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INDEPENDENT REGULATORY REVIEW COMMISSION

January 7, 2000

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

Dear Ms. Mitchell:

After reading the proposed regulations and attending the Joint House Insurance and Health and Human Services hearing on the regulations, the Pennsylvania Pharmacists Association make the following recommendations:

SECTION 9.604. PLAN REPORTING REQUIREMENTS

9.604(a)(6) Annual reports. The proposed regulations require the plan to report the number of physicians joining and leaving the plan.

This would be improved by requiring the plan to report the number of primary care providers, pharmacies, and specialty physicians joining and leaving the plan. [The loss of half the number of pharmacies originally serving Health Choices Southeast went unreported until a Philadelphia Inquirer reporter specifically asked the CEO of Eagle Managed Care for the numbers.]

SECTION 9.673. PRESCRIPTION DRUG BENEFITS

9.673.(b) Response time. The 30-day time frame for a plan to respond in writing to an enrollee's or prospective enrollee's inquiry whether a specific drug is on the plan's formulary is an unduly long time frame. Presumably that information is immediately available on a computer.

9673.(c) Formulary exception. The formulary exception process if a formulary drug has proved ineffective or if it can be expected to cause adverse reactions is commendable. However an exception should also be made where an enrollee has a chronic condition that has been difficult to manage and has finally been stabilized on another medication.

SECTION 9.679. ACCESS REQUIREMENTS IN SERVICE AREAS

9.679.(e) Frequently utilized service standards. This section provides that a plan shall ensure frequently utilized health care services are available to enrollees within 20 minutes/20 miles in urban areas; and 30 minutes/30 miles within rural areas. The minutes standard is reasonable in an urban area, but the miles standard is too loose for frequently utilized services like a primary care provider or pharmacy.

SECTION 9.712 AND 9.723. PLAN AND HEALTH CARE PROVIDER CONTRACTS

As Act 68 did not identify pharmacy benefit management companies as health care providers, and as the regulations make clear that the plan is responsible for its subcontracts, the section's title should be expanded to "Plan and health care provider and PBM contracts.

9.712(e)(2). Confidentiality. The Pennsylvania Pharmacists Association has previously pointed out to the Department the not uncommon practice of PBMs sending or selling enrollees names and prescription identifications to drug manufacturers and preferred chain pharmacies. This is a clear violation of patient confidentiality.

In as much as Act 68 does not identify a pharmacy benefit management company as a health care provider, as the regulations state that the plan is responsible for its subcontractors, and this section only states that "the plan and the health care provider" shall keep enrollee records confidential, the regulations should state that plan contracts with pharmacy benefit management companies or other subcontractors should specifically prohibit release of identifiable patient information.

9.712(f)(1). Plan Provider Reimbursements. Again, in as much as the plan is responsible for its contracts and subcontracts, and Act 68 does not identify a pharmacy benefit management company as a provider, it is necessary for the regulations to require plans to provide the Department with its pharmacy benefit management contract, its financial arrangement with the PBM, and the PBMs reimbursement to its pharmacy providers.

SECTION 9.725. IDS- PROVIDER CONTRACTS

As pharmacy benefit management are not specifically identified as health care providers in Act 68, this section should be retitled IDS-Provider and PBM contracts and should require the IDS to submit its PBM contract to the Department for review, and hold the PBM to the same standards as it holds IDS provider contractors.

The Pennsylvania Pharmacists Association appreciates the opportunity to comment on these proposed regulations and sincerely appreciates the great effort the Department has made in developing them. Please feel free to contact me if you have any further questions.

Sincerely,

Carmen A. DiCello, R.Ph.
Executive Director

CAD/TKL
cc: Members, House Insurance Committee
Members, House Health and Human Services Committee
Members, Senate Banking and Insurance Committee
Members, Senate Public Health and Human Services Committee
Members, PPA Executive Council
Members, PPA Legislative Liaison Committee
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January 10, 2000

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

Dear Ms. Mitchell,

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

Having recently read through the Department of Health proposed Act 68 regulations, I commend them for including several requirements. Establishing plan reporting requirements that will help ensure effective oversight as well as provide the public with data on plan practices; requiring that all definitions of medical necessity by a health plan be uniform in all documents to ensure consistency in medical decision making; and enabling managed care plans to create mechanisms for procedural errors and denials to be addressed between the plan and the providers without obtaining the consent of the enrollee will be beneficial to the patient and the care they receive.

