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Originally rec'd 1/21/00 12:34 p.m.

January 18, 2000

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

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

Dear Ms. Mitchell:

We are writing on behalf of the Pennsylvania Chapter, American College of Emergency Physicians (PaACEP), regarding the Department of Health's Proposed Rulemaking for the Quality Health Care Accountability and Protection Act, Act 68 of 1998. We appreciate the opportunity to offer our comments on the proposed rules and regulations.

We support the suggestions made by the Pennsylvania Medical Society. The following comments address areas not specifically covered by the Medical Society or expand on issues specifically pertinent to emergency medicine.

Section 9.602. Definitions.

Emergency service: This definition recognizes the importance of using the prudent layperson standard in determining coverage of emergency medical care. It should be noted that the medical condition could be of a chronic nature that could suddenly worsen.

PaACEP recommends that for the regulation to be consistent with the statute, "such" should be substituted for "so": "(1) A health care service ... sufficient severity or severe pain such that ..."

Section 9.606. Penalties and Sanctions.

Much experience has been gained in other states by regulators overseeing managed care plans' compliance with patient protection regulations. It has been clearly demonstrated that regulators need to have available to them strong administrative penalties, taken in conjunction with injunctive relief, to ensure that managed care plans comply with the regulations.

Section 9.621. Applicability.

It is important that all entities intended to fall under Act 68 be clearly designated to all interested parties.

PaACEP recommends that the department identify the specific plans that are covered by Act 68 and make this list available to providers and consumers.

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

Emergency physicians and hospitals must abide by the Emergency Medical Treatment and Active Labor Act (EMTALA) 42 U.S.C. 1395dd, which mandates that all patients presenting to the emergency department be given "an appropriate medical screening examination...to determine whether or not an emergency condition exists," regardless of their ability to pay. If it is determined that an emergency medical condition exists, EMTALA requires "such treatment as may be required to stabilize the medical condition...or... transfer of the individual to another medical facility...."

It is imperative, however, that enrollees not be required to utilize a participating health care provider for emergency services. For example, a patient with chest pain that could be a heart attack should go to the closest hospital for evaluation, even if that facility is not participating in the patient's plan. To travel a distance in order to reach a participating facility may result in detriment and possibly death to the patient.

PaACEP commends the department for applying the provision in subsection (c) (1) to the use of emergency services including ambulance services.

To be consistent with statute, an HMO shall provide and cover emergency services according to the prudent layperson standard, without requiring prior approval, and must disclose to the enrollee and health care provider the enrollee's financial and other responsibilities regarding emergency services. A managed care plan shall provide reasonable payment or reimbursement for emergency services.

In Section 9.651, subsection (c) (1), the following would clarify that the prudent layperson standard shall be used as the HMO's "definition of medical necessity" for the provision and coverage of emergency services, without requiring prior authorization.

PaACEP recommends inserting 2 sentences in subsection (c) (1): "In considering emergency services, the plan shall provide coverage according to the prudent layperson standard." and "Coverage of emergency services is not subject to prior approval."

PaACEP suggests in this subsection, substitution of the word "shall" for "may," to strengthen this provision as it was in the draft regulations.

PaACEP also recommends inclusion of the requirement for disclosure, and clarification of the extent of coverage, as described in the statute.

In Section 9.651, subsection (d), one may define "benefits" to include the right to be evaluated and stabilized in an emergency department as required under the Federal law EMTALA.

PaACEP recommends in subsection (d), after "An HMO shall provide," insertion of "reimbursement for."

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

As noted above, emergency physicians and hospitals are required to evaluate all patients seeking care regardless of their ability to pay. Consider again the example of a patient with chest pain who suffers adverse outcome by traveling to a more distant participating hospital, because of fear that he/she will be required to pay a greater amount as a co-payment or co-insurance for seeking care at the closest hospital.

PaACEP recommends that co-payments and co-insurances should be the same for patients seeking emergency medical care at both participating and non-participating facilities. The amount of co-payment or co-insurance should not be so high as to dissuade the prudent layperson's use of emergency services.

Section 9.672. Emergency services.

PaACEP appreciates the correction reported in the December 25, 1999, Pennsylvania Bulletin changing the language in subsection (c) to read, "A plan shall apply the prudent layperson standard...emergency services." Grammatically, we suggest using "adjudicating related claims" rather than "adjudication related claims."

There should be no requirement regarding the enrollee's selection of emergency transportation services. The word "shall" used in the draft regulations addressing this provision has been changed to "may" in subsection (e).

PaACEP recommends that in subsection (e), "shall" be substituted for "may."

Recognizing that, "A plan shall apply the prudent layperson standard to the enrollee's presenting symptoms and services provided in (adjudicating) related claims for emergency services," it is essential that a plan review documentation indicating "the enrollee's presenting symptoms and services provided." Preferably this would be through the use of a universal form that includes presenting symptoms and services.

PaACEP recommends requiring that managed care plans review the enrollee's presenting symptoms and services provided, preferably by use of a universal standard form on which "presenting symptoms and services provided" could be documented.

The proposed rulemaking is silent on several important components of Act 68. Section 2116. Emergency Services. PaACEP contends that this section needs clarification. We believe some elements may be contrary to federal regulations. These concerns were noted in our previous

communication with the department, but were not addressed in the department's proposed rulemaking.

Act 68. Section 2116. Emergency Services. states, "*If an enrollee seeks emergency services and the emergency health care provider determines that emergency services are necessary, the emergency health care provider shall initiate necessary intervention to evaluate and, if necessary, stabilize the condition of the enrollee without seeking or receiving authorization from the managed care plan.*"

PaACEP is concerned that this seems to give the provider the option of deciding whether treatment is necessary. We believe the legislative intent is to follow the federal law EMTALA that requires hospitals and physicians to provide a medical screening examination to all patients who present to the emergency department to determine the presence of an emergency medical condition. One does not know prior to evaluating the patient whether an emergency medical condition exists. If it is determined that the individual has an emergency medical condition, EMTALA further states, "the hospital must provide either within the staff and facilities available at the hospital, for such further medical examination and such treatment as may be required to stabilize the medical condition, or for transfer of the individual to another medical facility...."

Rules and regulations should make it clear that existing federal guidelines, such as EMTALA, should be followed.

Act 68 further states, "*The managed care plan shall pay all reasonably necessary costs associated with the emergency services provided during the period of the emergency.*"

The regulations do not establish any criteria to be used in determining what constitutes "reasonably necessary costs," who will determine this, and whether this will be subject to department oversight.

PaACEP suggests active DOH oversight to help ensure fairness regarding "reasonably necessary costs."

Act 68 further states, "*The emergency health care provider shall notify the enrollee's managed care plan of the provision of emergency services and the condition of the enrollee.*"

It is PaACEP's understanding that the legislative intent was to notify the insurer if additional treatment is required, i.e., hospital admission or transfer. The notification requirement for Medicare and Medicaid managed care plans applies to "post-stabilization" care and not services provided to the patient before the physician has determined the patient is stable. The notification requirement should apply in likewise manner for plans affected by Act 68.

Notification should be required only after the physician has determined the patient is stable. PaACEP believes that submission of a provider claim for emergency services should serve as notification to the managed care plan when the patient does not require admission or transfer. PaACEP suggests that health plans be required to respond in a timely fashion for authorization of "post-stabilization" care.

Act 68 further states, "*If an enrollee's condition has stabilized and the enrollee can be transported without suffering detrimental consequences or aggravating the enrollee's condition, the enrollee may be relocated to another facility to receive continued care and treatment as necessary.*"

PaACEP has commented that the language, "an enrollee's condition has stabilized *and* the enrollee can be transported..." is confusing and suggests that something more than stabilization is required before a patient can be transferred.

We recommend that the rules and regulations follow EMTALA which states: "The term 'stabilized' means, with respect to an emergency medical condition...that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility..."

As in the HCFA regulation regarding Medicare+Choice programs, the physician treating the patient must decide when the patient may be considered stabilized for transfer or discharge, and that decision must be binding on the health plan.

Section 9.677. Requirements of definitions of "medical necessity."

It is vital to have a clear, meaningful definition of medical necessity. This issue was thoroughly reviewed by the Pennsylvania Medical Society. It should be clarified that plans are to use the prudent layperson standard when determining medical necessity for emergency services.

PaACEP recommends emphasizing that a plan shall follow the definition of "Emergency Service" in the Act, using the prudent layperson standard when determining medical necessity for emergency medical care.

Subchapter G. HMOs
Section 9.633. HMO board requirements

As required by the Act, individuals rendering decisions regarding the medical necessity of services rendered or proposed are to be licensed and, depending on the level of review, have added qualifications including active clinical practice and certification. While certain provisions allow for review by a licensed physician in a "similar" specialty, it should be noted that emergency medicine is a unique specialty; there is none that is truly "similar." In addition, emergency physicians are numerous in Pennsylvania, making likely their availability for review of cases.

PaACEP recommends that decisions regarding the medical necessity and coverage of emergency services should be made by emergency physicians licensed in Pennsylvania, actively practicing emergency medicine at least 20 hours per week.

Subchapter I, Complaints and Grievances
Section 9.708. Grievance reviews by CREs.

The only standard the CRE needs when reviewing any grievance relating to the provision of emergency services is the prudent layperson standard as defined in the Act.

PaACEP recommends that the words in subsection (e) after "Act 68" be deleted.

Thank you for your consideration in reviewing PaACEP's comments on the regulations. If you have any questions concerning any of the issues raised, please contact Mr. David Blunk, PaACEP's Executive Director. We look forward to favorable action on the areas discussed.

Sincerely,

Marilyn J. Heine, MD. RO'Brien MD

Marilyn J. Heine, MD
Co-chair, Governmental Affairs

Richard P. O'Brien, MD, FACEP
President

cc: Chair, House Insurance Committee
Secretary of Health
Insurance Commissioner

Dcb/c/Act 68 DOH Proposed Rulemaking

Mitchell, Stacy

From: McCann Cannard & Associates, Inc [mccann@epix.net]
Sent: Tuesday, January 18, 2000 3:25 PM
To: samitche@health.state.pa.us
Cc: Lorraine Matthews
Subject: Comments on Act 68 Proposed Regs.

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To: Stacy Mitchell

Dear Ms. Mitchell:

The Pennsylvania Dietetic Association presented testimony during the first hearings on Senate Bill 100, which ultimately became Act 68. Lorraine Matthews was the spokesperson for the association, and her testimony is on the record.

Subsequently PADA contacted the Secretary of Health to offer services of its members in the preparation of regulations, since the Department has no positions for Registered Dietitians. We received no response.

We commented on the earlier proposed regulations. We shall make these present comments very brief, for this reason and also due to the fact that our members are not included in the legislation. Pennsylvania remains one of a small handful of states (nine) which do not license professional dietitians/nutritionists, and therefore when legislation is written which indicates that services be provided by "licensed health care professionals", this in effect precludes medical nutrition therapy.

For this reason, PADA wishes to focus on Section 9.677. Medical Necessity in our comments. Unless physicians are able to indicate that there is a "medical necessity" for medical nutrition therapy, for example in the case of a patient diagnosed with cardiovascular disease, that patient will be precluded from seeing a Registered Dietitian for the medical nutrition therapy critical to his/her health and longevity.

No less a body than the National Academy of Sciences Institute of Medicine has completed an independent study on the necessity - - and cost effectiveness - - of medical nutrition therapy, the results of which were announced within the last three weeks.

Data from the Pennsylvania Department of Health's own Division of Health Statistics show the high mortality and morbidity rates in the Commonwealth for most of the chronic diseases for which medical nutrition therapy is an indispensable part of treatment.

Specifically, our concerns with this Section of the proposed regulations are that it has been negatively revised since the prior draft and should be returned to the originbal proposed language. The earlier draft required that "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 the plan's medical director." This language has been eliminated. It had provided a level of fairness and uniformity that is now lost.

We would also strongly recommend that the regulations be revised so that plans are required to consider information provided by the nerollee, the enrollee's family, the primary care practitioner, as well as other providers, programs and agencies that have evaluated the individual in making their medical necessity determinations.

We appreciate this opportunity to express our concerns about the proposed regulations.

Sincerely,

M. Colleen McCann, MPH, RD

DISABILITIES LAW PROJECT

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January 18, 2000

Via Facsimile and First Class Mail

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

RE: Comments on Act 68 Regulations

Dear Ms. Mitchell:

I recently submitted comments on the new Act 68 regulations. Having just read the comments of the Pennsylvania Health Law Project, I would like to add our support for their detailed and thoughtful comments.

We are particularly concerned about the issues they have described under the heading "Complaints and Grievances". We have, in our work, seen so many inappropriate denials of service that we believe it essential that the grievance process be carefully tailored to ensure fundamental fairness to members of HMOs. The Pennsylvania Health Law Project has done an excellent job of detailing the changes necessary to accomplish this objective. Please give these, as well as their other comments, careful consideration.

Sincerely,

Ilene W. Shane
Executive Director

00-01-145

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To: Stacy Mitchell **Fax#:** 717-705-0947

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From: Diane Shane **Subject:** Act 68

Date: 1-18-00 **No. of pages:** 2

MESSAGE:

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Stacy

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January 18, 2000

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Ms. Stacy Mitchell
Director
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Dear Ms. Mitchell:

The Managed Care Association of Pennsylvania (MCAP) respectfully submits the following response to the Department of Health's proposed managed care organization rulemaking which appeared in the December 18, 1999 *Pennsylvania Bulletin.* The Association represents 12 Commonwealth HMOs which enroll over 1.5 million Pennsylvanians in various commercial, Medicaid and Medicare health plans. The Association's response is the result of extensive review by MCAP's internal Act 68 workgroup consisting of member health plan representatives with expertise in numerous and varied areas of managed care plan operations.

The Association is pleased to note that the content and format of the draft regulations have improved in comparison to the original draft released in April, 1999. We are also pleased that a number of MCAP's concerns and recommendations were addressed in the new draft regulations.

