ONE TIME. AFTER A REQUEST FOR ADDITIONAL INFORMATION OR CLARIFICATION HAS BEEN MADE, IF THE DEPARTMENT DOES NOT TAKE ANY ADDITIONAL SPECIFIC ACTION IN THE FORM OF AN APPROVAL OR DISAPPROVAL WITHIN THIRTY (30) DAYS OF THE RECEIPT OF THE ADDITIONAL INFORMATION OR CLARIFICATION, THE FILED PROVIDER CONTRACT(S) SHALL BE DEEMED APPROVED. NOTHING IN THIS SECTION SHALL SUPERCEDE REVIEW AND APPROVAL BY THE INSURANCE DEPARTMENT OF CONTRACTS SUBJECT TO THEIR APPROVAL UNDER 40 PA C.S. 6124 (RELATING TO HOSPITAL PLAN CORPORATIONS).	Issue: This language provides for timelines for review. If the Department does not provide a response within the established timeframes, plans can proceed with the presumption that the contracts are deemed acceptable.
9.722 (e)(2)(ii). Language which states that records are only accessible to ~~Department employees or agents with direct responsibilities~~ REGULATING AGENCIES AND THEIR AGENTS OR DESIGNEES under	Issue: This is inconsistent with requirements the Department has placed on plans to date. The term " agents with direct responsibilities" is

subparagraph (i).	undefined. The revised language is what the Department has required of plans in currently approved contracts.
9.724(a) INSERT NEW (1): (1) IF THE DEPARTMENT DOES NOT TAKE SPECIFIC ACTION IN THE FORM OF AN APPROVAL OR REQUEST FOR ADDITIONAL INFORMATION OR CLARIFICATION WITHIN 45 DAYS OF RECEIPT OF THE FILING, THE FILED PROVIDER CONTRACT(S) SHALL BE DEEMED APPROVED. THE DEPARTMENT SHALL USE REASONABLE EFFORTS TO MAKE ITS REQUEST FOR ALL ADDITIONAL INFORMATION OR CLARIFICATIONS AT ONE TIME. AFTER A REQUEST FOR ADDITIONAL INFORMATION OR CLARIFICATION HAS BEEN MADE, IF THE DEPARTMENT DOES NOT TAKE ANY ADDITIONAL SPECIFIC ACTION IN THE FORM OF AN APPROVAL OR DISAPPROVAL WITHIN THIRTY (30) DAYS OF THE RECEIPT OF THE ADDITIONAL INFORMATION OR CLARIFICATION, THE FILED PROVIDER CONTRACT(S) SHALL BE DEEMED APPROVED. NOTHING IN THIS SECTION SHALL SUPERCEDE REVIEW AND APPROVAL BY THE INSURANCE DEPARTMENT OF CONTRACTS SUBJECT TO THEIR APPROVAL UNDER 40 PA C.S. 6124 (RELATING TO HOSPITAL PLAN CORPORATIONS).	Issue: This language provides for timelines for review. If the Department does not provide a response within the established timeframes, plans can proceed with the presumption that the contracts are deemed acceptable.
9.724 (c)(1). An IDS, assuming financial risk from a HMO, is not required to obtain its own license to assume the risk, provided that the ~~ultimate~~ responsibility FOR HMO OPERATIONS ~~provision of care to enrollees~~ remains, as set forth in the enrollee contract, the responsibility of the HMO,	Issue: we question the intent of this provision. Does it really mean to say that the "ultimate provision of care to enrollees remains the responsibility of the HMO." The responsibility for provision of care rests with the provider per the terms of the provider contract. Thus we recommend the use of the term "HMO operations", as previously used in 9.635 Delegation of HMO operations.
9.725 IDS-provider contracts INSERT NEW (a) IMMEDIATELY PRECEDING (1):	Issue: This language provides for timelines for review. If the Department does not provide a

(a) IF THE DEPARTMENT DOES NOT TAKE SPECIFIC ACTION IN THE FORM OF AN APPROVAL OR REQUEST FOR ADDITIONAL INFORMATION OR CLARIFICATION WITHIN 45 DAYS OF RECEIPT OF THE FILING, THE FILED PROVIDER CONTRACT(S) SHALL BE DEEMED APPROVED. THE DEPARTMENT SHALL USE REASONABLE EFFORTS TO MAKE ITS REQUEST FOR ALL ADDITIONAL INFORMATION OR CLARIFICATIONS AT ONE TIME. AFTER A REQUEST FOR ADDITIONAL INFORMATION OR CLARIFICATION HAS BEEN MADE, IF THE DEPARTMENT DOES NOT TAKE ANY ADDITIONAL SPECIFIC ACTION IN THE FORM OF AN APPROVAL OR DISAPPROVAL WITHIN THIRTY (30) DAYS OF THE RECEIPT OF THE ADDITIONAL INFORMATION OR CLARIFICATION, THE FILED PROVIDER CONTRACT(S) SHALL BE DEEMED APPROVED.	response within the established timeframes, plans can proceed with the presumption that the contracts are deemed acceptable.
9.742.CREs. (b) ...~~chapter~~ SUBCHAPTER.	Issue: Correction
(c) ~~... the act~~ ACT 68....	Issue: Correction
9743. Content of an application for certification as a CRE. (c)(5)(iv) ~~... the act~~ ACT 68....	Issue: Correction
9.744.CREs participating in internal and external grievance reviews. (a)(4)(ii) ~~... the act~~ ACT 68....	Issue: Correction
9.744 (a)(4)(v) A fee schedule for the conduct of grievance reviews. SUCH FEES SHALL BE PUBLIC INFORMATION. An applicant will not be certified as A CRE unless the proposed fees for external reviews are determined to be reasonable by the Department.	Issue: Plans are unable to determine whether the bills they receive are consistent with the Department's approved reasonable fees.
9.745 Responsible applicant (a)(2)~~(i) Filed for bankruptcy~~	Issue: Broad and intrusive scope of requirements. The personal bankruptcy history of individuals, especially management personnel, is not relevant, and could be deemed discriminatory.
9.745 (a)(2)~~(v) Have a history of malpractice or civil suits, penalties or judgements against them.~~	Issue: Broad and intrusive scope of requirements
9.746. Fees for certification and recertification of CREs. (a) ... ~~By ___~~AFTER _____(Editor's note: The blank refers to the ~~effective~~ date of adoption of ~~this proposal~~THESE AS FINAL REGULATIONS) ~~each CRE that is already certified by the Department shall pay the fee to the Department.~~CRES ALREADY	Issue: The Department has told CREs that there will be no fees if filed before the adoption of final regulations.

CERTIFIED BY THE DEPARTMENT SHALL BE SUBJECT TO FEES FOR RECERTIFICATION 3 YEARS AFTER THE DATE OF ORIGINAL CERTIFICATION.	
9.748(a) Maintenance. To determine whether a CRE is complying with Act 68 and this subchapter, and maintaining its certification during the 3-year certification period, the Department ~~may~~ SHALL do one or more of the following:	Issue: The Department is the only entity with oversight over CREs. Since CREs make determinations affecting all managed care plans in the state, the Department should exert strong oversight on an ongoing basis.