However, while we appreciate the language in many of the Department of Health proposed regulations, there is also the need for some changes. There must be clarification in the standards that ensure enrollees receive the same benefit level for either emergency services provided by non-participating providers or services for which there are no participating health care providers capable of performing the needed service. These standards should not dictate provider payments in these situations. The way these provisions are described in the preamble goes beyond the scope of both the HMO Act and Act 68. This would remove any incentive to negotiate fair payment rates by, in effect, establishing default payment rates.

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

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

Thank you for your ongoing support of the Department of Health in the effort to require health insurers and managed care plans to demonstrate effective compliance with Act 68. We appreciate the continued work on behalf of hospitals and the patients we provide care to.

Sincerely,

John P. Wiercinski,
President and Chief Executive Officer

Story
60-0-193

Pennsylvania

Pennsylvania Chapter of the American College of Cardiology

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January 18, 2000

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

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

Dear Ms. Mitchell:

The Pennsylvania Chapter of the American College of Cardiology was pleased to have the opportunity to offer comments on the first round of draft regulations of HMO's and managed care plans covered by Act 68. We fully support the Commonwealth's commitment to "assure availability and accessibility of adequate health care providers in a timely manner..." [Section 2111] for patients enrolled in managed care plans. As health care providers who interact daily with managed care organizations, we fully understand the widespread public indignation, which preceded the passage of the Act. And because of this, we were disappointed to find, in the December 18, 1999 draft, that our comments were not addressed.

The Department of Health plays a central role in the implementation of Act 68. Effective, enforceable regulations are its backbone. With this in mind, we are respectfully submitting the following comments again with hope that our concerns will be addressed. Specific proposed changes are underlined:

Use of Pre-existing Condition Waiting Periods in HMO's.

We are concerned with this provision. This provision allows plans to institute a pre-existing condition waiting period and does not outline exceptions. Many cardiology patients require continuous, on-going treatment. Interruption in care may well occur during these waiting periods. Permitting this possibility would directly contradict the statute which states that one of its purposes is to: "Assure availability and accessibility of adequate health care...which enables enrollees to have access to quality care and continuity of health care services." [Section 2111(1)] We urge the Department to re-examine this provision carefully and institute exceptions including "life threatening, degenerative or disabling diseases."

9.676 Standards for enrollee Rights and responsibilities.
(section lettering is reflected from stakeholder draft copy, April 30, 1999, 9.26, section b,j,k)

Section (b) The right to obtain from the health care provider, unless it is not medically advisable as determined by the health care provider, complete, current information concerning the enrollee's diagnosis and treatment options without regard to cost or health plan coverage.

Who is to determine what is medically advisable and what is not? Certainly this function cannot be vested in the managed care plan whose regulation is the purpose of Act 68. In order to prevent abuse, this determination should be made by the enrollee's physician(s).

Section (j) In addition to the disclosures required above, the enrollee has right [sic] to receive the following information on an annual basis, or upon request within five (5) working days.

A once-a-year mailing will frequently be lost or misplaced by enrollees. Critical information should be rapidly available at the time it is needed.

Section (k) Enrollees must be provided with the following information should they request such information in writing within five (5) working days.

A duty, which is not time-limited, is unenforceable and therefore meaningless.

9.674 Quality Assurance Standards

Section (b)(3) The activities of the plan's quality assurance program shall be overseen by a quality assurance committee that is composed of at least 50% participating physicians in active clinical practice.

To merely state that the committee include physicians does not ensure a reasonable quality assurance process. The managed care plan could easily choose to give majority control to plan employees.

9.683 Standing referrals or specialists as primary care providers.

Section (a) Plans shall adopt and maintain procedures whereby an enrollee with a life-threatening, degenerative or disabling disease or condition shall, upon request, receive an evaluation, and, if the plan's established standards are met, permit the enrollee to receive either a standing referral to a specialist with clinical expertise in treating the disease or condition, or designation of a specialist to assume responsibility to provide and coordinate the enrollee's primary and specialty care.