As noted below, the Association has four overall comments/concerns with the regulations as drafted. Following the four overall comments is a review which is in numerical order as per proposed sections of the draft regulations. In addition to concerns raised, please note that the Association's suggested changes are in bold print, italicized and underlined for your reference.

✓ As required by Act 68, 1998, there are sections of the proposed regulations which overlap with those proposed by the Insurance Department and joint regulatory authority exists. The Association strongly recommends that, to the extent possible in all overlapping sections, the wording of the two sets of regulations be identical. Existence of any inconsistencies could result in different interpretations by respective agencies as well as plans, providers or consumers, all of which would inhibit effective regulatory oversight.

✓ Managed care plans that provide health care services to Medical Assistance beneficiaries are under contract with and heavily regulated by the Department of Public Welfare. As drafted, the regulations include numerous reporting, filing and approval requirements that duplicate current Department of Public Welfare requirements. Such duplication would

not only be costly, but could also create significant confusion among regulated entities, especially if the two Departments reach conflicting decisions. Numerous examples, including sections 9.675 (Delegation of medical management), 9.702 (Complaints and grievances), 9.710 (Approval of plan enrollee complaint and enrollee and provider grievance systems) and 9.722 (Plan and health care provider contracts) of the draft, are noted throughout this response. MCAP strongly encourages the Department to coordinate this entire regulation with the Department of Public Welfare in order to minimize duplication and costs for these plans and to prevent conflicting regulatory decisions. Failure to do so is certain to also negatively impact consumers and providers who participate in the Medical Assistance program.

✓ The draft regulations address complaints and grievances which, as per Act 68, are to be coordinated between the Department of Health and the Insurance Department. While we understand that both Departments have statutory authority to address complaints and grievances, some plans have been informed that the Insurance Department will handle complaints only and the Health Department will address grievances only. This is clearly inconsistent with the intent of the Act and will cause much confusion for consumers and managed care plans unless rectified and made clear internally and externally by the Departments.

✓ When the Department's final form regulations become effective upon publication in the *Pennsylvania Bulletin*, MCAP has strong concerns about the impact to managed care plans' forms filing requirements. As you know, the plans have been operating under the Department of Health's Statement of Policy issued October, 1998. However, significant forms changes will be necessary if the regulations are implemented as drafted. The changes will immediately impact plans which will then be out of compliance until all affected forms have been re-filed and approved by the Insurance Department. The Association asks that the Department's final form regulations specifically state and allow for an adequate period of time for managed care plans to comply with the necessary changes or provide for a delayed effective date.

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§ 9.602 - Definitions

As stated previously, the Association believes that, in order for both the Health and Insurance Departments to effectively and efficiently enforce the provisions of Act 68, both sets of regulations must be consistent. In terms of definitions, MCAP suggests that the Health Department regulations reference Section 2102 (Definitions) of Act 68 where applicable. This would be consistent with the Insurance Department final form regulations as per the recommendation of the Independent Regulatory Review Commission.

Gatekeeper - The Association suggests that the definition of gatekeeper be identical to the definition contained in the Insurance Department's final form regulations. The proposed definition incorrectly includes a managed care plan in the definition of a gatekeeper - this term should be removed.

HMO - Instead of citing the definition included in the HMO Act, MCAP suggests that the definition be: ***As defined in the Health Maintenance Organization Act (1972, Dec. 29, P.L. 1701, No. 364)***.

IDS - Integrated Delivery System - It is noted in the preamble of the proposed regulations that the Department is adding a definition of an IDS. However, the Association suggests that the definition be consistent with the Department's April 6, 1996 IDS Statement of Policy. In particular, the Association believes the language regarding risk-sharing arrangements needs to be included as follows: (v) ***Assumes to some extent, through capitation reimbursement or other risk-sharing arrangements, the financial risk for provision of the services to HMO members.***

Inpatient Services - In the preamble, the Department notes that it is proposing to include physician services in the definition of inpatient services. However, when reviewing the definition of inpatient services, it does not appear that physician services were included in the definition. MCAP asks that the Department provide clarification.

Medical Management - The Association suggests that the definition of medical management be amended as follows: "A function that includes any aspect of UR, quality assurance, case management and disease management and other activities for the purposes of determining, arranging, monitoring or ***arranging for the provision of appropriate health care services.***"

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§ 9.606 - Penalties and sanctions

Subsection (b)(1) - Since HMOs do not provide health care services, MCAP suggests the following language: "The HMO is ***arranging*** for inadequate or poor quality care . . ."

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§ 9.631 - Application for a Certificate of Authority

Subsection (1) - The preamble notes that the Department is proposing to eliminate the requirement that the applicant provide a description of the manner in which subscribers would be elected to the HMO's board of directors. However, in subsection (1) of the regulations, the provision is still included. This requires clarification by the Department.

Subsection (16) - The preamble states that the Department is proposing to eliminate current requirements that an HMO provide a detailed description of reasonable incentives for cost control within the structure and function of the HMO. The requirement remains in the regulations, however, and is included in Subsection 16. This section also requires clarification.

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§ 9.633 - HMO board requirements

Subsection (a) requires the HMO, within one year of receiving a certificate of authority, to establish a board of directors, at least one-third of whom are enrollees of the HMO. The preamble states, however, that the Department is proposing to remove this requirement. MCAP

requests clarification of the Department's intent and ***supports the preamble language to remove this requirement which has proven extremely onerous in managed care plan operations.***

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§ 9.634 - Location of HMO activities, staff and materials

Subsection (2) states that the medical director is responsible for overseeing services provided to enrollees "who are residents of this Commonwealth. . ." ***MCAP requests that this phrase be removed*** as not all enrollees are residents of Pennsylvania, specifically when the HMO's service area includes counties that border neighboring states.

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§ 9.635 - Delegation of HMO operations

Subsection (a) - As noted in the preamble, the Insurance Department has traditionally been responsible for oversight of management contracts. The Association would appreciate a clearer delineation as to how regulatory oversight will be coordinated by the Health and Insurance Departments in regard to delegation of HMO operations. Also, does this provision impact current IDS arrangements and filing requirements? If so, differences should be specifically stated.

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

Subsection (a) - MCAP asks that this subsection be revised as follows in order to clarify that services are provided according to a contractual arrangement: ***"An HMO shall maintain an adequate network of health care providers through which coverage for medically necessary and appropriate basic health services is provided to enrollees in accordance with the benefits included in the enrollee's contract or benefit category***."

Subsection (b) - The Association suggests that the phrase "as are customarily excluded by indemnity insurers" be deleted.

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§ 9.654 - HMO provision of limited networks to select enrollees

Subsection (a) - Development of limited network options has occurred as a result of purchaser preference and demand. The Association is concerned that the Department's prior approval requirement will negatively affect future development and implementation of such options. ***At a minimum, the Association asks that the Department define "limited subnetworks" and give managed care plans clear direction as to when prior approval is necessary***.

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§ 9.655 - HMO external quality assurance assessment

Subsection (a) includes the requirement that an HMO shall undergo an external quality

assessment by an external quality review organization ***acceptable*** to the Department. Should the Department decide to expand its current list of acceptable entities, the Association advocates that the regulations include a provision whereby plans may request review by an alternative organization if the plan can demonstrate good cause, such as a conflict of interest.

Also, as was previously the case, will the Department publish a list of authorized organizations? Will the Department also make available the criteria used to evaluate and identify "acceptable external quality review organizations?"

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

As an overall comment on this section, MCAP notes the fact that, since HMOs are specifically cited, preferred provider organizations offering point-of-service options would not be required to follow the Department's proposed approval standards.

In **subsection (b)(1)(i)**, MCAP objects to the requirement that the managed care plans periodically inform primary care physicians about enrollee self-referred services. In addition to being administratively burdensome for the plan, this requirement may also violate patient confidentiality. ***It is MCAP's suggestion that this requirement be removed.***

Subsection (b)(1)(ii) - The POS option was created in response to consumer demand for the ability to self-refer outside of the plan's contracted network. Therefore, "higher than average use of non-PCP referred care" would not necessarily reflect consumer dissatisfaction, but rather enrollee preference for a non-network provider or providers. In addition, it is unclear as to how the Department would quantify and enforce "higher than average use" of out-of-network care. ***MCAP respectfully requests that this subsection be revised to reflect this comment.***

Subsection (b)(2) - While Act 68 gives both the Health and Insurance Departments the authority to regulate disclosure, the Insurance Department has clearly been identified as the lead regulatory agency for purposes of disclosure compliance. The Association is concerned that further delineation of regulatory authority between agencies will prove confusing and duplicative for regulated entities. ***MCAP supports allowing the Insurance Department to regulate disclosure requirements.***

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§ 9.673 - Plan provision of prescription drug benefits to enrollees

Subsection (b) - The preamble for section 9.673 states that the Department is proposing to require that any refusal to permit an exception to the plan's formulary would be handled by the plan as a grievance under Act 68. MCAP believes that this may lead to additional confusion as the administration of prescription drug benefits is becoming increasingly complex, especially with plans that offer multiple tier coverage options. Multiple tier coverage is being utilized more and more frequently by managed care plans (as well as other insurers) as a way of helping purchasers mitigate the ever-increasing costs of prescription drug coverage.

For example, a three tier prescription drug program is offered to enrollees as follows: Tier one covers only generic drugs with a $5 copayment; tier two provides coverage for "preferred" drugs and requires a $15 copayment; and, tier three covers "non-preferred" or "non-formulary" drugs with a $40 copayment. Confusion may arise over whether or not "coverage" exists for a certain prescription. A certain drug may not be covered at tier two but would be covered at tier three as a "non-formulary" drug. If an enrollee chooses to file a 'grievance' for a drug not covered at tier two, would the drug be considered 'covered' at level three? Would this not be more appropriately categorized as a complaint since the drug was not a covered benefit at level two and therefore not a grievance as suggested in the preamble? ***MCAP proposes that the language be revised to note that exceptions may be handled as either a complaint or grievance as appropriate.***

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§ 9.678 - Primary care providers

Subsection (b)(4) - MCAP suggests that the word "admitting" privileges be removed and replaced with "***staffing***" privileges.

Subsection (d) - MCAP would appreciate clarification as to what "State law" the Department refers to in this subsection.

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§ 9.679 - Access requirements in services areas

Subsection (a) - The Association suggests that the following language be inserted: "A plan shall provide services to enrollees ***who live, work or reside*** only in those services areas . . ." for the same reasons stated in §9.634, subsection (2).

Subsection (d) - MCAP appreciates the Department's need to be aware of potential service disruptions to managed care enrollees. As written, however, this subsection is overly burdensome for plans, specifically in terms of "immediate" notification. MCAP suggests the following language for subsection (d): "A plan shall, ***within a reasonable time***, report to the Department any serious potential change in the plan's ability to provide services in a particular service area through termination, cancellation or nonrenewal of health care provider contracts."

A second issue in **subsection (d)** is application of the10 percent requirement. It is unclear how this will be applied to plans with service areas that span numerous counties and different geographic regions of the State.

In **subsection (e)**, the Association notes that the 20/30 standard differs from Medical Assistance program standards, specifically HealthChoices RFP requirements which are 30/60. In addition to creating a different standard for commercial and Medical Assistance plans, it will be extremely difficult to meet the standard proposed for rural areas.

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§ 9.681 - Health care providers

In subsection (a), MCAP recommends eliminating the words "by specialty." While some provider directories are currently organized by specialty, others are organized and arranged in various alternative formats, including by county as per the managed care plan's service area. This requirement would be a specific problem for plans that enroll Medical Assistance recipients as oftentimes such directories list providers by zip code for the ease of enrollees. The Association contends that eliminating the phrase "by specialty" will have no net effect on consumers being provided with appropriate information as required under the Act, yet the change will allow plan flexibility in developing useful provider directory formats.

In **subsection (b)**, MCAP notes that such disclaimers are typically under the regulatory authority of the Insurance Department which has been charged with disclosure compliance authority under the Act. Again, MCAP asks for consistency and clarity among regulatory agencies.

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§ 9.682 - Direct access for obstetrical and gynecological care

While the language in this section is similar to the final form regulations proposed by the Insurance Department, it is not exactly the same. The Association feels strongly that, when the respective Insurance and Health regulations are addressing the same issue, the final regulatory language should be consistent in order to prevent any misinterpretations.

In subsection (c), the Association recommends that the term "health care provider" be replaced with "obstetrical and gynecological providers" to ensure that those with the appropriate training and scope of practice are providing these services.

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§ 9.683 - Standing referrals or specialists as primary care providers

In subsection (b)(1), the Association supports eliminating the phrase, "including a process for reviewing the clinical expertise of the requested specialist." This, in essence, is the purpose of existing credentialing processes and is already occurring.

In subsection (5), the Association proposes to eliminate the last line, "Nonparticipating specialists may be utilized as appropriate." This language gives managed care plans little leeway in attempting to keep services in-network. ***The Association suggests reiterating the language which appears in Section 2111(6)(ii) of Act 68 which states that "When possible, the specialist must be a health care provider participating in the plan."***

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§ 9.684 - Continuity of care

Subsection (a) - The Association suggests amending the language as follows: "Provider terminations initiated by the plan, ***excepted as noted in subsections (j) and (k)***, shall be governed

as follows:"

Subsection (a)(1) - MCAP recommends changing the language to read that ***enrollees may continue an ongoing course of treatment for "up to" 60 days*** which is a direct reflection of the Act and will not lead enrollees to automatically assume that the continuity period will be 60 days.

Subsection (a)(2) - MCAP objects to plans having to supply ***"written" notice of primary care provider terminations and asks that this term be removed.*** Currently, many member plans make such contacts via telephone in order to begin to work as expeditiously as possible with enrollees on selecting another primary care physician. MCAP asks that flexibility in terms of notifying members be maintained.