EASTON
HOSPITAL
A member of Valley Health

January 15, 2000

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

Dear Mr. McGinley:

Act 68, "the Quality Health Care Accountability and Protection Act, was an important first step in establishing managed care accountability and improving health insurance practices in Pennsylvania. In addition, the Department of Health's proposed regulations, which implement Act 68 will address the important areas of certification of utilization review entities, consumer and provider grievances, quality assurance and contracting with integrated delivery systems. These proposed regulations would bring the Department of Health's HMO regulations up-to-date.

The Administration and Board of Trustees at Easton Hospital would like to commend the Department of Health for the following requirements established 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.
- 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.

On the other hand, we believe the Department of Health should consider the following changes to the regulations as proposed:

- Clarifying standards for ensuring that enrollees 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 capable of performing the needed service. These standards should not dictate provider payments in these situations. The way theses provisions are described in the preamble goes beyond the scope of both the HMO Act and Act 68. Establishing payment standards would interfere in the contracting processes between health plans and health care providers

by, in effect, establishing default payment rates, thus removing any incentive to negotiate fair payment rates.

- Ensuring that Department of Health standards regarding emergency services, continuity of care, and direct access to obstetric and gynecologic care are consistent with the Insurance Department's regulations.
- Ensuring that providers may advocate for their patients and may obtain written consent to do so at the time of treatment.
- Strengthening the utilization review standards to ensure that:
  1. Plans provide a clinical rationale in denial letters;
  2. There are ongoing standards for utilization review for licensed insurers and managed care plans;
  3. There is effective monitoring and enforcement by the Department of Health of utilization review practices; and
  4. Licensed insurers and managed care plans are held accountable for prospective and concurrent utilization review decisions.

Easton Hospital and the Valley Health System are appreciative of the administration's and legislature's efforts to support the Department of Health in requiring health insurers and managed care plans to demonstrate appropriate and effective compliance with Act 68. We believe that the effective implementation of Act 68 can benefit patients by fostering greater coordination and cooperation among health plans and health care providers. Thank you for the consideration of our recommendations.

Sincerely,

Michael H. Cox, Ph.D.
Vice President
Planning & Marketing

HEALTHSOUTH
Harmarville Rehabilitation Hospital

January 14, 2000

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

Dear Mr. McGinley:

As a health care provider it is our responsibility to provide each patient served the highest quality of care. That means providing the most up to date and appropriate medical interventions for their condition at the appropriate point in their recovery and for the appropriate length of time. In today's environment of managed care this is only possible if health insurance plans and health care providers work together in the best interest of the patient. We need to focus our efforts on managing patient care rather than managing insurance costs possibly at the expense of quality patient care.

Hospitals and health systems believe that the Department of Health Regulations for Act 68 is an important first step to providing managed care accountability. We support the establishment of plan reporting requirements to help ensure effective oversight and establishing consistency in the definition of medical necessity by health plans.

However there are several points in the Department of Health's regulations that need revision. The following points are essential in ensuring improvements in health insurance practices:

- Strengthening the utilization review standards to ensure that:

  1. plans provide a clinical rationale in denial letters;
  2. there are ongoing standards for utilization review for licensed insurers and managed care plans;
  3. there is effective monitoring and enforcement by the Department of Health of utilization review practices; and
  4. licensed insurers and managed care plans are held accountable for prospective and concurrent utilization review decisions.

- Ensuring that providers may advocate for their patients and may obtain written consent to do so at the time of treatment

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As a major health care provider in Pennsylvania, we are concerned about the ability to sustain quality health care services in today's environment without these important changes in the proposed regulations. When a patient purchases health insurance they are under the belief that their medical needs will be covered and that qualified medical personnel will make decisions on their treatment. We need to assure that cost management does not override sound medical management. I would appreciate your support of the Department of Health in requiring health insurers and managed care plans to demonstrate appropriate and effective compliance with Act 68.

Thank you for your consideration and support of this important regulation.

Sincerely,

Sharon Noro
Administrator/CEO

Pennsylvania Catholic Health Association

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pcha@pacatholic.org

Sister Clare Christi Schiefer, OSF
President

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January 14, 2000

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

Re: Proposed Rulemaking
Department of Health Managed Care Organizations
Pennsylvania Bulletin, Vol. 29, No. 51 - 12/18/99

Dear Ms. Mitchell:

On behalf of the Pennsylvania Catholic Health Association (PCHA) and the Pennsylvania Catholic Conference (PCC), I submit the following comments in connection with proposed regulations concerning Managed Care Organizations. The Pennsylvania Catholic Health Association, an associate of the Pennsylvania Catholic Conference, is a statewide organization that represents the Catholic Health Ministry in public policy matters and numbers among its members twenty-six hospitals, thirty-seven long term care facilities, numerous related health care entities that include six national health systems, and sponsoring congregations and dioceses. The Pennsylvania Catholic Conference is the public affairs arm of the Pennsylvania Catholic bishops and their ten dioceses that speaks for the Church in public policy matters affecting the common good and its ministry interest concerning morality, health, welfare, education, and human and civil rights.

Other organizations are submitting lengthy comments concerning all aspects of the proposed rulemaking. Particularly noteworthy are those submitted by the PA Health Law Project, especially as those comments note an inconsistency between the regulations and Act 68. Any weakening of the statute by more restrictive regulatory language is objectionable and would need to be corrected. As to all such objections not otherwise addressed in these comments, PCHA and PCC urge careful attention to the observations of the PA Health Law Project.

Comments of PCHA and PCC to the proposed regulations are as follows:

- Act 68 requires that a managed care plan "adopt and maintain a definition of medical necessity" which would be used by the plan in determining health care

services. (§2111(3)). The proposed regulation in this respect is standardless. There is no base definition of "medical necessity" to which all plans will be held. The result is that so long as *some* definition is set forth and it is used consistently in provider contracts, enrollee contracts and other materials (28 Pa. Code §9.677, proposed rule), the Department will not, it appears, objectively evaluate the propriety of the definition.

- Section 9.722 of the proposed regulations limits the contents of a provider contract. A catchall provision at §9.722(c)(4), states that a provider cannot be sanctioned, terminated or nonrenewed for (t)aking another action specifically permitted by section 2113 [of] (sic) the act..." For clarity, it should also be stated that no contract can exclude or terminate a provider for any of the reasons enumerated in 2121(e) of the act (40 P.S. §991.2121(e)) except as that might violate the rights of a plan as set forth at §2113 (d) of the act (40 P.S. §991.2112(d)).
- PCHA and PCC strongly recommend that these regulations, and those ultimately to be proposed by the Insurance Department, be complementary not duplicative. And, to the extent that the Department of Health believes certain aspects of administration and oversight permitted by the act are beyond its purview, that the Insurance Department address and exercise oversight over those aspects.

Your attention to these comments is appreciated.