(b) the plan's procedures shall:

Section(b)(3) Be under a treatment plan approved by the plan in consultation with the primary care provider, the enrollee, and as appropriate, the specialist.

The suggested verbiage is taken directly from Act 68 [Section 2111(6)(ii)]. By giving all power to the plan, the draft regulation contradicts the explicitly stated intent of the Legislature to require managed care plans to take the opinions of the patient and his/her physicians into account.

Section (b)(4) Be subject to the plan's utilization management requirements and other established utilization management and quality assurance criteria. This is in no way to be construed to restrict the right of the enrollee to receive an initial evaluation upon request as stated in (a).

Section (b)(4) as written introduces ambiguity into the patient's right to an initial evaluation "upon request," [as stated in Act 68] and not subject to the plans utilization management requirements and plan criteria.

Section (b)(6) Ensure the plan issues a written decision regarding the request for a standing referral or designation of a specialist as a primary care provider within a reasonable period of time taking into account the nature of the enrollee's condition, providing for an expedited review, with a decision and appropriate notification to enrollee and healthcare provider within 48 hours, should an enrollee's life, health or ability to regain maximum function be in jeopardy, but within 45 days after the plan's receipt of the request.

In enrollees with heart disease, a 30-day delay may be fatal. Provision for expedited review is essential.

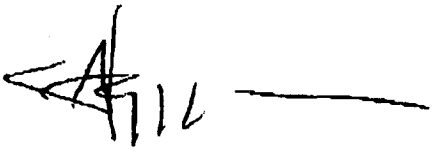
9.677 Requirements of Definitions of "Medical Necessity."

The concept of medical necessity is central to the oversight of managed care plans. In the proposed regulations you have addressed the medical necessity issue regarding health plans with multiple products and multiple operating procedures however, the vague wording of the proposed rulemaking for "medical necessity" still leaves the standard open to a variety of disparate interpretations. We propose that medical necessity be determined by professional organizations such as the American Medical Association which labor continuously to define standards of care and develop treatment guidelines which serve the interests of patients. That definition is offered as follows:

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

Thank you again for allowing the Pennsylvania Chapter to offer comments to the proposed regulations. I believe careful consideration of our comments will benefit the citizens of the Commonwealth. If you should have any questions, please feel free to contact me at (412) 578-4278 or Dani Stillo, our Chapter Administrator, at (717) 558-7750, extension 1475.

Very Truly Yours,



Alan H. Gradman, MD, FACC
Vice-President, Pennsylvania Chapter
American College of Cardiology

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NAMI Southwestern Pennsylvania

formerly the Alliance for the Mentally Ill of Southwestern Pennsylvania

January 14, 2000

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Stacy Mitchell, Director
Bureau of Managed Care
PA Dept. of Health
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Reference: Proposed Regulations to Implement Act 68

Dear Ms. Mitchell,

In response to the call for public comments on the referenced regulations, our first reaction is one of extreme disappointment in that the proposed regulations appear to be a step backwards from the present safeguards and protections. Further, from discussions we have had with Senator Murphy and his staff, they do not embody the spirit or intent of the legislation which we have heard from them. There appear to be many issues needing strengthening and reconsideration and we will address some of the more significant ones.

A. CRITERIA FOR GRANTING A NEW HMO CERITFICATE OF AUTHORITY
   1. No requirement to use generally accepted medical standards for utilization review.
   2. No standards for quality assurance.

B. INADEQUATE NETWORK DEFINITION
   1. No access standards such as distance, travel time, specialties, etc.

C. NO REQUIREMENT FOR DOH OVERSIGHT
   1. Permits external review by entities hired and paid by HMO.

D. LACK OF CLARITY ABOUT PCP TRAINING AND NETWORK AND SPECIALISTS ACTING AS PCP.

E. DRUG FORMULARY DISCLOSURE
   1. While the regulations require a plan to disclose existence of a restrictive formulary to members, it is not required to make the disclosure to prospective members. This enables the HMO to withhold vital decision making information from prospects and should be an unacceptable practice.