Subsection (f) is particularly problematic, specifically the phrase, "with the exception that a plan may not require nonparticipating providers to undergo full credentialing." While the Association can certainly appreciate the need for an expedited credentialing process for nonparticipating providers who will treat enrolled members, there simply is no credentialing process in lieu of the full process required by the National Committee of Quality Assurance (NCQA). A shortened process which requires only a minimal amount of information could have serious quality of care implications for members who are utilizing non-network, non-credentialed providers. If managed care plans are prohibited from conducting credentialing according to standards that must be submitted to and approved by the Department (according to § 9.761) as well as NCQA, ***then the Association would request that the following language be added to hold the health plan harmless from the care provided by nonparticipating, noncredentialed providers: "Managed care plans shall have no liability to enrollees who elect to receive care from nonparticipating, noncredentialed providers."***

Subsection (f) is also an issue for HMOs that enroll Medical Assistance recipients if the recipient is choosing a provider who does not participate in the Medical Assistance program. In addition to potential quality of care concerns, such providers would be unable to submit the encounter data required under the State's HealthChoices program.

Subsection (i) also presents quality of care and liability concerns. ***The Association recommends eliminating this subsection and replacing it with the language proposed in the Insurance Department's final form regulations, § 154.15 (g) (1-5).***

Subchapter I - COMPLAINTS AND GRIEVANCES

As an overall comment on the "Complaints and Grievances" subchapter, MCAP is suggesting an alternative order for the subsections. Specifically, the Association recommends moving § 9.703. (Health care provider initiated grievances) and either combining it with or placing it before §9.707 (External grievance process). This order would keep all provider-related grievance information in one location. ***In addition, the Association recommends renaming § 9.706 as follows: "Enrollee grievance system."***

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§ 9.702 - Complaints and grievances

Subsection (a)(3) presents a problem for managed care plans enrolling Medical Assistance recipients. Such plans currently submit copies of complaint and grievance procedures to the Department of Public Welfare for review and approval. There is concern not only about the cost of duplicative requirements but also that different agencies may have different outcomes, placing the plan in a precarious position in terms of regulatory compliance. The Association asks that this be an area where the Health Department work with the Department of Public Welfare to eliminate duplicative reviews and clarify regulatory authority.

In subsection (d)(2), MCAP suggests removal of the term "calendar" days as the Act and proposed regulations typically refer to either "days" or "business days." The Association also advocates that the timeframes in section (d)(2) and (d)(3) be the same - 45 days respectively. This would also mirror the Department of Insurance final form proposed regulations (§154.17 (d)) which allow at least 45 days to file a complaint.

At the same time, however, the Association asks that it be recognized that such timeframes differ under the Medical Assistance program which allows 30 days. HMOs participating in Medical Assistance would have to undergo considerable expense to make all necessary changes to existing systems and publications (member handbooks, member and provider notifications, etc.) in order to comply with the stated timeframe. Again, MCAP asks for consideration for these plans in terms of compliance.

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§ 9.703 - Health care provider initiated grievances

Subsection (a) should be amended to require "written" consent from enrollees.

As an overall issue in terms of provider appeal rights, the Association would ask that the Department clarify whether or not the provider appeal rights under Act 68 (providers with the consent of enrollees based on a denial of medically necessary services OR an alternative dispute resolution process as approved by the Department) are the only appeal rights currently being recognized by the Department.

Specifically, has the Department ceased to recognize provider appeal processes established as part of HMO provider contracts and as required by NCQA? The preamble to the regulations clearly states that, once final form regulations have been adopted, provider dispute mechanisms outside those provided in Act 68 will require prior approval by the Department as alternative mechanisms. The current position of the Department is that, until promulgation of final regulations, provider appeals will not necessarily be limited to those that fall under the parameters of Act 68. Distinct clarification on this matter, however, is an important operational issue for managed care plans and should be specifically addressed in the regulations.

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§ 9.706 - Enrollee and provider grievance system (As stated previously, MCAP suggests removing "and provider")

Subsections (3)(i)(ii) and (iii) all present concerns. As a matter of practicality, it will be difficult if not impossible for managed care plans to have the professional in the same or similar specialty as part of the review committees, most especially the first level review. In addition, this is contrary to the Act which states in Section 2161(d) that, "Any initial review or second level review conducted under this section shall include a licensed physician or, where appropriate, an approved licensed psychologist in the same or similar specialty that typically manages or consults on the health care service." ***The Association recommends that subsection (i) be amended to state that, "Both the initial and second level reviews shall include . . . "***

The Association also advocates that subsection (ii) be eliminated.

In **subsection (iii)**, MCAP opposes the requirement that plans provide the specialists' report to enrollees or providers "at least 7 days prior to the review date" ***and asks for elimination of the requirement.*** Not only does this represent a timeframe which will be challenging at best in terms of the specialists' review, it also exacerbates the fact that the reviewer is not protected under the PA Peer Review Protection Act. MCAP is aware of situations where such reviewers have been threatened with physical harm for their medical decisions. Providing such reports so far in advance stands to further aggravate an already contentious situation and will make it more difficult for managed care plans to secure the physician input necessary to comply with the Act.

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§ 9.707 - External grievance process

The Association appreciates and supports the change from the original draft regulations (April 30, 1999) which stated that CREs could review a managed care plan's definition of medical necessity and specifically comment as to whether the definition "deviates substantially from usual and customary language regarding medical necessity . . ." MCAP also supports the removal of language that would have permitted Departmental investigations pursuant to evaluations by a CRE.

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§ 9.709 - Expedited review

The Association recognizes and understands that this is an entirely new section of the regulations which was not part of the original Act. However, the Association would ask that the Department understand that, if approved, such changes will require managed care plans to revise member materials such as benefit documents, member handbooks, policies and procedures, etc. MCAP would ask that the Department remain cognizant of this fact and that plan flexibility in terms of formats and deadlines be specifically addressed in the final form regulations.

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§ 9.710 - Approval of plan enrollee complaint and enrollee and provider grievance systems

In **subsection (c)**, the Association once again asks for the Department's recognition that HMOs participating in the Medical Assistance program are already required to have such materials submitted to and approved by the Department of Public Welfare.

Subchapter J. HEALTH CARE PROVIDER CONTRACTS

As an overall comment on subchapter J, the Association notes that the proposed language far exceeds the intent of the Department's Statement of Policy Issued in April, 1996. While MCAP understands the Department's obligation to protect enrollees from potential disruption of services pursuant to an HMO/IDS agreement, the Association questions the Department's statutory authority to so excessively regulate IDSs through HMO contract agreements. As an example, the Association questions why the Department would require that IDSs acknowledge that the "HMO is directly accountable to the Department for compliance with the standards and for the provision of high quality, cost-effective care." (§ 9.724 (5)) Nowhere in current HMO statute or regulation are plans required to provide "high quality, cost effective care," yet IDSs are being asked to acknowledge this through contracting.

Another overall comment is the fact that the Commonwealth recognizes IDSs as entities duly regulated by the Health and Insurance Departments. While MCAP does not disagree with the Health Department's intent to more formally regulate IDS arrangements, it would be much more beneficial for all affected parties (plans, providers and consumers) if both Departments did so simultaneously to ensure consistency.

Other specific comments on this subchapter are as follows:

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§ 9.722 - Plan and health care provider contracts

In **subsection (a)**, submission of standard provider forms to the Department for review and approval is duplicative for HMOs participating in the Medical Assistance program which already requires Department of Public Welfare review and approval of such documents.

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§ 9.723 - IDS

In subsection (b), the Association proposes eliminating the word "proposed" as well as the final phrase "including institution of litigation, termination or nonrenewal notice by either party." The reasoning for providers being unable to deliver covered services is irrelevant and the Association finds it onerous to have to submit proposed actions to the Department.

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§ 9.724 - HMO-IDS provider contract

The requirement in **subsection (c)** that managed care plans submit to the Department copies of all IDS contracts with individual providers for approval is excessive. ***The Association seeks removal of this requirement.*** In an HMO/IDS arrangement, the HMO is ultimately responsible for services being delivered. This level of review by the Department would appear an unnecessary administrative burden for the plans.

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§ 9.761 - Provider credentialing

The Association seeks the elimination of the requirement in subsection (b) that changes to credentialing plans be submitted to the Department prior to implementation. MCAP does not object to submission per se, but would note that such changes are part of updates provided to NCQA and will therefore be available to the Department under this section, specifically **subsection (c)**.

Also in regard to **subsection (c)**, the Association would like to know when the Department intends to publish its list of nationally recognized bodies for credentialing purposes.

Subsection (d) once again prohibits "full credentialing" of nonparticipating providers. As noted previously, this raises serious potential quality of care concerns for managed care plan enrollees and would raise compliance issues with NCQA credentialing standards.

Thank you for the opportunity to submit the Association's comments. We would be glad to meet with you or other Department representatives to discuss any of our comments or recommendations and look forward to the Department's response.

Sincerely,

Kimberly J. Kockler
Executive Director

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January 18, 2000

Originally rec'd 1/21/00 12:35

VIA E-MAIL, FACSIMILE & FEDERAL EXPRESS

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

Re: Proposed Regulations implementing the Health Care Accountability and Protection Act (Act 68)

Dear Ms. Mitchell:

On behalf of Independence Blue Cross' (IBC) subsidiaries subject to the provisions of Act 68 (the Act), thank you for the opportunity to respond to the Pennsylvania Department of Health's (Department) proposed regulations implementing the Act.

IBC is pleased with the consideration the Department has given to a number of issues raised by plans following the preview of the draft regulations. IBC is also pleased with the Department's reorganization of the provisions regarding plan and HMO responsibilities and the clarification sections such as definitions. IBC also views the introduction of Department Technical Advisories as an advantageous undertaking which should foster the working relationships of the plans and the Department.

Specific comments of IBC are set forth in the attached document "Comments of Independence Blue Cross Re: Pennsylvania Department of Health Proposed Regulations Implementing Act 68," ("Comments"). IBC executives and staff have carefully reviewed the regulations and the issues they raise. As with Act 68 itself, many of the provisions set forth in the regulations are already followed by IBC and other managed care plans. However, the proposed regulations still raise issues which, if not addressed appropriately in final regulations, may result in conflicting and inconsistent interpretations of applicable requirements, unnecessary and/or duplicative administrative processes, and increased costs to Pennsylvania employer groups and consumers. IBC appreciates the Department's willingness to consider these and others' comments to avoid these results.

IBC is pleased to continue to work with the Department and other regulatory agencies to successfully implement all provisions of Act 68. Representatives of IBC and I remain willing and available to discuss the regulations and IBC's comments with you and your staff.

Please contact me directly at (215) 241-2098 if you have any questions or would like to discuss this further. Thank you very much.

Sincerely,

Katherine M. Keefe
Deputy General Counsel

enclosure

COMMENTS OF INDEPENDENCE BLUE CROSS
RE: PENNSYLVANIA DEPARTMENT OF HEALTH
DRAFT PROPOSED REGULATIONS IMPLEMENTING ACT 68

1. § 9.605 Department Investigations

In view of various state and federal confidentiality laws and the expanded purposes for Department access to medical records of HMO enrollees, this provision should state, "To the extent permitted by law, the Department shall have access..."

2. § 9.622(b) Prohibition Against uncertified HMOs

IBC recommends that instead of requiring a separate Certificate of Authority for a potentially very small amount of business by a Foreign HMO (out-of-state HMO), the Department rely on and exercise its regulatory oversight authority in the areas of access to care and quality of care issues. We also recommend that a provision be added to specifically exclude out-of-state HMO's that enroll a Pennsylvania resident under a group contract issued and delivered in another state where the Pennsylvania resident is employed and where the HMO has a valid Certificate of Authority.

3. § 9.631 Content of an Application for an HMO Certificate of Authority

The Department and the Insurance Department require the filing of a number of similar documents in connection with the COA application process. If concurrent or joint review by both Departments of certain items is to continue, the application process would be less burdensome if there were greater similarity in the language of each Department's regulations. IBC suggests consistent language and requirements be applied.

4. § 9.633 HMO Board Requirements

With regards to the selection of Board members, IBC still believes that the "diverse representation of broad segments of the subscribers" language and the language regarding "undue influence in the selection process by non-enrollee members of the board" exceeds the statutory authority for Board composition set forth in the HMO Act. The HMO Act requires only that one-third of Board Members be subscribers of the HMO and that the Board be elected in the manner stated in the HMO's charter and bylaws.

5. § 9.635 Delegation of HMO Operations

This requirement still appears duplicative of the Pennsylvania Holding Company Act, under which HMOs need to file management agreements with PID. If the provision will remain in the regulations, IBC requests: (a) clarification of what constitutes a delegation of "HMO operations" subject to this provision; (b) limitation of the delegation agreements to be submitted to reflect Department jurisdictional areas, such as delivery systems or quality or access to care;

and (c) clarification of what agreements are required to be produced, relative to other current Pennsylvania regulatory requirements, under the Departments of Health, Welfare and Insurance.

6. §9.636 Certificate of Authority for Foreign HMOs

IBC reiterates its comments under #3, above.

7. § 9.651 Provision of Basic Health Services

Subsection (b) appears very open-ended and IBC requests clarification regarding: (a) what the term "customarily excluded" means; (b) who will evaluate whether services are "customarily excluded" by indemnity insurers; and (c) how this will be evaluated now that commercial group products are not filed. This provision suggests that HMOs must lag behind in implementing exclusions requested by customers by having to wait for "indemnity insurers" to add an exclusion before such exclusion becomes "customary". Additionally for clarity, IBC suggests that the first sentence of Subsection (c) be amended to read that HMOs shall either provide or arrange for the provision of basic health services.

8. § 9.652 Provision of Non-Basic Health Services

IBC requests clarification as to what entity is responsible for offering and conducting the complaint and grievance process to enrollees in the case of non-basic health services offered by the HMO through contracts with ancillary service plans, such as vision and dental, which are not subject to the regulations.