Very truly yours,

Sister Clare Christi Schiefer, OSF

Sister Clare Christi Schiefer, OSF
President

SCC/mjs

cc: PCHA Board of Directors
Richard E. Connell, Esq.
Robert J. O'Hara, Jr.
Senator Harold Mowery
Senator Edwin Holl
Representative Dennis O'Brien
Representative Nicholas Micozzie
Senator Timothy Murphy
Representative Patricia Vance

PENNSYLVANIA CATHOLIC HEALTH ASSOCIATION

facsimile
TRANSMITTAL

to: Ms. Stacy Mitchell, Director
Bureau of Managed Care
PA Dept.of Health

fax #: 783-2664

re: Proposed Rulemaking
Dept. of Health Managed Care Organizations
PA Bulletin, Vol. 29, No. 51 - 12/18/99

date: January 14, 2000

pages: 3, including this cover sheet.

From the desk of...

Sister Clare Christi Schiefer, OSF
President
Pennsylvania Catholic Health Association
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Fax: 717-238-1473

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January 14, 2000

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

Dear Ms. Mitchell:

We have enclosed our comments on the promulgation process of and the product cited as Annex A, TITLE 28. HEALTH AND SAFETY, PART 1. GENERAL HEALTH, CHAPTER 9. MANAGED CARE ORGANIZATIONS (29Pa.B.6422-6441).

Yours very truly,

Gail M. Rockwood

Horace S. Rockwood III

Copy to:

✓IRRC
Senator Tim Murphy
Representative John Maher

Comments on the PA DOH ProposedRegulations to Implement Act 68 of 1998, the Managed Care Accountability Act (P.L. 464, No. 68)

The "stealth" nature of the release of the Proposed Regulations dictates that we first request an extension for an additional 30 days for comments, appropriately and widely advertised. The Proposed Regulations were released December 18, 1999, with comments due by January 17, 2000, a period when most agencies and citizens could be expected to be occupied with other things, including the coming Y2K as well as the holidays; do not not allow or encourage submission other than by mail; and the Proposed Regulations were not put on the DOH website--as confirmed by a phone call to DOH on January 11, 2000, when the person who answered thought they were on the website but couldn't find them either). Far too many citizens of Pennsylvania will be affected by the regulations to allow DOH to, in effect, "sneak" its Proposed Regulations by the general public.

The length and complexity of this rulemaking makes analysis especially difficult without having access to the previous (existing) regulations and guidance that are currently in effect, e.g., the DOH Fundamental Fairness Guidance and 28PACodeChapter 9 provisions governing managed care organizaitions. Since the new proposed regulations incorporate, by reference only (with no content appended), other in-force regulatory mechanisms, the reviewer has no comprehensive framework from which to evaluate this package and to determine whether or not it weakens or strengthens the enrollee protections intended to be enhanced by ACT 68. One needs also to understand those issues that are separately or jointly addressed by pending Dept. of Insurance regulations. As parents of and advocates for persons who suffer from serious mental illness and are enrolled by mandate (HealthChoices) in "managed care" entities, we are disturbed by what seems a shell-game constructed to obfuscate, rather than clarify, protections for the enrollee.

We are impressed by the detailed analysis put forward by the Pennsylvania Health Law Project and recommend that DOH respond thorougly to the concerns it has raised. We would also be interested to learn the identity of and association of members of the workgroups convened pursuant to Executive Order 1996-1, particularly the groups dealing with consumers, special needs, and behavioral health. We further request DOH's "Comment/Response" synopsis, showing changes from the draft it circulated to stakeholders (May 1999) and this proposed rulemaking.

From what we have seen of the Proposed Regulations, a small sample of the incorporated references, and the PHLP analysis, the Proposed Regulations appear to weaken, at virtually every opportunity, the existing safeguards that protect Pennsylvania citizens and the healthcare they deserve. To cite one glaring economic example, current regulations offer a layer of protection to citizens in what they can be charged for copayments: in Basic Health Services, Section 9.72. (b (1)): "To insure that copayments are not a barrier to the utilization of health services or membership in the organization, an HMO shall neither impose copayment charges that exceed 50% of the total cost of providing any single service to its subscribers nor 20% of the total cost of providing all basic health services." According to the PHLP "bullet" analysis, the Proposed Regulations do "away with limits on copayments, and [proovide] that DOH . . . review the impact of copayments on access, continuity of care, quality, and cost effectiveness **only** upon request by the Department of Insurance."

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Submitted by:

Gail M. and Horace S. Rockwood III
218 Hays Road
Pittsburgh, PA 15241
724-941-4167

Shamokin Area Community Hospital

4200 Hospital Road • Coal Township, PA 17866-9697
Phone 570-644-4200 • Fax 570-644-4338

January 10, 2000

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

Dear Mr. McGinley,

Statistics indicate that more than 2/3 of Pennsylvania's hospitals and health systems are losing money. Each day at Shamokin Area Community Hospital we must evaluate services and how they are provided to make them as efficient as possible without affecting the quality of care. We believe that Act 68, with effective implementation, can benefit patients by fostering increased cooperation between health plans and health care providers.

Having recently read through the Department of Health proposed Act 68 regulations, I commend them for including several requirements. 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 uniform in all documents to ensure consistency in medical decision making; and enabling managed care plans to create mechanisms for procedural errors and denials to be addressed between the plan and the providers without obtaining the consent of the enrollee will be beneficial to the patient and the care they receive.

However, while we appreciate the language in many of the Department of Health proposed regulations, there is also the need for some changes. There must be clarification in the standards that ensure enrollees 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 capable of performing the needed service. These standards should not dictate provider payments in these situations. The way these provisions are described in the preamble goes beyond the scope of both the HMO Act and Act 68. This would remove any incentive to negotiate fair payment rates by, in effect, establishing default payment rates.

Secondly, Department of Health standards regarding emergency services, continuity of care, and direct access to obstetric and gynecologic care must be consistent with the Insurance Department's regulations. Additionally, providers must be able to advocate for their patients and may obtain written consent to do so at the time of treatment.

Finally, the utilization review standards should be strengthened to ensure that plans provide a clinical rationale in denial letters, that there are ongoing standards for utilization review for licensed insurers and managed care plans, that there is effective monitoring and enforcement by the DOH of utilization review practices; and that licensed insurers and managed care plans are held accountable for prospective and concurrent utilization review decisions.

Thank you for your ongoing support of the Department of Health in the effort to require health insurers and managed care plans to demonstrate effective compliance with Act 68.

Sincerely,

John P. Wiercinski,
President and Chief Executive Officer

HEALTHSOUTH
Rehabilitation Hospital of York

January 14, 2000

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

Dear Mr. McGinley:

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

- Suggest strengthening utilization review standards to ensure that:
  - Plans provide a clinical rationale in denial letters;
  - There are ongoing standards for utilization review for licensed insurers and managed care plans;
  - There is effective monitoring and enforcement by the Department of Health of utilization review practices; and
  - Licensed insurers and managed care plans are held accountable for prospective and concurrent utilization review decisions.
  - Ensure that providers may advocate for their patients and may obtain written consent to do so at the time of treatment.
- 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 its decision at any time.

Hospitals and health systems are appreciative of the administration's and legislature's efforts to support the Department of Health in requiring health insurers and managed care plans to demonstrate appropriate and effective compliance with Act 68.