F. DISCLOSURE OF MEMBER RIGHTS AND RESPONSIBILITIES
   1. Does not require plans to inform members of their rights to get current and complete information from their physician about their diagnosis, treatment and prognosis.
   2. Does not require the plans to regularly tell members about rights under the complaint/grievance system and/or how to file a complaint/grievance.

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G. HEALTH CARE PROVIDER CONTRACTS

1. Does not place any limits on conflict of interest between the provider and the patient/member.
2. Permits sizable financial incentives to providers to limit care.
3. No objective standard to determine if the financial incentive compensates the provider for providing less than medically necessary and appropriate care.
4. No requirement that the HMO provide a reason for non-renewal or sanction of a provider.

H. THERE IS NO REQUIREMENT FOR AN EXPEDITED COMPLAINT REVIEW

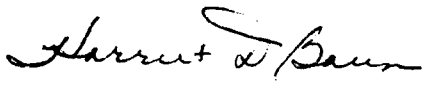
1. Does not spell out specifics of procedures to assure independent input to complaint resolution.
2. Allows plans to send notifications of complaint decisions to either the member or the provider which is contrary to language in Act 68 which requires both.

I. RELATIONSHIP TO INSURANCE DEPARTMENT

1. We understand that the Insurance Department prepared regulations which have been withdrawn. We further understand that there are conflicts between these Health Dept. proposed regulations and the Insurance Dept. withdrawn regulations. How are these differences being resolved? The Legislative Budget and Finance Committee Report "Commonwealth Efforts to Assure Quality of Care in the Changing Health Care Environment" dated June 1999 identified this type of ambiguity and conflict as a problem which needs to be addressed. We are disappointed that the writers of these proposed regulations apparently have not dealt with the departmental differences.

In summary, we do not support the regulations as written and, in view of the number and seriousness of objections, we recommend an extensive rewrite and second submission for public comment. Thank you for the opportunity to comment.

Yours truly,



Harriet Baum, Executive Director

cc: Senator Tim Murphy

IRRC

From: David Gates [gates.david@verizon.net]
Sent: Thursday, December 28, 2000 1:40 PM
To: IRRC
Subject: Reg 10-160

HLP comments.doc

ORIGINAL: 2079

Re: Regulation 10-160, Dept. of Health managed care (Act 68) final regulations

Attached please find our analysis of the Dept. of Health's final regulations
which are currently before the IRRC.

David Gates
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Pros (+) and Cons (-) of the newest version of DOH Act 68 Proposed Regulations Analysis by Pennsylvania Health Law Project -December 21, 2000

On January 3, 2001, the Department of Health (DOH) has reserved the Rachael Carson Building auditorium (4th Street and Market in Harrisburg) from 1-3 PM to hear from stakeholders on DOH's proposed final Act 68 regulations. This is an unusual step because the public comment period for these regulations has closed. Rumor has it that this unusual step is occurring because the HMOs were upset with the draft final regulations and were requesting meetings with DOH. DOH has elected to do this via a public process, giving others an opportunity to hear the comments and make their own comments on January 3rd. The meeting is open to the public. Comments are limited to 10 minutes per group. DOH will decide thereafter whether to proceed with these final draft regulations or continue to revise and delay their implementation.

Generally, these proposed final regulations represent a significant improvement from the first draft, particularly in the Complaint and Grievance and Utilization Review sections. DOH has added important consumer protections and has strengthened the utilization review requirements. Although there are several areas that could still be improved, it is important not to lose the improvements contained in the draft final regulations.

Act 68 was passed in 1998 and became effective January 1, 1999. It will soon be over a year without the benefit of regulations. PHLP staff has seen great variation in how the plans interpret their obligations under Act 68 and significant erosions of consumer protections in grievance and appeal proceedings conducted by the HMOs. Our clients believe that they stand to benefit by the immediate approval of regulations.

Groups that commented on the draft regulations can call Terry Oren of DOH at 717-787-5193 to reserve time to speak on January 3rd. Other people will be able to address DOH thereafter, as time permits.

The Act 68 regulations will govern consumer rights and HMO obligations for many years. The following represents our analysis of the draft final regulations. Those items with a (+) represent positive provisions for consumers. Those items with a (–) could still use improvement. Please call PHLP at 1-800-674-3258 if you need any further information.