9. § 9.654 Provision of Limited Networks to Select Enrollees

IBC requests clarification of "limited subnetworks". This is a new term which appears open to many interpretations. For example, is this referring to closed panel products only?

10. § 9.655 HMO External Quality Assurance Assessment

IBC also requests clarification as the latitude the Department will grant regarding external reviews conducted by national accrediting organizations (such as NCQA). This provision seems to imply that where the requirements of the national accrediting organization differ from those of the Regulations, the Department may request that the national accrediting organization review incorporate areas specific to the Regulations or assist the Department staff with their participation with the review. An example of an area where this might occur is the processing of enrollee complaints and grievances, as defined by the Regulations.

11. § 9.656 Standards for Approval of HMO Point-of-Service Options

There are confidentiality issues with respect to informing an enrollee's primary care provider of non-PCP referred services in Subsection (b)(1). IBC believes it is the member's responsibility and privacy right to decide whether the specific nature of those services should be communicated to his or her PCP. Moreover, IBC believes the Regulations provide for ample quality safeguards to ensure that patient self-referrals are not a reflection of access or quality problems on the part of

the PCP practice.

12. § 9.672 Emergency Services

With respect to Subsection (f), IBC requests that the Department add certain protections regarding what is covered and payment obligations for emergency services. Since these services have to be covered by plans and plans must cover services provided by non-participating providers at the same level of benefits as participating providers, there is no incentive for most organizations providing emergency services to become participating providers. Plans will have to cover such services regardless of a negotiated participation contract. To avoid unreasonable costs, we suggest that the Department require non-participating providers that refuse to contract with plans to accept plan rates for emergency services.

13. § 9.674 Provision of Prescription Drug Benefits

IBC requests clarification as to whether this provision applies only to closed formularies, as opposed to formularies with a tiered-copay structure where all drugs are available, but with varying copayment obligations.

14. § 9.675 Delegation of Medical Management

IBC requests clarification as to whether each medical management contract or the plan's form generic medical management contract be filed with and approved by DOH prior to implementation. What is the Department's expectation as to its review and approval time frames?

Moreover, IBC requests clarification regarding: (a) whether the Department will deem approved a delegation plan which has received approval by a national accrediting organization (e.g. NCQA). For example, NCQA accreditation review encompasses oversight of delegated activities, including quality assurance, utilization review and credentialing; (b) the latitude the Department will grant regarding such national accrediting organization's requirements for subcontractor oversight. For example, IBC suggests that a subcontractor's certification by NCQA as a CVO should relieve the plan of some oversight functions for credentialing delegation, consistent with NCQA accreditation standards; (c) the applicability of this section to ancillary service plans for any functions other than utilization review. Current NCQA standards do not require any oversight of vision or dental subcontractors. Finally, IBC requests that the Department's requirements for independent review of delegated subcontractors will not conflict with the requirements of the NCQA or other national accrediting organization's review process.

15. § 9.678 Primary Care Providers

IBC requests clarification as to whether plans will still need to file and receive approval of a waiver for CRNPs to serve as PCPs.

16. § 9.679 Access Requirements in Service Areas

This provision fails to recognize the existence of enrollees who may live outside the service area

and require medical care in geographic proximity to their homes. Plans should not be precluded from contracting with providers who are conveniently located to enrollees who may live outside the service area, but who are enrolled through an employer located within the plan's service area.

17. §9.682 Direct Access for Obstetrical and Gynecological Care

This provision has been broadened from the language set forth in the Act. It does not appear that the statute intended the direct access to include laboratory and diagnostic procedures. The statute specifically provides for "referrals for diagnostic testing related to maternity and gynecological care, thereby implying the need for a referral. Patient care may be negatively impacted in the event that laboratory test results and results of mammograms are not coordinated with the member's PCP or the ob/gyn if the member can self-refer.

18. § 9.684 Continuity of Care

IBC requests clarification of the Department's expectations as to when the 60 day time period for continuation of services commences. As written, it begins with enrollee's notice of the provider's termination or pending termination, and not the effective date of the termination. This seems impractical and contrary to the intent of the provisions of the Act regarding Continuity of Care. For example, if a provider notifies a plan on February 1, that it intends to terminate effective June 1, and the plan notifies its enrollees as to the possible termination by March 1, according to the current language of this provision, the enrollee would be entitled to "continuity of care" from March 1 to May 1, even though the provider's contract hasn't even terminated. Additionally, IBC requests clarification of the duration of the "period of negotiation" in subsection (i), which appears confusing as written and impractical in application. Finally, IBC requests that the non-participating provider be obligated to accept the plan's reimbursement for the short continuity of care period.

19. § 9.702 Complaints and Grievances

§ 9.702 (c) Complaints versus grievances. IBC still believes that it is important that the regulations address the nature of complaints and grievances by providing guidance that goes beyond the scope of the definitions. (This is especially important because the Statements of Policy will no longer be in effect.) The Regulations could provide actual examples as was done in the Statements of Policy. For ease of administration and in recognition of the evolution of the classifications through practice, the Regulations could indicate that the Department would periodically provide updates on its interpretation of the two classifications in its web site or through Technical Advisories. This information will be practical, useful and generally available to plans so that they may properly classify appeals as part of their Act 68 administrative responsibilities. Moreover, it is a necessary addition to the individual plan consultations with the Department that are currently described in the Regulations.

§ 9.702(d) Time frames.
The Regulations now state that short time frames, such as five days, be measured by business days. This approach should be extended to all time frames under the Regulations and Act 68. The same pressures that make business days a reasonable time period in short time periods also apply when there is a greater time period and more work to be done to comply with the time period. We would recommend consideration of 30 *business* days to complete level one review, even if 45 business days to complete level 2 review is considered too lengthy. (NCQA allows 30 business days to resolve and 5 business days to notify.)

Alternatively, IBC would suggest that time frames be clarified so that the period for completion of the review—30 days for level 1 and 45 days for level 2—are separate from the 5 business day period for notifying the member of the decision. In other words, the 5 business day period for notification should not be included in (and thereby cut-short by 5 days) the maximum 30-day and 45-day periods respectively available for resolving matters at level 1 and level 2.

Here or elsewhere in the Regulations it would be helpful for the Department to describe how to treat a member's cancellations or failures to participate in a complaint or grievance meeting scheduled for level 2 review. May the plan schedule twice then proceed without member participation if the third scheduled meeting results in a no-show and the member has been given written notice of that action? How does a member's failure to participate affect the compliance time frames? Will the time begin to run on a provider grievance on behalf of a member only when a written consent form is obtained?

20. § 9.703 Health Care Provider Initiated Grievances
Further clarification in this area would be helpful either by Regulation or by Technical Advisory. Under what circumstances, if any, may there be implied or verbal consent from the member for the provider-initiated grievance that will be sufficient for Act 68 compliance at level 1 and/or level 2? Also, to dispel concerns about the content and sufficiency of a consent form, perhaps the Department might generate a sample consent form that plans could use as a model and adapt to the specifics of their appeal processes. The logistics of obtaining the written consent is particularly difficult given the current time frames. Finally, this section would be an appropriate place to underscore the fact that providers may not rely on a "standing consent" obtained in advance of disputed service or procedure to satisfy the consent requirements for a provider-initiated grievance on behalf of a member.

21. § 9.704 Internal Complaint Process
IBC is concerned about the proposal that plans be required to send the notice of the second level decision to the enrollee by a method which would permit the plan to document the enrollee's receipt of the decision. This requirement will increase the mailing costs for all second level

notifications and create a filing problem when these are returned. Would the Department accept as the receipt date, either actual proof of receipt or five business days after the date of the notification letter? The latter would be a workable alternative to sending all our mail certified at $ 2.98 per letter, especially if the business-day measure for level 2 compliance is adopted.

22. § 9.705 Appeal of a Complaint Decision

The Department does not specify the time period for its review and issuance of its determination on a member's external complaint. Specification of a time frame would help clarify the process and build appropriate expectations for plans and members regarding this stage of the appeal process. The norm could be specified and provisions made for notice regarding delay.

23. § 9.706 Enrollee and Provider Grievance System

Protections should be added to permit the plan to safeguard the identity of a matched specialty reviewer who is not participating in the appeal meeting. Disclosure of the reviewer's report and credentials, if necessary, may be made without disclosing the name of the reviewer.

24. § 9.707 External Grievance Process

In subsection (b)(4), is the reference to subsection (k) correct? Is the plan still permitted to charge a nominal processing fee of $25 or less in connection with this stage? IBC urges the Department to reconsider the position stated in subsection (k). Upon request and on good cause in a close case, a plan should be able to request that implementation be stayed pending judicial review or proceed only subject to certain agreed limitations or protective arrangements that preserve the dispute as "live." To do otherwise could effectively undercut the plan's right to judicial review by making the issue virtually moot, even in a case when expedited judicial review or injunctive relief might be sought.

25. § 9.709 Expedited Review

The Regulations should make it clear that the plan makes the determination regarding expedited status. This area may need to be addressed in a manner that parallels classification of appeals as complaints or grievances.

26. § 9.711 Alternative Provider Dispute Resolution Systems

Subsection (b) of this section should be clarified to convey the intent indicated in the comments. As written, the section allows providers to appeal contractual/administrative appeals (when the member is held harmless) through the grievance process as long as they have the member's consent. It should be clarified that the availability of a provider appeal for a member-hold-harmless matter should preclude use of the grievance process for the same matter.

27. § 9.722 Plan and Health Care Provider Contracts

IBC questions why the 45-day deemer provision for approval of plan form provider contracts has

been deleted and requests that a deemer provision be reinserted. Additionally, IBC suggests that the reference to "any" change or amendment forms which must be filed with DOH for prior approval be replaced with "substantive" or "material." Filing all minor corrections or operational changes would be considerably burdensome on plans.

Is it the Department's expectation that the contract provisions detailed in this section need to be specifically set forth in all provider contracts? The majority of plan provider contracts require general compliance with state and federal regulatory requirements. IBC suggests that the listing of provisions not be required to be specified in the contract itself, but rather may be included in a provider manual. Most plans require that providers comply with the requirements set forth in a provider manual and this would be an effective way to communicate such requirements which may change from time to time.

28. § 9.723 IDS

Subsection (a) appears to conflict with § 9.724(b), and IBC requests clarification as to whether form agreements or all HMO IDS agreements are required to be filed. (See discussion below). Additionally, under Subsection (b) the plan and the IDS have an affirmative obligation to notify the Department at least sixty (60) days in advance of any proposed action affecting IDS participating providers ability to provide services, including "institution of litigation..." Many times the plan or IDS may not have knowledge sixty days in advance of a proposed action. IBC suggests that the requirement be that the plan or IDS notify within a certain number of days of knowledge of a proposed action or within a certain number of days of institution of litigation. Any other requirement would be difficult for the IDS or Plan to meet.

29. § 9.724 HMO- IDS Provider Contracts

The HMO-IDS agreements need to be filed with the Department for review and approval prior to their use. Section 9.723 (a) and the prior IDS Statements of Policy required the filing of a generic/standard form agreement, which many plans have done and base risk arrangements on filed and approved generic agreements. IBC recommends that the Department amend this requirement so that the plan must file the contract with the Department prior to its use only if it is not based on the generic approved contract that has already been filed and approved by the Department.

30. § 9.744 & 9.746 CREs Participating in Internal and External Grievance Reviews

IBC questions the rationale for the extension of the additional requirements applicable for external grievances and additional filing fee to internal grievances.

31. § 9.747 DOH Review of a Certification Request

IBC requests clarification of what "other information the Department finds necessary to determine Act 68 compliance" may be reviewed. The language appears overly broad.

32. § 9.761 Provider Credentialing

The definition of a health care provider set forth in Section 9.602 includes durable medical equipment providers, physical therapists, RNs and physicians assistants. The term health care provider is used in this provision. Are plans now required to credential all of these provider types? NCQA does not require credentialing of allied health providers and HCFA does not include DME suppliers as providers of health care.

If the plan meets or exceeds the standards of a nationally recognized credentialing body, how will it demonstrate this and will it still be required to submit its credentialing plan or changes thereto prior to implementation?

3006136

Ms. Stacy Mitchell, Director
Bureau of Managed Care
PA Department of Health
P.O. Box 90
Harrisburg, PA 17108-0090
RE: Proposed Regulations to Implement ACT 68
January 18, 2000

Dear Ms. Mitchell:

I am writing this letter to you on behalf of the Consumer Health Coalition, of which I am a board Member. I wish to express our concern to you with respect to the proposed regulations to implement Act 68 as published by you office in the December 18, 1999 edition of *The Pennsylvania Bulletin.*

Among the many points on which I would offer comment, I feel the need to stress the following issues that are of concern to me:

1. Medical Necessity:
   - The regulations eliminate language which require that plans adopt a definition of "Medical Necessity."
   - They fail to require managed care plans to consider information by the plan participant, the family, primary care practitioner, other providers and agencies that have evaluated the individual when determining the "Medical Necessity" of a given service.
2. Health Care Provider Contracts:
   - The concerns in this area are too numerous to fully amplify within the body of this letter; however, our paramount concern involves the failure of the regulations to place any limit of the conflict of interest which can be found to exist between health care providers and their patients, and instead to permit huge financial incentives which plans afford to providers who limit the care which they provide to patients. In other words, if physicians are beholden to insurance companies, who offer incentives to their practices if they limit the care which they provide to patients, the physician then has a financial incentive to treat a patient in a way which is inconsistent with the patients' needs, wants, and, quite possibly, the canons of professional responsibility. The mere appearance of impropriety necessarily creates a conflict of interest between physician and patient.
3. Complaint and Grievance Process:
   - We are extremely concerned about the consumer "take-aways" apparent in this section. The Fundamental Fairness Guidelines of HMOs previously issued by the Department and currently in place have many excellent consumer protections that are inexplicably not contained in these proposed regulations. We understand that unless these protections are incorporated they will be lost. The regulations, as currently drafted, eliminate far too many of the protections which were provided for previously.