Thank you for your consideration.

Sincerely,

Cheryl Fleming
Chief Executive Officer

CF/dg

ACMH
Armstrong County Memorial Hospital
One Nolte Drive • Kittanning, PA 16201 • (724) 543-8500

January 14, 2000

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

Dear Mr. John R. McGinley, Jr.:

I am writing to you on behalf of Armstrong County Memorial Hospital to express our concerns regarding the proposed regulations implementing Act 68.

We believe that the Department of Health should be commended for including requirements in the regulations which establish a method for reporting information to the public regarding plan practices. We are impressed with the regulations requiring all definitions of medical necessity to be consistent across all material and literature published by a plan and that the regulations provide for a mechanism to correct routine procedural errors and denials between the plan and the provider without the need of enrollee consent.

We feel it is also imperative that the Department of Health regulations be improved by clarifying standards for insuring that enrollees receive the same benefit level for either emergency services provided by non-participating providers or for services for which there are no participating health care providers capable of performing the needed service. We feel that establishing payment standards would interfere in the contracting process between the health plans and the health care providers. The plans and the providers should have the latitude to negotiate fair payment rates. The Department of Health standards regarding emergency services and direct access to obstetrics and gynecological care are consistent with the insurance department regulations. These regulations should insure that providers may advocate for their patients and may obtain the written consent to do so at the time of treatment. We also feel that strengthening of utilization review standards should be established to ensure that plans provide a clinical rational in denial letters. There should be standards for utilization review of licensed insurers and managed care plans that there is an effective monitoring and enforcement by the Department of Health of utilization review practices. Licensed insurers and managed care plans should be held accountable for prospective and concurrent utilization review decisions.

We appreciate the efforts of the Commonwealth of Pennsylvania which has resulted in legislation such as Act 68 protecting the quality of care and the rights of patients and providers to receive fair payment for the provision of care to our citizens.

Sincerely yours,

Richard W. Szymkowski (csb)

Richard W. Szymkowski
VP Finance/CFO

RWS/csb

cc: Jack Hoard
Liz White

HEALTHSOUTH
Rehabilitation Hospital Of Greater Pittsburgh

January 10, 2000

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

Dear Mr. McGinley:

With more than two-thirds of Pennsylvania's hospitals and health systems losing money on patient care, there is no ability to sustain inappropriate or unreasonable denials of payment for care without affecting quality.

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.

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.

It is imperative that the Department of Health's regulations be changed by:

- Clarifying standards for ensuring that enrollees receive the same benefit level for either emergency services provided by non-participating providers for services for which there are no participating health care providers capable of performing the needed service. These standards should not dictate provider payments in these situations. The way these provisions are described in the preamble goes beyond the scope of both the HMO Act and Act 68. Establishing payment standards would interfere in the contracting processes between health plans and health care providers by, in effect, establishing *default payment rates*, thus removing any incentive to negotiate fair payment rates;

- Ensuring that Department of Health standards regarding emergency services, continuity of care, and direct access to obstetric and gynecologic care are consistent with the Insurance Department's regulations;
- Ensuring that providers may advocate for their patients and may obtain written consent to do so at the time of treatment;
- Strengthening the utilization review standards to ensure that:

    1. Plans provide a clinical rationale in denial letters
    2. There are ongoing standards for utilization review for licensed insurers and managed care plans
    3. There is effective monitoring and enforcement by the Department of Health of utilization review practices, and
    4. Licensed insurers and managed care plans are held accountable for prospective and concurrent utilization review decisions.

Hospitals and health systems are appreciative of the administration's and legislature's efforts to support the Department of Health in requiring health insurers and managed care plans to demonstrate appropriate and effective compliance with Act 68.

Sincerely,

Faith Deigan

Faith A. Deigan
Administrator/CEO, Vice President

FAD/vls

FAX TRANSMITTAL

EPILEPSY FOUNDATION
WESTERN PENNSYLVANIA

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TO: Stacy Mitchell

FROM: Peggy Beem

DATE: 1-6-2000

FAX#: 717-705-0947

PAGES: (5) (including cover page)

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COMMENTS:

Please deliver to Ms. Mitchell as soon as possible.

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PITTSBURGH, PA 15219

VIA FAX ONLY

January 6, 2000

Stacy Mitchell
Director, Bureau of Managed Care
PA Department of Health
P.O. Box 90
Harrisburg, PA 17120

Dear Ms. Mitchell:

Richard Lee, Deputy Secretary for Quality Assurance suggested in a November 22, 1999 correspondence that the Epilepsy Foundation Western Pennsylvania contact you to arrange a meeting to discuss the PA Department of Health proposed regulations on Act 68, the Quality Health Care Accountability Protection Act.

We would like to arrange a meeting to discuss Act 68 regulations the afternoon of Tuesday, January 18, 2000. I understand that this is the last day for public comment on the proposed regulations and we will certainly prepare and submit written comments prior to this date.

However, we were asked to meet Department of Health officials from the Bureaus of Family Health and Community Health Systems to discuss unrelated issues on Wednesday, January 19, 2000 and have already scheduled that meeting. Because we will be traveling from the western region of the state, it would be very much appreciated if we can schedule our meeting with you and Mr. Lee in conjunction with our January 19th meeting at the Department of Health.

I would also like to bring to your attention that we have a December 14, 1999 letter from Physician General Dr. Robert Muscalus agreeing to attend our meeting with you and Richard Lee. I have attached copies of the letters from Mr. Lee and Dr. Muscalus and hope that their schedules might permit them both to meet with us on January 18, 2000.

Please contact me at your earliest convenience to discuss scheduling this meeting. If there is something that I can do to help facilitate this meeting, please do not hesitate to ask.

I look forward to meeting you.

Sincerely,

Peggy Beem
Program Director

Cc: Richard Lee, Deputy Secretary for Quality Assurance
Physician General Dr. Robert S. Muscalus

DEPARTMENT OF HEALTH
...in pursuit of good health

January 10, 2000

Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

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Re: Proposed Regulations
Managed Care Organizations
No. 10-160

Dear Mr. Nyce:

The Pennsylvania Department of Health has recently received the enclosed public comments to the above-referenced regulations.

Sincerely,

Stacy Mitchell

Stacy Mitchell
Director
Bureau of Managed Care

ENCLOSURE

Stacy
00-01-18

THOMSON, RHODES & COWIE, P.C.

Attorneys At Law

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January 18, 2000

VIA FACSIMILE [1-717-705-0947] and U.S. MAIL

Stacy Mitchell, Director
Bureau of Managed Care
Pennsylvania Department of Health
Health and Welfare Building, Room 1030
Box 90
Harrisburg, PA 17130

Re: Comments regarding proposed managed care regulations

Dear Ms. Mitchell,

I offer the following proofreading and comments for your consideration. The comments are not offered on behalf of any client or organization, they represent my personal opinions.

1. Comments section. Section 9.671, third line: insert the word "regulations" after "current".

2. First page of Regulations, Subchapter E: The words "are deleted in their entirety" are missing from the end of the cites to the sections.