Subchapter F. General 9.601-9.606

General Comment: Little change since the December '99 version. There are additional reporting requirements, including the reporting of the number, type and disposition of all complaints and grievances, and a requirement that plans of correction for violations of Act 68 be available to members on request. It removes disenrollment data from the plan reporting requirements.

- The regulations are not made applicable to ancillary service plans, such as dental, vision and Medicare Supplement at risk plans. Section 9.601(d)
- Removes disenrollment data from the plan reporting requirements. 9.604(a)(1)

+ Adds number, type and disposition of all complaints and grievances filed with the plan or subcontractors to the plan reporting requirements. 9.604(a)(3)
- Standardized provider contracts are not available to the public. 9.604(a)(8)
+ If the department changes the annual reporting requirements, it must publish the change in the Pennsylvania Bulletin. 9.604(c)
- Apart from inadequate or poor quality care, false advertising and inability to fulfill contractual obligations, plans are fined or lose their license only for substantial violations of the HMO Act. 9.606(b)(4)
+ Plans of correction for violations of the governing Acts are available to enrollees upon written request. 9.606(d)

Subchapter G. HMOs 9.621-9.656

General Comment: This section generally takes a hands off approach with respect to coverage limitations and the imposition of costs on consumers. It does preclude plans from limiting their networks without disclosure.

+ The department must be given a detailed description of plan reimbursement methodologies as part of the application for a certificate of authority. 9.631(4)
- Plan reimbursement methodologies are a secret, which cannot be disclosed without plan consent. 9.631(4)
- Eliminates the previously proposed requirement that an applicant for a certificate of authority submit a detailed description of the applicant's incentives and mechanisms for cost control. 9.631(16)
+ Requires the submission by an applicant for a certificate of authority of a procedure for referral of enrollees to nonparticipating providers, a copy of general subscriber literature, and a copy of the HMO's most recent financial statement.
- A plan has a year from the receipt of a certificate of authority to appoint its board of directors, of which one third must be enrollees. 9.633(a)
+ Enrollee members of the HMO board of directors may not be employees or have a direct family relationship with a member of the board or an employee of the HMO. 9.633(a)(2)
- The state can waive regulatory requirements for foreign HMOs seeking to do business in Pennsylvania. 9.636(e)
- HMOs may make reasonable exclusions from coverage, such as durable medical equipment for home use. 9.651(b)
-HMOs may limit inpatient coverage to 90 days per year. 9.651(c)(3)
- Permits copayments that are not nominal and can cost up to 50% of the cost of a service. 9.653
- Permits HMOs to limit members to subnetworks of its provider network. 9.654
+ Requires disclosure to potential and current enrollees if they will be limited to a subnetwork. 9.654(1)
+ Adds a requirement that the department perform a site visit to the HMO within 12 months of the issuance of a certificate of authority. 9.655(a)(1)

+/- Provides for an assessment of plan compliance with Act 68, the HMO Act and these regulations, but permits an External Quality Review Organization (EQRO), possibly from out of state, to handle this department function. 9.655(c) and (d)
+/- EQRO reports are to be available to the public upon request, however, proprietary information, which is not defined, is not available. 9.655(f)
+ Requires HMOs with a point of service option to have a system for tracking to see if high out of network usage is a result of an access or other problem. 9.656(b)(1)

Subchapter H. Availability and Access 9.671–9.684

General Comment: Includes a number of changes from the December '99 version, some of which increase consumer rights to information and service, especially as regards restrictive drug formularies, and some of which reduce proposed rights to access.