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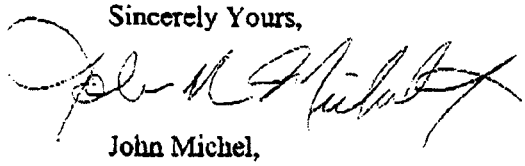
4. Disclosure of Consumer Rights:
   - The proposed regulations no longer require plans to advise member of their right. Simply stated, it is CHC's position that lack of knowledge of a right negates a person's potential exercise of the right, which effectively works to eliminate the right itself.
5. Subcontracted Services:
   - We find it particularly disturbing that the regulations appear to permit plans to subcontract out almost all plan functions to unlicensed entities who are not subject to these regulations.

In summary, we urge you not to go forward with these regulations as written.

Sincerely Yours,



John Michel,
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January 18, 2000

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Harrisburg, PA 17108-0090

Re: Proposed regulations to implement Act 68

Dear Ms. Mitchell,

We are pleased to submit, on behalf of our clients, the following suggestions regarding the proposed regulations for HMO's and managed care plans covered by Act 68. We have organized our comments by the section of the proposed regulations to which they refer.

9.634. Location of HMO activities, staff and materials.

This section ought to place meaningful staffing obligations on managed care organizations which control crucial health care decisions affecting Pennsylvanians' lives. In its current form, the proposed regulation applies only to HMOs, and requires only a medical director to maintain a license in Pennsylvania; the disappointingly modest requirements of the section governing staffing obligations is evidently an outgrowth of the modest goal asserted in the preamble, that the HMO "demonstrate its ability to assure both availability and accessibility." Act 68, however, imposes much more specific obligations on managed care plans, and there is no reason either to limit staffing obligations to HMOs alone or to hold back from imposing meaningful obligations on all plans. Managed care plans other than HMOs also serve to "provide or arrange for the provision of basic health services," which is the concern of this section, and those plans too should be required to maintain adequate numbers of essential staff in the Commonwealth.

The draft proposed regulation 9.9(a) sensibly required "a place of business... that is accessible to enrollees [and] providers", and "personnel sufficient to respond to complaints, grievances, and urgent/emergent requests for assistance concerning the provision of health care services," and these requirements should be maintained.

Either here in Section 9.634, or else in the several individual sections, the final regulations should contain specific requirements for all managed care plans to maintain sufficient staff to carry out all functions required by Act 68, including performing utilization review by appropriate specialists, answering requests for information, providing documents to which enrollees are entitled to have access, and responding to complaints and grievances. MCOs do not want to spend time or money on these tasks, and they will be assigned to, and performed by, people whose primary responsibilities are elsewhere, and hence these tasks will be unreasonably delayed, unless the MCO is required to have maintain staff with responsibility for performing these tasks in a timely fashion. The current regulation would leave it up to the managed care plan to decide whether to maintain adequate staff, and would probably result in state oversight only after a serious problem developed and enrollees' and providers' complaints about inaccessibility had

grown loud enough: the Department should instead act on its mandate to effectuate Act 68's purpose of patient protection by requiring adequate staffing in the first place, in order to ensure that managed care plans in the Commonwealth will be prepared to serve their clients at all times.

9.673. Plan provision of prescription drug benefits to enrollees.

We support the requirement that plans provide information about their formularies and listed drugs to their enrollees and potential enrollees. We do not see any reason, however, why in 9.673(b) plans should be allowed 30 days to respond to a written query about a specific drug's formulary status; the plan should be able to obtain this information instantaneously by searching a computer file once the request is received; a period of five days to respond to a request ought to be fully adequate, and would even allow for several days' lag time if a request is temporarily backlogged.

9.676. Standards for enrollee rights and responsibilities.

The purpose of the promulgation of regulations by government agencies is to provide specific guidance which elucidates the intent of the legislature. We are therefore disappointed that the proposed regulation governing enrollee rights, which in a real sense is the primary focus of Act 68, is so abbreviated and redundant. The Department has full authority to spell out and elaborate the protections required by Act 68, as well as the concomitant means of implementing those protections. Instead, the proposed regulation would hand virtually all responsibility for such elaboration to the plans themselves, and moreover the regulation would couch this requirement in equivocal language without any standards, so that a plan which "adopt[ed] policies and procedures to ensure implementation of enrollee rights" would be in technical fulfillment of its obligations under this section if the procedures it adopted were ineffectual and the implementation of enrollee rights uncertain. In contrast to the Department's narrow view of the appropriate scope of this section of the rules, however, Section 2136(b)(10) of the act states that enrollees must provide upon request such "other information as may be required by the department," an unambiguous affirmation of the Department's full authority to effectuate Act 68's intent with broad requirements.

The final rules ought to recapitulate and, where appropriate in accordance with the overall intent of Act 68, extend the Act's requirements. For instance, Act 68's intent that enrollees be able to obtain information from their plans in a timely fashion ought to be enforced in this section, or elsewhere, with a clear enrollee right to speak to someone at the plan over the phone, even in non-emergencies, within three minutes of having called. Proposed regulation 9.743(c)(5)(i) is limited but entirely appropriate example of the Department's use of its regulatory and oversight authority to effectuate Act 68: applicants for certification must explain to the Department their "ability to respond to each telephone call received as required by section 2152 of the act." This limited requirement still leaves the possibility, however, that the phone would ring for a significant period of time before being answered, since the language of section 2152 of the act does not explicitly state a standard for response to telephone calls. Section 2152 does, however, clearly contemplate that telephone calls will indeed be answered within a reasonably brief time, and this is a perfect example of an appropriate case for using rule promulgation to fill in the gaps in a statute

written broadly by the legislature: where the legislature passes a law with the clear intent that MCOs be obligated to answer enrollees' phone calls, the Department can and should promulgate specific rules to ensure that the MCOs' performance will satisfy the legislature's intent.

HealthChoices enrollees in Philadelphia, in particular those trying to get through on the telephone to Eagle Managed Care, the former pharmacy benefits subcontractor for several HealthChoices MCOs, have been deeply frustrated by a scheme which meets the minimal requirements of Section 2152 with a toll-free telephone number for enrollees to call, but which does not provide the meaningful "access" Section 2152 seeks to establish because the phone is unanswered for periods of a half-hour or more. The Department can and should provide a definite standard for enrollee's right to speak with someone within a reasonable time when they call their plan or its agents.

Section 2152 of the act strictly applies only to inquiries to utilization review entities regarding utilization review decision. The Department should go beyond this, however, to establish an affirmative duty for MCO's, and MCO subcontractors who directly manage health care, to respond promptly to phone calls and other requests for information, with standards for promptness which will allow monitoring and quantitative measurement of MCO performance. While financial management offices, for instance, need not be especially responsive to urgent consumer inquiries, any unit in a MCO or a benefits management subcontractor that could prevent or delay the delivery of medical benefits by a failure to respond to a phone contact must be required to respond, within a reasonable but definite time period, to incoming calls.

Sections 2136(a)(6) and (8)(i) of the act contemplate a duty to respond promptly. Rather than simply mandating the establishment of a passive means of communication with Pennsylvania MCO's, such as the publication of a mailing address, the Legislature has decreed that MCO's maintain, and inform their enrollees of the existence of, "telephone numbers necessary to enable an enrollee to obtain approval or authorization of a health care service or other information." As the example of Eagle demonstrates, this requirement would be inadequate and fail to meet the statutory requirement of "necessary phone numbers" sufficient to respond to calls in a timely fashion.

Section 9.676(1) of the proposed regulations also needs strengthening. As written, it only obliges the plans to "adopt policies and procedures to assure implementation of enrollee rights... includ[ing]... access to the information required by Act 68...". The Department can and should effectuate Act 68 by requiring the provision of important information to enrollees. One important example is that at the time that services or items are denied, reduced, or terminated by an MCO, enrollees should receive notice informing them of their right to file a grievance or complaint, and explaining the difference between those two methods of dispute resolution. Act 68 requires that enrollees receive notice of some of their rights on an annual basis, but practically speaking, we can expect that many enrollees, if not most, will overlook boilerplate language which does not arrive contemporaneously with any care denial or restriction or other dispute. This predictable information breakdown would also affect enrollees' understanding of plan grievance and complaint procedures.

Sections 2136(a)(8)(i) and (ii) of the act mandate that MCOs "supply each enrollee... with the following written information... a summary of all complaint and grievance procedures, including... the procedure to file a complaint or grievance... [and] the right to appeal a decision." The Act does not place any limits on the frequency of the provision of this information, but simply says that the MCO "shall supply" it to enrollees; the Act does not say that this must happen only once a year, nor does it say in what manner the information shall be provided. The Act does, however, state that "such information shall be easily understandable to the layperson," language evincing a concern that enrollees receive notice of their rights in a manner which will allow them to comprehend those rights. Since, under the Act, Section 2136(a)(8)(iv), enrollees must also be told that "all notices of decisions will include information regarding the basis for the determination," the Act clearly contemplates that enrollees will receive such a "notice of decision" whenever a service is denied, reduced, or terminated. To give effect to the Act's overt and implicit concern for actual enrollee comprehension, each such notice should include "the procedure to file a complaint or grievance... (and) the right to appeal a decision." The regulations should ensure that, in addition to receiving annual announcements via mass communication, enrollees will also receive notice of their rights at a time, post-service denial, and in a format which will encourage them to take the time to read and understand their rights to pursue appeals.

Along with a description of the right to file a grievance or complaint, the "notice of decision" should also include some explanation of the difference between the two methods of dispute resolution, and the consequences of selecting the wrong method. Such an explanation will help make the operation of dispute resolution reviews more smooth and efficient, as enrollees will have both the ability and the incentive to file the correct type of appeal at the outset. While we recommend that proposed regulation 9.702 be amended to clarify that enrollees have the right to choose the method of resolution which will be applied to the issue in dispute (see below), we also appreciate the importance of fully informed enrollee decisions to allow speedy and efficient dispute resolutions, for all parties' benefit. In addition to explaining the different categories appropriate for complaints and grievances, MCOs should inform enrollees that complaints may achieve faster resolution, as they can be filed orally, and can be reviewed and investigated without any delays for the accommodation of medical specialists; likewise, enrollees should know that grievances may be more thorough but take more time, as they must be converted into written form, and both initial and second level grievance reviews will include a medical specialist. Finally, the notice should inform enrollees that if they choose an inappropriate category, the MCO may decide to consult with the Department, and that this consultation may take additional time before resolution is achieved and may result in a reversal of their choice, so that it is in their interest to select the appropriate category at the outset.

In addition, the draft proposed regulations appropriately implemented Act 68 by stating that enrollees had to be informed of all of their rights, not just some, on an annual basis. The proposed rules retreat from that salutary advance, but the requirement should be restored for the final rules.

Finally, under the authority of Section 2136(b)(10) of the act, the Department should specify that enrollees have the right to receive information from their plan about alternate sources of coverage for their health needs whenever an MCO denies or terminates a service, or when an

enrollee is approaching some annual cap or other limit. The MCO will be the party with the power to control the enrollee's access to health care, so when the MCO is on the verge of ending coverage of a benefit to an enrollee who does not have information about other possible sources of coverage, the MCO, as the entity which has the best access to such information, and upon which she has come to depend, bears an obligation to inform her about how she may try to obtain alternate coverage. For instance, seniors in Pennsylvania may sign up with a Medicare HMO that places annual or quarterly limit on drug coverage; the MCO with its computerized tracking systems would be better able to keep track of when an enrollee is reaching the limit of her coverage than would be the enrollee herself. At such a point, the MCO ought to inform the enrollee about the existence of the PACE program, which provides prescription benefits to senior citizens, and information about how to apply. The enrollee might then be able to avoid a break in her drug coverage.

9.677. Requirements of definitions of 'medical necessity'.

We are disappointed that the section governing the definition of medical necessity does not require any minimal substantive content. While we support the obligation to maintain a consistent medical necessity definition, we do not believe plans should be allowed to use any definition they desire so long as they are consistent. The Department has the authority to require that a definition of medical necessity which will actually offer safeguards to Pennsylvania residents. The draft proposed regulation 9.47 would have required 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." That requirement should be maintained. The final rules should require that plan's medical necessity definition meet or exceed national standards. Otherwise, the proposed regulations will not result in any obligation on the part of MCOs to actually provide quality care: Section 9.651, governing operational standards for HMO provision and coverage of basic health services, says only that the HMO shall provide the degree of basic health services that it deems medically necessary under its own definition, so that a plan with a weak definition could legally deny care to virtually anyone.

A requirement of a strong substantive standard for definitions of medical necessity follows naturally from Act 68, which clearly contemplates that MCOs not be allowed to operate in Pennsylvania if they intend to deny needed care. The purpose of Article XXI, after all, is to protect "*quality* health care." Section 2111(1) of Article XXI requires that plans "assure... access to quality care," and Section 2112 prevents plans from paying providers for anything less than "medically necessary and appropriate care." As managed care spreads through Pennsylvania, more and more consumers will have to choose plans without being sophisticated enough to assess the merits of a technically worded medical necessity definition. It would be perverse if, under the command of the proposed regulation, plans placed a complete yet weak definition of medical necessity in the enrollee contract, and thereby confused enrollees with a complicated definition which sounded like a strong guarantee of benefits. The Department can and should protect quality health care by requiring a medical necessity definition meeting national standards.

9.702(c). Complaints and grievances: complaints versus grievances.

This subsection of the proposed regulation obscures the intent of Act 68 to allow enrollees to decide whether to file their appeals as complaints or as grievances. The language of the proposed regulations does not state that enrollees are allowed to choose and that MCOs must respect that choice, but rather leaves the impression that MCOs may classify any appeal they receive as they please, either as a grievance or a complaint. Indeed, the comments to 9.702 suggest that the Department has read Act 68 to give the prerogative of appeal classification to MCOs.