3. Section 9.672 (c): I saw the correction in the Dec 25, 1999 PA Bulletin but there still seems to be a wording problem that could lead to interpretation problems. Since this section is similar to Act 112 of 1996, Section 2 (c), I suggest using the language of Act 112 for consistency and clarity.

4. Section 9.722 (b): Please add the word "standard" before "health care provider contract". This modification is requested to clarify that this section does not refer to amendments to contracts affecting only an individual provider.

5. Section 9.724 (13) IMPORTANT: This section will hinder the ability of HMOs to enter contracts with certain IDSs that insist on longer initial terms, especially during the beginning of the contract when the IDS may have a lot of start-up costs. I suspect that out-of-state limited service IDS contractors will be

discouraged from doing business in Pennsylvania if this requirement is promulgated. Further, this provision may affect an HMO's ability to satisfy requirements of the safe harbor rules under the federal fraud and abuse laws. To establish that a contract is subject to the protections of the safe harbor rules for management contracts and price reductions, the HMO must establish that the contract term is for one year. The safe harbor for management contracts may applicable where there is a fee paid for the delegation of an administrative function. The 60 day requirement will make it difficult to meet the one year requirement. Finally, plans must have the ability to immediately terminate Finally, plans must have the ability to immediately terminate under circumstances involving harm to members.

I respectfully request the revision of this section so that it is consistent with the requirement in 9.722 (e) (2)(i)(7), i.e. IDSs must give at least 60 days notice to the plan prior to termination.

Thank you for your consideration of my comments.

Sincerely,

L. Jane Charlton

LJC/cam

PENNSYLVANIA ACADEMY OF FAMILY PHYSICIANS

Rec'd
1/20/00 10:10 Am. KCG

January 14, 2000

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

Re: Department of Health Proposed Regulations;
Quality Health Care Accountability and Protection Act
Implementation (Act 68 of 1998)

Dear Ms. Mitchell:

The Pennsylvania Academy of Family Physicians (the "Academy") represents over 4,500 physician members. The following comments are submitted in response to the Department of Health's proposed regulations implementing Act 68 of 1998, the Quality Health Care Accountability and Protection Act, which were published at 29 *Pa. Bulletin* 6409-6441 (December 18, 1999).

Definitions - § 9.602

Gatekeeper - The Academy believes the term "gatekeeper" is both unnecessary and pejorative. It is unnecessary because it can easily be replaced with the phrase "primary care physician" throughout the regulations. It is pejorative because it implies physicians intentionally restrict access to needed services, which is not the case. In the alternative, a more accurate and less offensive term would be "Care Coordinator." If the Department refuses to modify the phrase "gatekeeper", the definition of "gatekeeper" should be modified to strike the word "provider" and replace it with the word "physician." As currently drafted, the term implies non-physician providers possess the ability to practice independent of physicians, which is contrary to law. Similar changes should be made to the definition of "Gatekeeper PPO."

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Primary Care Provider - The definition of this phrase in the proposed regulation tracks the statutory definition of the phrase. A potential ambiguity in that definition, however, should be addressed and resolved in the regulations.
The existing HMO regulations require HMOs to make available to each subscriber "a primary care physician to supervise and coordinate the health care of the subscriber." 28 Pa. Code § 9.75(c). Nothing in Act 68 changed the accessibility requirements under § 1555.1(b)(1)(i) of the HMO Act upon which § 9.75(c) was based. Accordingly, no authority exists in Act 68 to alter the primary care physician supervision and coordination requirement. Therefore, the regulations should clearly state that a "primary care physician shall supervise and coordinate the health care of an enrollee." Advanced practice nurses and physician assistants should not be expressly or impliedly authorized in the regulations to possess supervisory and coordination authority or to practice independently of a primary care physician.

As § 2102 of Act 68 makes clear, Act 68 did not expand the scope of practice of any health care provider. Neither APNs nor PAs can practice independent of a primary care physician. Act 68 does not authorize substitution of a primary care physician with an APN or PA. Physician-approved protocols and standing orders, where appropriate, should guide the APN's or PA's approach to patient-described conditions. Standing orders should implement treatment following the diagnosis. An APN and a PA should be prohibited from being held out as a "primary care provider." Therefore, the regulations should define a "primary care provider" as "a physician who is Board certified or Board eligible in and limits his practice to family medicine, general internal medicine or pediatrics; or is a generalist physician who renders primary care at least 50% of the time in which he engages in the practice of medicine."

Primary Care - Act 68 mentions the phrase "primary care" several times, but fails to define this crucial term. The Academy believes the Department of Health possesses regulatory authority to promulgate a definition of "primary care", and submits the following definition, which was developed and endorsed by both the American Academy of Family Physicians and the Pennsylvania Academy of Family Physicians, for adoption in the regulations:

> **"Primary Care."** Care provided by physicians specifically trained for and skilled in comprehensive first contact and comprehensive continuing care for persons with any undiagnosed sign or symptom of health concern, the "undifferentiated" patient, not limited by problem origin, gender or diagnosis. The term includes health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses in a variety of health care settings, including office, inpatient, critical care, long-term care and home care. Primary care is performed and managed by a personal physician, utilizing other health professions, consultation and referral, as

appropriate; provides patient advocacy in the health care system to accomplish cost-effective case management and care coordination of health care services; and promotes effective doctor-patient communication and encourages the role of the patient as a partner in health care.

Primary Care Physician - On page 6410 of the Department of Health's official comments, the Department proposes to delete the term "primary care physician" from the regulations because the phrase "primary care provider" is used in Act 68. The Academy strongly objects to this proposed deletion. There are significant and substantial differences between an appropriately trained and experienced "primary care physician" and a "primary care provider" identified in Act 68. A "primary care provider" is not interchangeable with a "primary care physician." A CRNP is not a fungible substitute for a physician. Deletion of the term "primary care physician" may dilute the quality of health care provided to Pennsylvania's residents. Accordingly, the Academy recommends the definition of "primary care physician" at existing 28 Pa. Code § 9.76(a)(2) be retained.

Technical Advisories - § 9.603

Section 9.603 accurately addresses the legal effect of a technical advisory opinion. In the past, specifically with respect to certified registered nurse practitioners being allowed to practice independent of physicians, both advanced practice nursing interests and the Department have used the technical advisory process as a waiver mechanism. Stakeholders should be put on notice that, unlike TAM 95-1, the technical advisory process cannot be utilized to secure a waiver of statutory and regulatory requirements.

A provision should be added to the end of § 9.603 requiring the Department to publish the text of Technical Advisories in the *Pennsylvania Bulletin*. Alternatively, the Department should publish in the *Pennsylvania Bulletin* a description of the nature of the Technical Advisory, allowing the public to obtain the document upon request to the Department (much as the Pennsylvania Human Relations Commission publishes a notice of its decisions in the *Pennsylvania Bulletin* and allows any individual or organization to obtain a copy).