+ Now specifies that the evaluation, testing, and if necessary, stabilization of the patient are covered as emergency services. 9.672(d)
- Deletes the provision, in the previous draft, that emergency services must be covered at the same rate as if the provider were participating in the health plan. There is now no provision about payment, which may leave the consumer with an unexpected bill.
+ Reduces the time for a plan to respond to a request for information about a plan's restrictive drug formulary from 30 to 5 days, permits the request to be oral, and requires the plan to tell the enrollee or prospective enrollee what drugs in the same class are on the formulary. 9.673(c)
+ Requires the plan to have an exception process and respond within two business days if the formulary drug has been ineffective or is expected to cause adverse or harmful reactions to the enrollee. 9.673(c)
+/- Requires 30 days notice to health care providers of formulary changes, but does not provide for notice to the enrollee. 9.673(e)
+ Requires that the health plan's quality assurance plan have regularly updated standards for health promotion, early detection and prevention of disease, injury prevention for all ages, systems to identify chronic and acute care needs at the earliest possible time, access to routine, urgent and emergent appointments, and conduct annual studies of access and availability. 9.674(c)
- The plan can delegate medical management to another entity, with reimbursement information to remain secret. 9.675(a)
+ If the plan uses a medical management contractor, the contractor must cooperate and participate in quality assurance activities of the plan. 9.675(d)(5)
+ Enrollee rights are expanded, and the enrollee must be notified of a number of rights, including the right to truthful and accurate literature and materials that can be easily understood, the right to emergency services without unnecessary delay, and the right not to be refused membership due to the individual's health care needs. 9.676
+ Keeps the requirement that the definition of medical necessity be the same in the provider and member contracts and other materials. 9.677
+ Requires that a participating provider may arrange for on-call coverage by a nonparticipating provider only if the plan approves the arrangement, agrees to cover the

cost of services covered by the nonparticipating provider, and agrees to hold the enrollee harmless for any errors committed by the nonparticipating provider that would result in noncoverage of covered benefits or would mislead the enrollee into believing that a noncovered service would be covered. 9.678(b)(2)
+ Requires the plan to meet the requirements of Act 68 regarding standing referrals or the designation of specialists as PCPs. 9.678(c)
- Keeps the provision that leaves it up to the plan to establish the circumstances under which, and the amount of advance notice required before which a member can change PCPs. 9.678(f)
- Eliminates the requirement that plans have an adequate number and range of health care providers by specialty to ensure adequate access.
+/- No longer requires the immediate reporting to the department of the potential loss from a plan's network of any provider that affects 10% of a plan's network, but instead requires notification, without time limits, of the loss of general acute care hospitals or PCPs, including group practices with 2000 or more enrollees. 9.679(d)
- Eliminates the requirement that primary care and frequently utilized services must be available within 20 minutes or 20 miles in urban areas, and 30 minutes or 30 miles in rural areas. Instead requires that at least 90% of enrollees in each county designated as a metropolitan statistical area be within 20 miles or 30 minutes, and 45 miles or 60 minutes in other counties. Requires the plan to describe to the department how it will meet the health care needs of enrollees if it cannot meet these standards. 9.679(d) and (f)
+ Specifies that the following services must be available in accordance with the access standards: acute hospital, common lab and Rx services, primary care, general surgery, orthopedic surgery, ob/gyn, ophthalmology, allergy and immunology, anesthesiology, otolaryngology, physical medicine and rehab, psychiatry and neurology, neurological surgery, urology. 9.679(e)
+/- Provides that payment of out of plan services must be reimbursed at no less than the plan rate when the plan has no available network provider, but fails to protect the enrollee against excess charges. 9.679(g)
- An enrollee is entitled to only one full provider directory plus annual updates, no matter how many changes occur within the network. 9.681(a)
+/- Removes the previous provision allowing plans to prior authorize non-routine services ordered by an ob/gyn, but substitutes language permitting prior authorization for selected services such as diagnostic testing for subspecialty care such as reproductive endocrinology, oncologic gynecology, and maternal and fetal medicine. 9.682(b)
+ Requires in situations where a standing referral to a specialist, or specialist as PCP is approved, that a treatment plan be developed in consultation with the PCP, enrollee, and as appropriate, the specialist. 9.683(b)(3)
- Permits a plan to escape payment to a nonparticipating provider and shift payment responsibility to the enrollee during the transition period by notifying the enrollee that no agreement could be reached as to the terms and conditions under which the care would be offered. 9.684(i)

Subchapter I. Complaints and Grievances 9.701-9.711

General Comment: Substantial change since the December '99 version. Many consumer protections formerly found in the department's fundamental fairness bulletin have been added back. Some protections are still missing.