There is no authority in the Act for assigning appeal classification responsibility to the MCO. Act 68, Sections 2111(8) and (9), Responsibilities of Managed Care Plans, says only that plans shall "adopt and maintain a complaint process as set forth in [Section 2141[... [and] a grievance process as set forth in [Section 2161]." Neither Section 2141 nor Section 2161 assigns appeal designation responsibility to the plans. Section 2141, Internal Complaint Process, states in paragraph (a) that MCO's " shall... maintain an internal complain process... by which an enrollee shall be able to file a complaint," which seems to imply that the choice to select the classification of "complaint" will be left to the enrollee. Similarly, Section 2161(a), Internal Grievance Process, has parallel language stating that an enrollee or an authorized provider "shall be able to file a written grievance," without any language granting the MCO authority to reclassify a written grievance as a complaint.

Naturally, some poorly written or poorly worded appeals will not fall clearly into one category or the other, and some appeals will have been filed in the wrong category by the enrollee; it is appropriate to have some mechanism for determining the correct review committee to which an appeal should be directed. The initial choice, however, belongs to the enrollee; the MCO should have the option to contact the Department for reconsideration if necessary. The final rule should clarify that MCOs must respect the enrollee's choice unless it is unclear or the MCO reasonably believes it to be mistaken. If it is unclear, then the MCO should have the ability to make its own classification decision after consultation with the Department as 9.702(c)(2) provides.

The enrollees' stake in a correct appeal classification becomes all the more important when we recognize that the MCO's have an incentive to classify appeals as complaints, so that they will not have to bring in medical specialists for the review committees, nor state any "clinical rationale" for their action in the notice of decision, nor pay "all fees and costs" related to any external grievance which may be subsequently filed by the enrollee (as provided for by Section 2162(c)(7) of the act). The Department itself confirms in the comments to proposed rule 9.702 that "the possibility exists that the plan could classify a matter in such a way as to confer an advantage on itself."

To ensure that enrollees are able to benefit from the safeguard of a medical specialist's appeal review participation, even in cases which the MCO might tend to classify as complaints, the enrollee's choice of appeal classification must be respected. If the enrollee calls the MCO, or the enrollee or authorized provider sends in a written appeal, and the choice of procedure is clear, then that should be treated as the enrollee's choice. If it is not clear from a telephone message or

a written document which procedure the enrollee would prefer, then the MCO should make a tentative classification and attempt to contact the enrollee immediately in order to find out whether they prefer to designate the appeal differently. The enrollee's decision on appeal designation will have been informed by the information accompanying the original notice of the decision to deny, terminate, or reduce the service (see our comments re: proposed rule 9.676). The MCO will thus have the opportunity to point out to the enrollee why they might choose the other procedure; if the MCO does not agree with the enrollee's choice, then the MCO should have the burden of "contact[ing] the Department directly for consideration and intervention" for possible reclassification. The proposed rule would place the burden of contacting the Department to seek reconsideration on the enrollee, which is inappropriate. Enrollees seeking to appeal an MCO decision are attempting to deal with a medical problem affecting themselves or their loved ones while still making ends meet; the MCO, on the other hand, has paid professional staff to run a grievance and complaint process, and does not have a personal stake in achieving the most appropriate consideration of its claims.

If the Department does not accept our view that the enrollee's choice controls and that the MCO should bear the burden of consulting with the Department on reclassification, then the proposed rules would pose a significant problem for enrollees, because enrollees would be bearing a burden without having access to the informational tools needed to relieve that burden. In a system in which the regulations award the MCO de facto authority to classify all appeals as it saw fit, even directly contradicting the enrollee's choice, the only checks on misclassification would be enrollee complaints and the provision in 9.702(c)(2) for MCOs in doubt to contact the Department. 9.702(c)(2) is not a reliable safeguard, because the trigger for consulation with the Department is "doubt" about the correct classification, and this entirely subjective doubt is in the mind of the MCO, an entity which, as the Department's comments point out, has an incentive to misclassify appeals. Where there a financial incentive to misclassify, and no disincentive for making the wrong choice, MCOs will simply deny having doubts. Aside from MCO consultations, the proposed rules, without clarification that the enrollee's initial choice prevails, would establish a system of purely passive Department oversight, and they would tacitly rely upon enrollee complaints to correct problems. Not only would enrollees be burdened with other problems already, but, without adoption of our recommendation that they be given updated notice of their appeal options and the layout of the grievance/complaint system at the time of any denial, reduction or termination of a service or item (see comments to 9.676), enrollees would not know what to do and would not even be aware of what they could do. For example, proposed rules 9.676 and 9.702 do not even state that enrollees have a right to be told that they have the right to contact the Department directly if they feel their appeal has been misclassified.

Therefore, in lieu of reorienting the rules to clarify the primacy of the enrollee's choice, the final rules should at least guard against the dangers of a system of enrollee ignorance, MCO perverse incentives and passive oversight with two changes: establishment of affirmative enrollee rights to information, and a disincentive against misclassification by MCOs. Enrollees should have a clear right to receive, and MCOs an obligation to provide, full information about the appeals process whenever that process becomes relevant due to an appeal by themselves or by a denial, reduction or termination by the MCO; this information should include the right to contact the right to contact the Department if they feel their appeal has been misclassified. Furthermore,

if the Department finds that an MCO has misclassified an appeal, the MCO should have to provide the benefit (if that is what is being contested) until the correct appeal process has been completed. This rule would probably be invoked very rarely, since MCOs have professional employees to classify appeals in the correct manner. The threat of its invocation, however, would encourage MCOs to be careful not to confer improper advantages on themselves, and the actual application of the rule would avoid sick or disabled enrollees bearing the burden of a longer delay without their prescribed benefit.

We support the proposed regulation's provision for monitoring of MCO complaint and grievance reporting, and we suggest that this should include, under an enrollee-controlled designation procedure, monitoring of the frequency with which MCO's seek reconsideration by the Department, and of whether this is done in good faith and not so as to delay proceedings and deny due process to the enrollee.

9.704(c) Internal complaint process.
9.706(c) Enrollee and provider grievance system.

The final rule should require that MCOs provide access to the documentation compiled by the MCO on the specific matter being appealed. The complaint and grievance processes are opaque to enrollees, who do not generally understand the process by which a decision is made or the criteria used in making that decision. Without some sense of what errors to correct, what arguments to counter or on what points to present evidence, the appeals process will be of little value to enrollees. Prior to the settlement in Metts v. Houstoun, which set explicit standards for denial notices, HealthChoices HMOs provided virtually no information whatsoever in their notices to enrollees; they simply indicated that the service or item would not be provided. The Department should improve these notices in the non-Medical Assistance context by requiring specific, comprehensible information about decisional standards, but even improved notices would be inadequate to enable enrollees to navigate the appeals process with some chance of success. Inevitably, MCOs will err on the side of less information rather than more in their denial notices, and without the right to see the supporting documentation and the more elaborate explanation of the MCO's thinking, the average enrollee cannot possibly target her appeal at the most relevant points of consideration and possible flaws in the MCO's reasoning, other than by lucky coincidence. If lengthy internal policies, nursing notes, extended evaluations and the like are available to everyone except the enrollee, the enrollee will never be able to put the appeal process to good use by addressing the true merits of the case. Part of this problem would also be alleviated by clarifying the second level review process requirements to require that the MCO present its case in full at the hearing, in front of the enrollee, as we recommend below, but the enrollee will not have any chance to prepare a meaningful response if they are met with the detailed case against them for the first time only after their appeal hearing has gotten under way.

In addition, since the appeal hearing itself will often pass by a nervous enrollee in a blur, and they cannot take detailed notes and talk at the same time, a thorough paper record of the process is essential so that any necessary further steps in the appeal process can be taken, and the Department can provide comprehensive retroactive oversight when problems arise. To that end, the notices of decisions of first and second level reviews, described in Sections 9.704(c)(1)(iv)

and (c)(2)(vii) and 9.706(c)(1)(iv) and (c)(2)(vi), should be required to contain a description of the reviewer's understanding of the substance of the dispute and references to the evidence and documentation used as the basis for the decision. The Department's proposed rule, requiring only mention of the "basis for the decision," is another disappointing example of the Department's failure to embrace its responsibility to promulgate regulations in sufficient detail to ensure that the patient protections envisioned by Act 68's authors will have guaranteed substance.

9.704(c)(2). Internal complaint process: Second level review.
9.706(c)(2). Enrollee and provider grievance system: Second level review.

We heartily endorse the Department's imposition in the proposed regulation of a "duty to be unbiased" on all second level review committee members. We suggest that the regulation take a further step to prevent prejudicing of the committee members, by clarifying in 9.704(c)(2) that the review committee must base their decision solely on materials and testimony presented at the hearing, and that the MCO and its representatives bear an affirmative duty to present their case at the second level review and answer the enrollee's questions, rather than engaging the review committee in private and placing the entire burden of presentation on untrained enrollees who are ignorant of the substance of the case against them and unable to question the MCO's spokesperson.

Our suggested clarification would further the goals of the Act by allowing the committee to hear the MCO's case in context and allowing the enrollee to make a full response. The MCO's arguments would be juxtaposed with those of the enrollee, and the enrollee would be able to respond to all elements of the MCO's case, rather than perhaps leaving unanswered several points which they unwittingly neglected to address. Despite the admirable requirement in Section 2136(a)(8)(iv) of Article XXI of the act that all notices of decision will include "information regarding the basis for the decision," we know from our experience in the Medical Assistance context that denial notices are woefully uninformative, and the specific elements of the MCO's case are usually not made clear to the enrollee prior to responses to requests to view case file contents pursuant to external fair hearings. Too often in HMO grievance hearings, an enrollee, having received only a single sentence in a denial letter as the explanation for the denial, enters a room, hears an HMO lawyer read aloud the relevant sections of the denial letter, and then is given 20 minutes to explain to the committee why the denial was incorrect. Some of the enrollees' bewilderment should be ameliorated by more detailed explanations in denial notices, but that cannot be the whole answer; enrollees need to have the details of the case against them presented, however briefly, so that they can make a knowledgeable response.

Sections 2141(c)(1), and 2161(b)(1) and (c)(1) of the act contemplate a requirement of affirmative case presentations by MCO's. These provisions require that the complaint and grievance reviewers not have participated in the original decision to deny the service, a requirement that would be unimportant if the only purpose of the internal appeal process was to allow the enrollee a chance to be heard and to ask the MCO as a corporate entity to reconsider its action. The purpose of bringing in fresh reviewers is to ensure some measure of independence in order to guarantee that the process is fundamentally fair. This purpose would be defeated if the reviewers were prejudiced by one-sided, open-ended MCO presentations, given before and after

the enrollee's chance to respond, and out of the enrollee's hearing, by fellow MCO employees (for the majority of reviewers). The reviewers' ignorance of the reasoning that formed the basis of the original decision to deny the service is purposeless if that same reasoning is then presented to them by their fellow employees as the correct approach to the issue, without the enrollee even receiving a chance to rebut, point out flaws or suggest alternatives.

On the other hand, we applaud the Department's proposed requirement that the plan "provide reasonable flexibility in terms of time and travel distance" to enable enrollee participation in second level review hearings, and we suggest that the Department add a requirement that the plan provide equal flexibility in the time allotted for the enrollee's presentation and the committee's chance to ask questions while the enrollee is present. Too often, HealthChoices HMO's schedule appeal hearings 20 minutes apart, forcing the committee to rush and often to forego collecting their thoughts and asking follow-up questions. While many grievances can be heard in 20 minutes, more complicated appeals may necessitate more extended sessions for presentation and question-and-answer, and to "ensure that the complaint and grievance process is fundamentally fair," the MCO's should be required to provide that flexibility.

In addition, the goal of ensuring unbiased decisionmaking would be furthered by restoring the language of the draft proposal requiring that the 1/3 of review committee members who are not MCO employees be enrollees. The MCO's own enrollees should offer a wide base of people who can be easily contacted, and who will be much more likely to understand, and sympathize with, a fellow enrollee's constraints and obligations than would a non-MCO enrollee who was sufficiently friendly to the MCO that he would take time out to sit on a review committee.

9.706(b). Enrollee and provider grievance system.

The proposed regulation states that enrollees or providers "may file a written grievance with the plan." This wording could be read to require that enrollees actually put their appeal into writing and hand, mail, or fax it in to the MCO. Such a requirement would a misreading of Act 68, and does not allow the flexibility that fully occupied providers and sick or disabled health care consumers often require. The regulations should clarify that enrollees can orally initiate grievances, whereby the enrollee or provider can speak to someone at the MCO or, in emergencies, can leave a voice mail message, and their appeal can then be reduced to written form with the MCO's assistance.

Section 2161 of Article XXI of the act calls for an "Internal Grievance Process... *by which* an enrollee... shall be able to file a written grievance" [emphasis added]. Under this language, a grievance could begin with a phone call, so long as it ends up in writing. Indeed, Section 2136(a)(8)(i) of the act already contemplates that enrollees can call their plan toll-free for help in filing a complaint or grievance; there is no reason not to allow the issue about which the enrollee is calling the MCO to be reduced to writing while they are on the phone.

Whether or not a procedure for initiating grievances orally is required by the Americans with Disabilities Act, it would be fundamentally unfair to deny access to the grievance system by sick, disabled or overwhelmed enrollees who lack the time, strength, or ability to file a written

grievance. In an age of managed care and drug formularies, when doctors must spend increasing amounts of their precious time on prior authorizations and other administrative tasks, it makes no sense to limit providers to written grievances.

Filling out a grievance form does not take long, in any event, under HealthChoices - the HMO employee simply takes a few minutes to talk to the enrollee, ask them some basic questions to get the essential information, summarizes their answers in a few boxes on one side of a sheet of paper and sends it to the plan grievance coordinator. If the enrollee leaves a voice mail message, or is not able to stay on the phone for long, the MCO can fill out a written grievance with the information they have, call the enrollee back to get more information, or send a simple form to the enrollee's last known address to be filled out and signed.