Plan Recording Requirements - § 9.604

Section 9.604(a)(3) requires MCOs to submit "data relating to complaints and grievances" in its annual report to the Department. This vague provision could result in MCPs submitting sparse information substantially less than what the Department may intend, and to which consumers and physicians may be entitled to review under the Right to Know Act. Accordingly, the Academy recommends § 9.604(a)(3) be supplemented to include more specific detail about the number and types of complaints and grievances MCPs receive and process, number and types of complaints that were resolved internally in favor of the enrollee or physician, etc.

Prohibition Against Uncertified HMOs - § 9.622

Section 9.622(a) prohibits only corporations from engaging in HMO activity. As a technical matter, inasmuch as this provision is a broad prohibition, the first four words should be stricken and replaced with "no person, partnership, corporation or limited liability company or other entity shall..."

Certificate of Authority - § 9.632

Under § 9.632(b), the discretionary public meeting on new HMO applications should be mandatory to better serve the public interest.

Character and Competency of HMO Owners/Officials - § 9.633

Rules concerning the character and competency of HMO owners and officials at § 9.7 of the Department's draft proposed regulations were deleted in the proposed rulemaking. The Academy believes these rules should be reinserted. In addition, the Academy believes that any HMO which employs an officer, director or management personnel who has been "convicted" of a federal offense as defined by Medicare regulations should be disapproved until the "convicted" official is removed. If this type of individual is involved in any direct or indirect ownership or control of a health care entity, the Office of Inspector General may automatically exclude that entity from participation in Medicare. *See* 42 C.F.R. § 1001.1001. The same rationale is applicable here.

In addition, under § 9.633(a), the one-third "member" minimum is appropriate; however, the regulations should expressly state that the members must be informed and educated about managed care, and not be employed by an HMO or Managed Care Plan as defined by Act 68.

Change of Ownership or Control

Under the Department of Health's draft proposed regulations at § 9.12(a), the Department outlined requirements HMOs must satisfy to effectuate a change of ownership or control in the HMO. The Academy believes those requirements should be reinserted in the final rulemaking.

Use of Co-Payments and Co-Insurance - § 9.653

Section 9.653 gives the Department of Health authority to analyze an HMO's use of co-payments and co-insurances to determine their effect on the availability, accessibility or continuity of services. The Department's authority appears to be conditioned upon "the request of the Insurance Department" to initiate such an investigation or analysis. The Academy believes the introductory clause ("Upon request of the Insurance Department") should be stricken. Any potential negative effect of excessive co-payments and co-insurance amounts addresses quality of care concerns, fully within the jurisdiction of the Department of Health. The Department of Health's authority to

investigate or sanction HMOs for quality of care infractions (under 40 P.S. § 991.2182) should not be conditioned upon or limited by the Insurance Department's involvement or recommendation in the matter, but should be triggered by its own investigation, consumer complaints or physician/hospital complaints.

HMO External Quality Assurance Assessment - § 9.655

Under § 9.655(a), HMOs are required to have an external quality assessment conducted using an external quality review organization acceptable to the Department. The Academy assumes the Department is relying on NCQA, and presently has no objection to relying upon that organization's standards. The Academy believes the Department should establish a mechanism in the final regulations to disclose to the public those external quality review organizations acceptable to the Department of Health.

Standards for Approval of POS Options - § 9.656

Under § 9.656(b)(ii), an HMO, as a condition to offering POS options, must have a system to "promptly investigate any PCP practice in which enrollees are utilizing substantially higher levels of non-PCP referred care than average, to ensure that enrollee self-referrals are not a reflection of ***access or quality problems on the part of the PCP practice***."

The assumption inherent to this provision that patients' use of non-referred care is a function of family physicians' quality problems lacks any reasonable foundation in fact. On the contrary, the Academy's experience is that patients utilize non-referred care due to **the HMO's** (a) lack of approval for referrals, (b) lack of adequate specialists in the network, and (c) lack of coverage for particular care or services offered through the more tightly managed care products. This provision should be substantially revised to require investigation of the real reasons for higher levels of non-referred care as stated above.

Emergency Services - § 9.672

Under § 9.672(c) in the December 18, 1999 proposed rulemaking, a plan "may" apply the statutory prudent layperson standard when adjudicating related claims for emergency services. The Academy believes it is virtually impossible to establish a clear demarcation between initial emergency services and "related claims." The Academy believes the permissive "may" should be replaced with the mandatory "shall." The Academy notes that the Department of Health recognized this oversight in a subsequent clarification published at 29 *Pa. Bulletin* 6470 (December 25, 1999). The Department should publish final rulemaking consistent with this clarification.

Drug Formularies - § 9.673

The Academy's members report significant problems with MCP drug formulary restrictions that negatively affect the quality of care delivered. Accordingly, the Academy believes the following provisions should replace § 9.673(c):

1. If the MCP maintains one or more closed drug formularies, the MCP shall establish a process to allow an enrollee to obtain without additional cost-sharing beyond that provided for formulary prescription drugs in the plan, a specific, medically necessary non-formulary prescription drug if the formulary drug is determined, after reasonable investigation and consultation with the enrollee's prescribing physician, to be an inappropriate therapy for the medical condition of the enrollee.

2. The MCP shall be required to act on requests for non-formulary prescription drug coverage in an expedited fashion, within one business day of receipt of the request. Any denial should be subject to the expedited review procedures set forth in § 9.709.

3. Prior to the MCP's modification of its closed drug formulary, participating physicians in the plan shall have the opportunity to receive written notice of such changes and the opportunity to comment prior to the MCP's final decision.

4. An MCP shall include on its closed drug formulary committee at least one primary care physician in active practice and licensed in Pennsylvania.

5. Enrollees shall be allowed to continue receiving coverage and reimbursement for medications while an MCP closed formulary committee is reviewing the drug for addition to or deletion from the formulary, and throughout the entire duration of the formulary exception appeal process.

6. Patients already receiving certain drugs covered by the formulary shall continue to be able to receive coverage and reimbursement for the same drug if the MCP subsequently removes that particular drug from its closed formulary.

7. MCPs shall develop a consistent policy regarding the amount of formulary medications dispensed at one time and a consistent method of payment. (Academy physician

> members are confounded by numerous different MCPs' dispensing requirements.)

At least one Attorney General (in Connecticut) has filed suit against that jurisdiction's largest managed care company alleging its drug formulary policies pose "potentially harmful and dangerous restrictions on consumers." See Connecticut v. Physicians Health Services of Connecticut, Inc., and related story in December 23, 1999 BNA *Health Law Reporter*. This is a very serious issue and the Department's draft proposed regulations do not provide sufficient protection to enrollees on this subject.

Further, under § 9.673(b), the MCP should be required to distribute drug formulary information to the enrollee on an expedited basis, i.e. within one business day, since quality of care could be compromised without expedited MCP response. Moreover, some procedure should be created to allow physicians to request and receive this information on behalf of enrollees. Regulatory authority exists for this type of provision under 40 P.S. § 991.2111(1) pursuant to the availability and accessibility of adequate health care in a timely manner.