+ Gives an enrollee the right to contact the department to complain of the plan's administration of the complaint/grievance process, and the department will investigate and take appropriate action. 9.702(a)(2)(I)
- Articulates the enrollee's right to designate a representative to participate in the complaint or grievance process on the enrollees behalf, but requires the representative to provide unspecified "evidence" of the designation. If more than an enrollee's oral acknowledgment during a phone call is required, this could serve to delay the process inappropriately. 9.702(a)(3)
+ Reestablishes the obligation of the plan to have a staff member assist with the presentation of the complaint or grievance. 9.702(a)(4)
+ Requires the plan to establish a toll-free telephone number to obtain information regarding the filing and status of a complaint or grievance, and requires reasonable accommodation of persons with disabilities and non-English speaking enrollees. 9.702(a)(5)
+ Makes the department the final arbiter on the issue of whether a request for an internal review is a complaint or grievance. Both requires the plan to consult the Insurance or Health Department in close cases, and permits the member to contact the departments if he or she disagrees with the plan's classification. 9.702(c)
+ Gives the member at least 45 days to file a complaint or grievance. 9.702(d)(2)
+ Provides that the plan must acknowledge receipt of the complaint, note its characterization as a complaint, and inform the enrollee of several rights, including the right to representation and to review information related to the complaint. 9.703(c)(1)
- Does not require the plan to give enrollees information on how to contact the department in the event of disagreement with the characterization of the matter as a complaint.
+/- Requires the plan to appoint a neutral employee to assist in preparing and presenting the enrollee's case, whereas under the departments' previous requirement the plan employee acted as a patient advocate. 9.703(c)(1)(I)(D) and 9.703(c)(1) (iv)
+/- Requires the plan to provide the enrollee access to all information relating to the matter being complained of, but permits the charging of a "reasonable fee" for reproduction. 9.703(c)(1)(iii)
+Decision must be made in 30 days. 9.703(c)(1)(v)
+/- Requires specific information to be included in the first level decision, including: a statement of the issue, basis and rationale for the decision, references to documentation supporting the decision, including contract references, and an explanation of the appeal process. Should add that the enrollee may appear at the second level review, and may submit additional evidence. 9.703(c)(1)(vi)
+ An explanation of procedures for second level review, including: right to help from a plan employee and to appear, must be articulated. 9.703(c)(2)(i)
+/- The second level review committee must be impartial and include one third non-employees, but regs. still would permit board members and relatives. 9.703(c)(2)(ii)

+ Enrollee gets 15 days advance written notice of the review and right to reasonable accommodation to facilitate participation. 9.703(c)(2)(iii)
+ Enrollee has right to insist on the appearance for questioning of the person or persons who made the decision. 9.703(c)(2)(iii)(G)
+ A number of protections, including that the committee may not discuss the matter ahead of time, must be physically present to vote, may not intimidate the enrollee, and must arrive at a decision within 45 days of the plan's receipt of the request for review, are added. 9.703(c)(2)(iii)(H) through (M) and 9.703(c)(2)(v)
+ The decision requirements are more specific, akin to the first level decision requirements. 9.703(c)(2)(vii)
- Eliminates language that said that the decision was binding on the parties unless appealed by the enrollee, suggesting that the plan can appeal its own decision.
- Does not prohibit the plan from basing its decision on new grounds which were never discussed at the first level review, thereby creating the possibility that the enrollee will be surprised at the hearing. 9.703(c)(2)(iv)
-Permits the plan to provide the department with a summary (rather than transcript or recording) of the hearing, upon appeal by the member.
+ The department has established a toll free telephone number, and fax for appeal purposes. 9.703(d)
+/- Establishes certain time frames for appeal to the department, including a presumption that the member received the plan decision within four days of the decision letter, but makes no provision for rebutting the presumption, or for notifying the member of a defective appeal and allowing for cure. 9.704(a)
+ Comments above to the complaint process are applicable to the grievance process and will not be repeated here.
+/- Eliminates the provision that the licensed physician or psychologist can vote at the first or second level grievance review without having participated either in person or by phone, but still gives the expert an opportunity to weigh in without appearing or being subjected to questioning by the enrollee, including questioning his/her credentials. 9.705(c)(3)
+/- Sets out a number of provisions governing health care initiated grievances, which generally help the consumer. However, the consent form lasts for 24 months instead of being grievance specific. 9.706(E)
- Eliminates the prior requirement that the provider filing a grievance must pursue it through the second level.
+ Expedited review must be granted if the enrollee's physician certifies that the enrollee's life, health or ability to regain maximum function would be jeopardized by the delay occasioned by the normal review process. 9.709(c)

Subchapter J. Health Care Provider Contracts 9.721-9.725

General Comment: Little change since the December '99 version. There are minimal restrictions on financial reimbursement/incentive arrangements between providers and plans, and minimal oversight of unlicensed integrated delivery systems (IDS), which can take over most plan functions via subcontracts with the plans.