9.709. Expedited review.

As we read this section, it provides for expedited review in all cases in which delay might jeopardize the enrollee's health, no matter how the enrollee might have categorized her appeal and no matter how the MCO might have determined it ought to be qualified - complaints as well as grievances can be performed in an expedited manner if requested in a case in which the enrollee's life, health, or ability to regain maximum function would be jeopardized by delay occasioned by the standard review process. We strongly support the proposed rule under this reading of its terms, because even people whose dispute involves the coverage status of a service or item can be at risk of ill health or death without the service/item they are seeking. If complaints could not be expedited under this section, then people facing disability after an improper denial (such as a denial based on a mistaken view that coverage was excluded) would have no recourse to preserve their health, since the time it would take them to appeal to the Department and get their appeal reclassified would prevent expeditious approval of their care. We would recommend that the Department clarify this rule, in order to avoid any possible mistakes by MCOs failing to recognize their obligation to provide expedited review: the final rule should state that plans shall make an expedited review available for both grievances and complaints.

Thank you for your consideration of our comments. Please do not hesitate to contact us if we can be of any assistance in clarifying our remarks, or in otherwise aiding in your work.

Sincerely,

Richard P. Weishaupt, Senior Attorney

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MESSAGE: comments on managed care regs

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January 18, 2000

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

RE: Comments on Proposed Act 68 Managed Care Organization Regulations, 28 Pa Code Chapter 9

Dear Ms. Mitchell:

On behalf of Capital Blue Cross, we are providing the below listed questions and comments concerning the Department of Health's (DOH's) proposed adoption of 28 Pa Code Chapter 9, Managed Care Organizations, published for comment in the Pennsylvania Bulletin on December 18, 1999.

To facilitate your review of our comments and questions, quoted sections of the proposed regulations appear in italics.

Specific Comments

- **Section 9.604, Plan reporting requirements.**

  Section 9.604 provides, in pertinent part:

  (a) Annual reports. A plan shall submit to the Department on or before April 30 of each year a detailed report...which shall include...the following information: (2) Health care services utilization data...

  (b) Quarterly reports. Four times per year, a plan shall submit to the Department two copies of a brief quarterly report summarizing key utilization..." (Emphasis *added.)*

The exact utilization data the DOH is requesting is not defined. We assume Section 9.604 of the proposed regulations is only intended to apply to the utilization data that is currently collected by the DOH as a part of its current annual and quarterly reporting requirements. If our assumption is not correct, we would be concerned about the costs involved in changing systems if it became necessary to collect additional data. Accordingly, we believe that the specific utilization data requirements should be defined, and we would urge the DOH to retain its current utilization reporting requirements, which we believe are adequate.

- **Section 9.673, Plan provision of prescription drug benefits to enrollees.**

  Section 9.673(e) provides, in pertinent part:

  If the plan does not approve a health care provider's request for an exception, 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).*

  We assume that Section 9.673 of the proposed regulations is not intended as a prohibition of any contractual exclusion of specified drugs from coverage or limitation of usage under a prescription drug plan offered by a managed care plan. As one example, if Viagra is excluded, the question is not one of medical necessity but of the coverage being offered.

  In its introductory comments, the DOH states: "The Department is proposing this requirement because any decision not to provide a drug that is not on the formulary would be based on a determination that there is a prescription drug on the formulary that would be appropriate and therefore, would come within Act 68's definition of a grievance." This comment fails to take into account a managed care plan's rights to exclude certain drugs or supplies or classes of drugs or supplies. As another example, many employer groups choose to exclude contraceptives from coverage. In such a case, any determination not to provide the excluded item is <u>not</u> based upon the fact that there is an alternative available on the formulary.

  For the reasons set forth above, we believe a clarification of the intent of this section is appropriate. In so doing, we note that if any member expresses dissatisfaction because a drug is not covered as a result of an exclusion, the member should be directed to file a complaint (and *not* a grievance) --a further clarification that DOH should consider.

- **Section 9.675, Delegation of medical management.**

  Section 9.675(a), provides, in pertinent part:

  The plan shall submit the medical management contract to the Department for review and approval prior to implementation.

  We request clarification of DOH's statutory authority to require submission and prior review and approval of the medical management contract entered into between a non-HMO managed care plan (such as a gatekeeper PPO/POS product) and a subcontractor. Managed care plans should be free to contract with various vendors, such as entities specializing in disease management, without prior review and approval of such contracts by DOH. We believe it is DOH's responsibility to review the results of a plan's medical management efforts, not the vendor relationships it chooses in the medical management process. We also believe that such contacts contain proprietary and confidential information that should not be available to our competitors.

- **Section 9.679, Access requirements in service areas.**

  Section 9.679(c), provides, in pertinent part:

  A plan shall demonstrate at all times that it has an adequate number and range of health care providers by specialty and service area to ensure that enrollees have adequate access to and availability of health care services covered by the plan.

  We suggest that the DOH modify this section to reflect its long-standing practice to require contractual arrangements only with PCPs and "frequently utilized" specialties. If non-frequently utilized specialists are either not available within the geographic criteria stated or refuse to contract with the plan, we assume the DOH would still approve the service area, on the condition that the plan has adequate provisions to address these issues (by, for example, referrals outside the 20 or 30 mile zone or referral to a non-participating provider while holding the enrollee harmless for costs in excess of authorized deductibles or co-insurance.)

- **Section 9.681, Health care providers.**

  Section 9.681 provides, in pertinent part:

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

  We believe that such specificity is unwarranted and is already provided under the continuity of care provisions of Act 68. The continuity of care provision addresses the concerns of members affected by provider terminations. Finally, the last phrase, "with equivalent training and experience", is subjective and can cause unnecessary member dissatisfaction.

- **Section 9.702, Complaints and grievances**

  Subsection 9.702(a)(3) provides, in pertinent part:

  A plan shall provide copies of its complaint and grievance procedures to the Department for review and approval. The Department will use the procedures as a reference when assisting enrollees who contact the Department directly.

  DOI also reviews complaint and grievances procedures as a part of its Act 68 compliance activities and review and approval of forms. We do not believe that both Departments should have approval authority over complaint and grievance procedures. We request clarification of the DOH's authority to require prior review and approval.

- **Section 9.703, Health care provider initiated grievances.**

  Section 9.703(c) provides, in pertinent part:

  Once a health care provider assumes responsibility for filing a grievance, the health care provider may not refuse to grieve the issue through the second level grievance review.

We request clarification of DOH's intent in this provision. The provider becomes at risk when an external review is requested, since, according to Act 68, the losing party has to pay the costs of the external grievance review. Could DOH clarify its expectation of what happens to the grievance if the provider decides not to request an external grievance appeal? Since the provider's decision at this point directly impacts the member, we believe that the member should be advised of the provider's decision, and its implications. Most importantly, DOH should specify the provider's responsibility to inform the member of his/her/its decision not to request an external grievance review. We believe it inappropriate to make this a plan responsibility, and plans should have the right to refuse an external grievance review if not timely filed due to the failure of a provider to timely notify the member of the provider's determination not to request an external grievance review.

- **Section 9.706, Enrollee and provider grievance system**

  Section 9.706(c)(3)(ii) provides, in pertinent part:

  The physician or approved licensed psychologist, in the same or similar specialty, need not personally attend at the review, but shall be included in the hearing, discussion and decision making by written report, telephone or videoconference.

  We have assumed that the physician of the same or similar specialty or approved licensed psychologist is not required to be a voting member of the grievance committee and that it is sufficient for him/her to provide a written report of his/her findings and recommendations for the grievance committee to review as a part of its review process. However, we believe this is a matter which merits clarification.

  We also request that the DOH clarify in the regulations its interpretation of the phrase "in the same or similar specialty". For example, if the matter under consideration relates to a disputed abdominal surgery recommended by a general surgeon, may the review be conducted by a gastroenterologist, or must it be conducted by a general surgeon.

- **Section 9.709, Expedited review.**

  Section 9.709 (e) provides, in pertinent part:

  The enrollee has two business days from the receipt of the expedited internal review decision to contact the plan to request an expedited external review.

Additional subsections require a plan to contact DOH within one business day of receipt of the enrollee's request, and to transfer a copy of the case file to the assigned review entity "on the next business day".

The DOH was silent on this issue in its Statement of Policy. We wish to note that our procedures were reviewed and approved by DOI, and we incurred significant costs in distributing the new Act 68 grievance process in the form of policy form changes, member handbook modifications, and notices to members and providers. This change in the handling of expedited grievance appeals will cost us and the rest of the managed care industry significant costs to implement. If changes are necessary, it is reasonable to assume that they not be enacted piecemeal--but coordinated in advance with the DOI with provision for sufficient lead time prior to implementation.

We also are concerned about the practicality of the time frames provided. Given the contracted time frames, it may be physically impossible to gather all necessary case records for transfer to an external review agency within such a short period of time. Confidentiality of medical records could be breached in the rush to forward the complete case file to the review agency.

We recommend DOH consider modifying these sections to reflect the process adopted by most of the managed care industry, i.e., that the next step after the plan's expedited review decision is for the grievance to proceed to the 2nd level grievance committee review, and then, if applicable, to an external grievance review.

We respectfully request that the DOH consider extending the time frames for a plan to forward the member's request to DOH, and for the plan to forward the complete case file to the designated review agency. Two business days for notification to DOH, and five business days for collection and forwarding of the case file to the review agency would be more practical.

Since Act 68 does not include DOH's proposed method of handling expedited grievance appeals, we request clarification of DOH's authority to require its proposed expedited external appeal process.

- **Section 9.710, Approval of plan enrollee complaint and enrollee and provider grievance systems.**

Section 9.710(a) provides, in pertinent part:

The Department will review the plan's enrollee complaint and grievance systems under its authority to review the operations of the plan and its quality assurance systems, and complaint and grievance resolution systems, to ensure that they are satisfactory to the Secretary.

We request clarification if a plan is under any obligation to file its enrollee complaint and grievance systems (which currently have been reviewed and approved by DOI) to DOH for review and approval prior to use.

- **Section 9.722, Plan and health care provider contracts.**

Section 9.722 (e) provides, in pertinent part:

Language requiring the health care provider to adhere to State and Federal laws and regulations, including State reporting requirements concerning communicable and noncommunicable diseases and conditions.

We respectfully suggest that such a provision is not usual and customary for inclusion in managed care plan contracts, and relates to enforcement of State and Federal laws far outside the scope of managed care.

Subsection (2)(ii) which provides, in pertinent part:

Language which states that records are only accessible to Department employes or agents with direct responsibilities under subparagraph (I).

We do not believe that such a provision is necessary or appropriate for addition to existing approved managed care plan contracts. Such language may be appropriate for internal DOH standards, but we see little value in being required to add it to our provider contracts.

In general, we are concerned that DOH is adding required provider contract provisions, which add to its long-standing informal list of such required provisions. We request that DOH consider the costs associated with requiring managed care plans to renegotiate contracts, distribute amendatory riders, inform providers of the reasons for contract changes, and related implementation issues, with the alleged benefits arising from adding additional language.

If DOH adopts any additional contract language requirements beyond those found in currently approved contracts, we request it provides managed care plans with sufficient and significant lead time to come into compliance.

- **Sections 9.723, IDS and 9.75, IDS-provider contracts.**

  We believe that DOH should explicitly recognize the right of all managed care plans, not just HMOs, to enter into IDS contracts. We encourage DOH to amend these sections by replacing the term "HMO" with "plan". The requirements of Sections 9.723 and 9.75 provide adequate oversight and protection to permit both HMOs and managed care plans to subcontract for the delivery of health care services on a risk transfer basis.

We appreciate your consideration of Capital Blue Cross' questions and comments. If you have any questions, would like additional clarification of our comments, or would like to discuss any of these issues further, please feel free to contact me at (717) 541-7412.

Sincerely,

Deb Cohen
Senior Director, POS Programs
Business Development and Planning

cc: Anita M. Smith, Executive Vice-President
Business Development and Planning
Capital Blue Cross

Ref:dohact68regsdec99-5

Children's Hospital of Pittsburgh

3705 Fifth Avenue
Pittsburgh, PA 15213-2583

January 18, 2000

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

Re: Comments on Proposed Regulations for Act 68

Dear Ms. Mitchell:

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

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

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

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

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

Finally, I want to commend the Department for including provisions which should ensure more accountability for managed care such as that all definitions of medical necessity by a health plan be the same. I also want to thank you for your time and consideration in this very important matter.

Very Truly Yours,

Rhonda L. Comer

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

0501124

CHILDREN'S HOSPITAL OF PITTSBURGH
3705 Fifth Avenue
Pittsburgh, PA 15213

LEGAL SERVICES

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Fax: (412) 692-5639
FACSIMILE COVER SHEET

Date: 1/18/2000 To: Stacy Mitchell, Director

Total Pages: 3 Fax: 717-705-0947

From: ✓ Rhonda L. Comer, General Counsel
___ Jodi K. Innocent, Corporate Compliance Officer and Associate Counsel
___ Lorina W. Wise, Associate Counsel
___ Eleanor B. Reigel, Paralegal
___ April P. Kennedy, Administrative Assistant

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MESSAGE: Comments on Proposed Regulations for Act 68

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Very Truly Yours,

Rhonda L. Comer

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

0361124

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LEGAL SERVICES

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MESSAGE: Comments on Proposed Regulations for Act 68

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January 18, 2000

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

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Re: Proposed Managed Care Regulations

Dear Ms. Mitchell:

We appreciate the opportunity to provide comments on the proposed regulations for Managed Care Plans covered by Act 68 of 1998.

We commend the efforts of your department for this in-depth endeavor and the extensiveness of these regulations. We have limited our comments to areas which we have the greatest concerns and to which we would like to offer recommendations.

§ 9.678. Primary care providers.