Quality Assurance Standards - § 9.674

Under § 9.674(b)(3), the MCP's QA program must be overseen by "plan participating physicians in active clinical practice." The Academy supports this provision; however, the phrase "active clinical practice" is not defined in the proposed rulemaking, but is defined at 40 P.S. § 991.2102. The Academy believes restating the statutory definition would be helpful for stakeholders. The Academy also suggests the language be clarified to include plan participating physicians who are "not employed by the plan."

"Medical Necessity" Definition Requirements - § 9.677

The Department's draft proposed regulations at § 9.47 contained the following provision:

> "A plan shall adopt and maintain a definition of medical necessity which is consistent with national and industry standard definitions of medical necessity, is not unduly restrictive and does not rely on the sole interpretation of the plan or plan's medical director."

The Academy, in its stakeholder comments, agreed this provision was a positive step in the right direction, but needed additional refinement. The Academy objects to the Department's deletion of this clause in its proposed rulemaking, and requests re-inclusion of the removed provision and additional parameters discussed below.

The Legislative Budget & Finance Committee issued a report in June 1999 entitled *Commonwealth Efforts to Assure Quality of Care in the Changing Health Care Environment*. In that report, LB&FC recommends the Department of Health

promulgate regulations, *inter alia*, "establish[ing] the criteria to be used in defining 'medical necessity.'" (*See* p. S-14) The LB&FC report goes on to state that "the Department should establish the limits for a range of acceptable practices and sources of standards plans may use in developing their definitions." *Id.* The Academy fully supports LB&FC's conclusion. Moreover, the Academy presents the following rationale in support of more detailed parameters than existed in the Department's proposed draft rulemaking.

Act 68 does not contain an objective definition of the term "medical necessity." MCPs, however, must adopt and maintain a definition of medical necessity of their own. 40 P.S. § 991.2111(3). MCPs must also disclose to enrollees and physicians the definition of medical necessity it utilizes. 40 P.S. § 991.2136(1). If an MCP's contract prohibits or restricts disclosure of medically necessary and appropriate health care information by a physician, that provision is void and unenforceable. 40 P.S. § 991.2113(b). The "gag clause" provisions in 40 P.S. § 991.2113(c)(1)-(3) address the prohibition against squelching the disclosure of medically necessary information from physicians to patients. Thus, medical necessity definitions are an integral part of MCP operations, and (quite obviously) the physician's practice of medicine.

The provisions of Act 68 cited above permit the Department of Health to regulate the *parameters* of an acceptable "medical necessity" definition used by MCPs. Indeed, the Department's proposed regulations make reference to the phrase "medical necessity" repeatedly. For example, proposed § 9.651 outlining the basic health services HMOs must provide to enrollees uses the phrase no fewer than three times. Along with liability for health plans, the definition of medical necessity has emerged as one of the two most contentious issues in the managed care reform debate. States are beginning to enact statutory definitions of the phrase. It is simply too important to patients (and physicians) to allow this crucial term to go undefined. While the Academy supports the proposed regulation under § 9.677 (in its very limited form), the Academy nevertheless believes the Department possesses sufficient statutory authority to include the following medical necessity definition parameters in its proposed regulations:

- Any therapeutic treatment, care or services reasonably expected by a prudent physician to improve, restore or prevent the worsening of any illness, injury, disease, disability, defect, condition or the functioning of any body member.

- Objective clinical determinations which will be or are reasonably expected by a prudent physician to prevent the onset of an illness, condition or disability; reduce or ameliorate the physical or mental effects of an illness,

condition, injury or disability; or alleviate the patient's pain or mitigate the severity of the patient's symptoms.

- All relevant clinical data pertaining to the patient's condition as a whole must be taken into consideration.

- The prevailing practice and standards of the medical profession and community must be taken into consideration.

In the alternative, the Academy supports the American Medical Association's working definition of "medical necessity" as the standard against which all MCP definitions should be judged, as follows:

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

These parameters strike the necessary balance between patient protection and utilization control.

Primary Care Providers - § 9.678

The Academy's comments and recommendations regarding definitions of the terms "primary care providers" and "primary care physicians" should be incorporated under § 9.678. Under § 9.678(c) relating to non-primary care specialists to be considered as primary care providers, the Department of Health should require physicians to meet the criteria outlined under § 9.683 (below) and ensure that such physicians have the training and experience to:

1. Provide comprehensive first contact and comprehensive continuing care for persons with undiagnosed signs and symptoms of health concern (not limited by a problem, origin, gender or diagnosis).

2. Plan and carry out health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses.

3. Coordinate care with regard to other health care providers.

4. Promote effective physician-patient communication.

5. Encourage the role of the patient as a partner in health care.

Under § 9.678(d), the Academy is adamant that certified registered nurse practitioners are not fungible substitutes for family physicians or other primary care physicians. This provision, as drafted, implies CRNPs may function independent of a primary care physician, which is contrary to law and finds absolutely no statutory support in Act 68. Accordingly, this provision should be stricken in its entirety.

Health Care Providers - § 9.681

Under § 9.681(a), an MCP is required to provide enrollees a provider directory including information about the health care provider listed, including "specialty." Many Academy physician members are extremely well trained and experienced in the provision of obstetrical services. The Academy has met in person with Highmark and representatives of other MCPs in an effort to provide this consumer disclosure benefit. Highmark has flatly refused to do so, ***notwithstanding its publication of non-physician certified nurse midwives as "specialists" under the heading "Obstetrical/ Gynecological Services" in its provider directory***. The Academy finds this conduct to be unsupportable legally and clinically, and therefore recommends the Department include the phrase "or area of practice concentration substantiated by clinical training and experience" in final rulemaking.

Direct Access for OB/GYN Care - § 9.682

Under § 9.682(a), the direct access to obstetrical and gynecological services under § 2111(7) of Act 68 is restated. Many of the Academy's Board certified family physicians are well trained in and actively practice obstetrics and gynecology. In fact, JCAHO standards require each family practice residency to have one Board certified family physician teach OB/GYN in residency. Scores of family practice residents then provide OB/GYN services in active practice.

Moreover, § 2111(7) of Act 68, as well as Act 68's access to care requirements, **obligate** MCPs to permit enrollees to obtain direct access to OB/GYN services (regardless of the type of provider); to provide reimbursement coverage for such services; to allow self-referral to a family physician other than the patient's primary care physician for such services without prior approval from the enrollee's primary care provider; and, implicitly, to credential family physicians for the provision of OB/GYN services where they have obtained requisite training and experience.

MCPs are routinely ignoring these obligations to the detriment of enrollees. The Academy met with Highmark officials on December 10, 1999 to secure compliance with this mandate *vis-à-vis* patients' rights to direct access to and reimbursement for OB/GYN services provided by family physicians. Highmark flatly refused to comply and, during the course of the meeting, stated four different reasons for its non-compliance: (1) "The regulations are not published in final form"; (2) "Act 68 is not self-implementing"; (3) "There is no case law" requiring Highmark to comply with this provision; and (4) "The direct access provision only requires Highmark to pay a Board Certified OB/GYN for § 2111(7) services." Highmark's positions lack any reasonable foundation in fact or in law. Accordingly, § 9.682 should be amended to expressly include the rights stated in the preceding paragraph inuring to the benefit of enrollees.