(b) A primary care provider shall meet the following minimum standards, unless a specialty health care provider is approved by the plan to serve as a designated primary care provider as provided for in § 9.683 (relating to standing referrals or specialists as primary care providers):
(1) *Provide office hours of a minimum of 20 hours-per-week.*

Comments:

First Priority Health requires clarification of this regulation. Currently, if a group of providers practice in a singular location they can combine their office hours to reach the required 20 hours. For example, Dr. X has 15 and Dr. Y has 18 in the same location, and the Member could make an appointment with either Dr. X or Dr. Y as they are in a coverage group. Would this meet the intent of the proposed regulation?

Recommendation:

Each Primary Care Physician or group of Primary Care Physicians in a medical office must have a Provider Network physician available for scheduled visits a minimum of twenty (20) hours a week, either individually or in the aggregate.

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

(b) The plan's procedures shall:
(2) Provide for evaluation by appropriately trained and qualified personnel.

(3) *Be under a treatment plan approved by the plan and provided in writing to the specialist who will be serving as the primary care provider or receiving the standing referral.*

Comments:

First Priority Health feels that clarification is needed regarding who will develop the treatment plan and what it includes. If it is a clinical plan of care, the member's physician (PCP and/or specialist) should be developing this treatment plan.

Recommendation:

The specialist physician will develop a treatment plan in coordination with the member's Primary Care Physician as applicable. This treatment plan will be presented to the managed care plan for approval.

§ 9.706. Enrollee and provider grievance system.

(2) Second level review.
(A) The plan shall provide reasonable flexibility in terms of time and travel distance when scheduling a second level review to facilitate the enrollee's attendance.

Comments:

Does this require the site for the second level grievance to change depending on the member's county of residence? This would place an unreasonable hardship on the plans who currently allow members to attend the hearing via phone if necessary.

Recommendations:

The plan should provide flexibility in terms of time when scheduling a second level review to facilitate the enrollee's attendance.

§ 9.708. Grievance reviews by CRE.

(b) The assigned CRE shall review the second level grievance review decision based on whether the health care service denied by the internal grievance process is medically necessary and appropriate under the terms of the plan.

Comments:

First Priority Health believes it is necessary to define "appropriate". Does appropriate mean "appropriateness of site" or "appropriateness of service"? If "appropriateness of service", who does the "appropriateness of site" reviews? We believe that the "appropriateness of service" review is a part of the "Medical Necessity" review and should be clarified.

Recommendation:

We recommend that the term "appropriate" mean "appropriateness of site" and not "appropriateness of service". We would consider an "appropriateness of service" review to be included as a part of the Medical Necessity review.

§ 9.709. Expedited review.

(b) The plan's internal expedited review process shall be bound by the same rules and procedures as the second level grievance review process with the exception of time frames. It is the responsibility of the enrollee or the health care provider to provide information to the plan in an expedited manner to allow the plan to conform to this section.

Comments:

Does this mean that if a Plan receives a member expedited grievance request, we must meet the requirements of 9.706., Enrollee and provider grievance system (c) (2), Second level review? If yes, does this mean that the member would bypass the first level requirements as indicated in 9.706., Enrollee and provider grievance system, (c) (1)? We believe that it would be more efficient and effective if we met the requirements of the first level instead of the second level.

Recommendation:

We recommend that the internal expedited review process be bound by the same rules and procedures as the first level grievance review process, with the exception of time frames.

(e) The enrollee has 2 business days from the receipt of the expedited internal review decision to contact the plan to request an expedited external review.

Comments:

Does this mean that the Plan only has one level of internal review in an expedited grievance? Does that one level of internal review have to meet the requirements of the standard first level or standard second level?

Recommendation:

First Priority Health recommends that the member only go through the first internal level in the expedited review process and that we bypass the second level review and go directly to the external review entity.

(j) External expedited review decisions may be appealed to a court of competent jurisdiction.

Comments:

For expedited reviews at the third level, there is an appeal right; but in 9.707 there is no appeal right listed. Is the appeal right only applicable to members or providers or does the Plan have the right of an appeal?

Recommendation:

This process needs a detailed explanation of its procedure. If an appeal right is being granted, it should be more specific as to the process and procedure; otherwise we recommend that it be deleted.

§ 9.711. Alternative provider dispute resolution systems.

(b) Procedural errors and administrative denials in which the enrollee is held harmless by virtue of the provider contract or when the enrollee has never been advised by the plan in writing that continued health care services would not be covered benefits, will not be automatically viewed as grievances for the purposes of this subchapter and may be addressed by alternate dispute systems.

Comment:

Does this mean that we do not have to accept member grievances where there is no member liability? Will these complaints be handled through an alternative provider dispute resolution system because the issue is with the provider and not the member?

Recommendation:

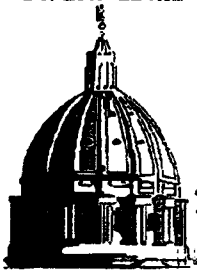
We recommend that we should not have to accept a member complaint and/or grievance where the member has no financial liability. If the provider is not satisfied with payment, the Plan should have an alternative provider dispute resolution system in place to allow the provider to file a complaint/grievance.

Once again, we appreciate the opportunity afforded us to bring our concerns/comments to your attention in order to continue to improve managed care for all parties. Please feel free to contact me at 570 829-6069 should you have any questions or concerns.

Sincerely,

Frank G. Rollman
Senior Director, Research & Development
Legal Department

cc: Denise S. Cesare, President & CEO
Michael P. Gallagher, Senior Vice-President & CFO
William Reed, Senior Vice-President, Operations
Robert R. Brittain, Jr., Esq., Vice-President, Legal/General Counsel
Eric L. Dove, Vice-President, Sales
John E. Gardner, Vice-President, Administrative Services
Linda Kanyuck, Acting Vice-President, Customer Service Division
William J. Phelps, Vice-President, Sales & Marketing
Brian J. Rinker, Vice-President, Provider Services
Edward J. Rolde, Vice-President, Medical Affairs &CMO



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[redacted]

to: Stacy Mitchell

fax #: 717 705 0947

re: DOH proposed reg response

date: 1/18/00

pages: 6, including this cover sheet

COMMENTS:

Making Better Health Easier

From the desk of...

Gloria Blandina
Government Affairs Representative
Blue Cross of Northeastern Pennsylvania
70 North Main Street
Wilkes-Barre, PA 18711

717-819-8611
Fax: 717-819-8606

Avalon Health[SM*], Ltd.

January 18, 2000

2300 Herrington Ave
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Stacy Mitchell
Director, Bureau of Managed Care
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REVIEW COMMISSION

Re: Comments on Proposed Regulations

Dear Ms. Mitchell:

On behalf of Avalon Health, Ltd., a Pennsylvania health maintenance organization (HMO), and a subsidiary of Capital Blue Cross, we appreciate the opportunity to provide comments on the Department of Health's comprehensive proposed revisions to its HMO and managed care regulations, as published in the December 18, 1999, issue of the Pennsylvania Bulletin.

Our comments follow below.

- **Section 9.601, Applicability**

  We support the applicability of these regulations for any IDS that subcontracts with an HMO or other managed care plan.

- **Section 9.604, Plan reporting requirements**

  We note that Section 9.604(a)(2) of the proposed regulations does not specify the exact utilization data to be submitted. As a result, we assume this section is only intended to apply to such utilization data as is currently required to be reported by the Department of Health (DOH). We believe that the specific utilization data requirements should be defined, and we would urge the DOH to retain its current utilization reporting requirements (which we believe are adequate).

*Avalon Health is a service mark of Capital Blue Cross.

Section 9.604(a)(8) requires not only copies of the currently utilized standard form health care provider contracts but also copies of any deviations from the standard contracts and reimbursement methodologies. This requirement raises a number of practical and other concerns. There may be a number of minor variations to standard form contracts, particularly as more providers retain counsel and other advisers to assist with the negotiation of contracts. It would not be practical or informative to file these changes with the DOH. In addition, requiring the filing of deviations from reimbursement methodologies raises serious concerns as to confidentiality. We believe that so long as the provider contracts contain the consumer protection and other provisions required by DOH regulations, there is no need for the DOH to seek this additional information. We think it is in the interests of all concerned if managed care plans are given the freedom to negotiate appropriate contractual modifications with particular providers.

- **Section 9.633, HMO board requirements**

  Section 9.633(a) provides, in pertinent part:

  A corporation that has received a certificate of authority, shall within 1 year of its receipt of the certificate, establish and maintain a board of directors at least one-third of whom are enrollees of the HMO.

  As a practical matter, in order to assure that there are a sufficient number of qualified individuals to serve as members of the board of directors, we suggest that this requirement for board representation by enrollees be applicable one year after enrollment of the first HMO subscriber.

- **Section 9.652, HMO provision of other than basic health services to enrollees**

  Section 9.652 provides, in pertinent part:

  An HMO may provide coverage for other than basic health services including dental services, vision care services, prescription drugs services, durable medical equipment or other health care services, provided...

  We request that DOH clarify this section regarding the extent to which an HMO may offer such other product lines independently of provision of basic health services. May an HMO, for example, offer its dental program/product to members of an enrolled group who do not select enrollment in the basic HMO benefits package? May an HMO offer its dental plan to a group which does not offer its HMO benefits package as an option to its employees? May an HMO offer a PPO product?

- **Section 9.653, Use of co-payments and co-insurances in HMOs**

  Section 9.653 provides, in pertinent part:

  Upon request of the Insurance Department, the Department will review requests by an HMO to incorporate co-payments and co-insurance in the HMO benefit structure...

  The Insurance Department separately reviews rates, and we feel that this section may unnecessary impose two levels of review as part of the regulatory approval process, with resultant delays and extra costs. In addition, we feel that an HMO should have the freedom to meet the expectations of the marketplace in terms of the levels of co-payment and co-insurance available as part of a benefit package.

- **Section 9.655, HMO external quality assurance assessment**

  Subsection 9.655(a) provides, in pertinent part:

  Within 18 months of receipt of a certificate of authority...an HMO shall have an external quality assessment...

  There must be sufficient data compiled to ensure that the review by the external quality review organization is meaningful and cost-effective. Accordingly, we suggest that this requirement be made applicable 18 months after enrollment of the first subscriber.

- **Section 9.673, Plan provision of prescription drug benefits to enrollees**

  Section 9.673(e) provides, in pertinent part:

  If the plan does not approve a health care provider's request for an exception, the enrollee or the health care provider with the written consent of the enrollee may file a grievance under Subchapter I...

  We assume that Section 9.673 of the proposed regulations is not intended to prohibit any contractual exclusion of specified drugs or equipment from coverage or any limitation of usage under a prescription drug program offered by a managed care plan.

  We also note that if a member is unsatisfied because a drug is not available due to an exclusion, the member should be directed to file a complaint -- and *not* a grievance. In such a case, the question is one of coverage, and not medical necessity.

- **Section 9.678, Primary care providers**

  Section 9.678(a)(2) provides, in pertinent part:

  Be available directly or through on-call arrangements with other plan participating health care providers...

  We are concerned that the standard set forth in subsection (a)(2) might be too restrictive if on-call arrangements can be made only with plan participating providers. We believe that plans should have the flexibility to review and approve alternative coverage arrangements, as long as consumers are properly protected.

- **Section 9.683, Standing referrals or specialists as primary care providers**

  A plan shall adopt and maintain procedures whereby...if the plan's established standards are met, the procedures shall allow for the enrollee to receive either a standing referral to a specialist...or the designation of a specialist to assume responsibility to provide and coordinate the enrollee's primary and specialty care.

  We recommend that the DOH clarify that a plan is not obligated to offer eligible members a choice between a specialist as a PCP or a standing referral to a specialist. The HMO, depending upon its administrative systems and other factors, should determine the approach that is most consistent with its program to administer. Either option achieves the same goal of providing members who have complex conditions with appropriate access to specialty care.

- **Section 9.684, Continuity of care**.

  Section 9.684(f) provides, in pertinent part:

  A plan may require nonparticipating health care providers to meet the same terms and conditions as participating health care providers with the exception that a plan may not require nonparticipating health care providers to under go full credentialing.

  We recommend subsection (f) be clarified through insertion of a the underlined phrase, "A plan may require nonparticipating health care providers to meet the same terms and conditions, <u>including fee schedules</u>, as participating providers..."

  We interpret Section 9.684 to mean that the plan is not responsible for paying a non-participating provider charges, but only the fee on its fee schedule that

would have been paid to a participating provider for the same service. If our understanding is incorrect, we would appreciate being so notified.

- **Section 9.706, Enrollee and provider grievance system**

  Section 9.706(c)(3)(ii) provides, in pertinent part:

  The physician or approved licensed psychologist, in the same or similar specialty, need not personally attend at the review, but shall be included in the hearing, discussion and decision making by written report or videoconference.

  We have assumed that the physician of the same or similar specialty or approved licensed psychologist is not required to be a voting member of the grievance committee and that it is sufficient for him/her to provide a written report of his/her findings and recommendations for the grievance committee to review as part of its review process. However, we believe this is a matter which merits clarification.

- **Section 9.761, Provider credentialing**

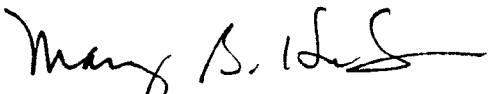
  Section 9.761(a)(2) provides, in pertinent part:

  The credentialing system shall include policies and procedures for the following...(2) recredentialing at least every 2 years.

  Subsection 9.761(a)(2) establishes a standard of recredentialing at least every 2 years. We request that DOH clarify whether this requirement applies only to professional providers, or also to facility providers. We believe that facility providers need not be re-credentialed every two years because they are subject to their own independent credentialing programs (such as JACHO) which help assure the quality of care being provided to members.

We appreciate your consideration of our comments. If you have any questions, or if you would like to discuss any of these issues in more detail, please do not hesitate to contact me at (717) 541-6438.

Sincerely,



Mary B. Henderson
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c: Anita Smith, Chief Operating Officer, Avalon Health, Ltd.