Finally, when enrollees seek direct access to a specific OB/GYN provider, the regulations should specifically state that an MCP cannot penalize a family physician economically or in any other manner, including a negative credentialing decision, based upon an enrollee's direct access to OB/GYN services. A family physician's lack of control over an enrollee's direct access decision mandates this conclusion.

Standing Referrals or Specialists as Primary Care Providers

Consistent with the Academy's policy position regarding primary care providers and primary care physicians, the Department should establish the following criteria in § 9.683 for considering physicians in non-primary care specialties as primary care physicians:

> The primary care physician must determine that a patient requires a specialist to act as the patient's primary care physician, permanently or for a specified period of time, for the treatment of a severe medical condition. Severe medical conditions include the following:
>
> (a) oncology cases where the patient requires intense observation and treatment by an oncologist who is trained in the use of aggressive medication protocols which require the oncologist to order laboratory tests and x-rays and to treat all infections which are crucial to the patient's best outcome; or
>
> (b) a medical condition which requires the continuous expertise of a specialist who is trained and competent to treat the patient's unique, severe condition as well as all primary care conditions, and for which the simultaneous treatment by a

primary care physician would (i) represent duplicative care or (ii) hinder expedient treatment due to time constraints or other logistical or geographical barriers.

Health Care Provider Initiated Grievances - § 9.703

Under § 9.703(c) and (d), physicians must continue to challenge the medical necessity denial through at least the second level of review, and may not bill the enrollee until the external grievance review has been completed. These are disincentives against physician challenges to MCP medical necessity denials, and are not supported by Act 68. They should be removed from the final rulemaking.

Internal Complaint Process - § 9.704

Under § 9.704(c)(2)(i), there should be some method for the enrollee or physician to confirm or "discover" whether the members of the second level review committee are "unbiased."

Under § 9.704(c)(2)(ii)(C), it should be specified that the enrollee may be accompanied by a legal or medical advocate.

Appeal of Complaint Decision - § 9.705

Under § 9.705(a), the enrollee's deadline to appeal the second level review decision should be thirty (30) days, not fifteen days.

Under § 9.705(g), the Department of Health retains the discretion to decide whether to hold an administrative hearing on the appeal. If no hearing is held, and the enrollee or physician wishes to appeal to Commonwealth Court, there will have been no record upon which to base the appeal, resulting in a due process denial and a remand to develop a record, all of which may consume resources unnecessarily. A more prudent approach would be for the Department to notify the "appellant" of his or its (a) right to have an administrative hearing, and (b) obligation to request one. If the "appellant" does not request a hearing, then that individual or entity will have knowingly waived rights, thereby avoiding inadvertent due process violations and remands.

Enrollee/Provider Grievance System - § 9.706

The Academy's comment with respect to ascertaining the "unbiased" nature of second level review members pursuant to § 9.704(c)(2)(i) is applicable to § 9.706(c)(2)(i).

Under § 9.706(c)(3)(i), there is a different standard established for physicians and licensed psychologists in terms of the type of provider subject to review. The Academy is well aware that this dichotomy was established in Act 68; however, the Academy believes both the statutory provision and the proposed regulation violate the Equal Protection clause under the 14th Amendment to the U.S. Constitution as well as Article I, § 1 of the Pennsylvania Constitution. Case law has developed in the Commonwealth

of Pennsylvania over the last decade that an agency may cure a constitutional defect in a statute via the regulatory process. The Academy respectfully recommends the Department of Health seriously consider adopting in its final rulemaking consistent standards for both physicians and psychologists to avoid a constitutional challenge. The Academy believes this section should be revised to require that the reviewer performing these reviews "shall be licensed by the Commonwealth of Pennsylvania in the same profession and Board-Certified in the specialty of the provider subject to review." This is consistent with the Commonwealth's position under the workers compensation regulations, 34 Pa. Code § 127.466.

Under § 9.706(c)(3)(iii), the Academy believes it is unclear whether the last sentence requiring the MCP to disclose the UR report is conditioned upon the reviewer not participating in the internal review. It should be clarified that distribution of the UR report should be made as a matter of course at least two weeks prior to the review date, not seven days contingent upon the written request of the enrollee or physician. This unnecessarily adds a layer of hassle to the physician or enrollee, both of whom should be entitled as a matter of law to the UR report.

Under § 9.707(b)(1), the fifteen-day limit to appeal should be increased to thirty days.

Under § 9.707(b)(6)(iv), the MCP is required to submit its contractual definition of "medical necessity" and other written documentation to the CRE which the MCP used to make its internal decision. This section should also require the MCP to send such documentation to the enrollee and the enrollee's physician, without request.

Expedited Review - § 9.709

Under § 9.709, the Academy's concern about drug formulary exceptions should be specifically included under this provision. In addition, under § 9.709(c), plans are required to conduct any expedited internal review "within 48 hours." This section should be clarified to state 48 hours "from the time the MCP receives the appeal either by fax, mail or other electronic transmission."

Plan and Health Care Provider Contracts - § 9.722

Under § 9.722(e)(2)(7), a provider must give at least sixty days advance written notice to the MCP of termination of the contract. To the extent terminations without cause by an MCP are lawful and not violative of public policy (which may be the case under some circumstances), MCPs should be required to provide sixty (60) days notice of the termination without cause.

Content of Application for CRE Certification - § 9.743

Under § 9.743(d)(1), the Academy's suggested modifications to § 9.706(c)(3)(i) should be incorporated with respect to the same profession/same specialty requirement applicable to physicians.

Credentialing - § 9.761

Under § 9.761(a)(8) and (9), the Academy respectfully urges the Department to incorporate its comments, concerns and negative experiences with MCPs outlined above pursuant to § 9.682 and § 9.683. Moreover, nothing in Act 68 precludes physicians, such as family physicians, who are experienced in, well trained in and provide quality of care in obstetrical services from being prohibited access by patients pursuant to the direct access provision. To that extent, and to the extent § 9.761(a)(8) may be construed by MCPs to restrict enrollees direct access to family physicians for OB services, that provision contradicts Act 68 and should be modified or stricken.

Finally, there should be some opportunity for a physician to secure a review with the Department of Health in the event an MCP refuses to credential a physician initially, or terminates the physician's agreement, in a manner inconsistent with the MCP's written credentialing standards. None currently exists. Act 68 gives physicians clear rights on this issue, but the Department has not established a procedural remedy.

Exceptions

In the Department's draft proposed rulemaking at § 9.54, the Department included an exceptions or waiver process. The Academy was unable to locate this provision in the proposed rulemaking, assumes it has been deleted, and supports its deletion.

* * * *

Thank you in advance for your consideration of the Academy's issues and concerns relating to these important public policy and legal matters. If you have any questions, or would like to discuss any of the issues raised, please contact us at your convenience.

Sincerely,

Christine M. Stabler, M.D.
President

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Hon. Harold Mowery, Chairman Senate Public Health & Welfare Committee
Hon. Nicholas Micozzie, Chairman House Insurance Committee
Hon. Dennis O'Brien, Chairman House Health & Human Services Committee