- DOH reviews, but need not approve, material changes to provider contracts. 9.722(b)
+ Providers must get 30 day notice of contract changes from the plan. 9.722(e)(8)
- Requires that provider contracts include "reimbursement methods"" to be approved by the department, but fails to require enough specificity for the department to identify impermissible conflicts of interest between providers and their patients. 9.722(f)(1)
- Allows up to half of the provider's reimbursement to be based on levels of their patients' utilization of services. 9.722(f)(2)
- Allows a plan to subcontract virtually all functions to an unlicensed integrated delivery system (IDS), over which the department has no direct regulatory authority. 9.724
- Imposes no specific monitoring requirements on plans which delegate functions to unlicensed IDS. 9.724
+ Requires plans to submit IDS contracts to the department for review and approval before implementation. 9.724(b)

Subchapter K. Utilization Review (UR) 9.741-9.751

General Comment: Significant changes have been made since the December '99 version. In this version, plans and certified utilization review entities (CRE) must have a written process for developing and annually reviewing a UR plan, and must share the process with the department. Clinical criteria must be developed with input from health care providers in active practice, and must be available on request to health care providers. Standards for UR decisions are set out. Plans and CREs must consider the enrollee's individual circumstances, and UR criteria may not be the only basis for the decision. The department will not, however, review individual decisions of CREs on a regular basis.

- Fails to define conflicts of interest between a plan and CRE. 9.744
- Permits the department to substitute accreditation by a nationally recognized accrediting body for its statutory obligation to oversee CREs. 9.747 and 9.748.
- Does not require the department to review individual decisions of CREs as part of its renewal of CRE certification process. 9.748
+ Establishes UR program standards which require input from health care providers in active practice in the development of clinical criteria, annual review of the appropriateness of clinical criteria, consistency of decisionmaking, staff resources and training, and timeliness of decisions. 9.749
+ Requires plans and CREs to make available its UR criteria upon written request of any health care provider. 9.749
+ Requires a written description of the UR program, available to the department for review. 9.749
+ Establishes UR standards, including that the enrollee's individual circumstances must be considered, and that UR criteria may not be the sole basis for a decision. 9.750
+ Establishes additional UR standards, including requirements of physician/psychologist review of denials, timely notification to the provider for additional facts, documents or information needed to render a decision, and notification of clinical reasons and applicable contract language in UR denials. 9.750

+ Establishes time frames for UR decisions and notification. 9.751

Subchapter L. Credentialing 9.761-9.763

General Comment: Since the December '99 version, the department has added oversight of plan credentialing to its responsibilities. There is still no prohibition against basing recredentialing on economic factors, and although the current version adopts a minimum set of elements which must be verified prior to credentialing, no minimum standards relative to these elements are established.

+ Plans must adhere to their credentialing system. 9.761
- There is no prohibition against a plan basing recredentialing on economic factors such as the cost of a physician's patients.
+ The department must approve the credentialing plan and prior approve any amendment thereto. 9.761
- There is no timeframe for departmental approval of the credentialing plan.
- Recredentialing takes place every three rather than every two years, as previously proposed 9.761
+ Requires reporting to the department every two years of the number of applications made, approved and rejected, along with the number of providers terminated for reasons of quality. 9.761
+ Establishes minimum credentialing elements such as current licensure, malpractice claims history, etc., to be verified by the plan. 9.762
- There is no common set of standards to which plans are to be held in credentialing.

60 01 616

Nightingale Health Center

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

December 27, 1999

Dear Ms. Mitchell,

I have reviewed Annex A TITLE 28. HEALTH AND SAFETY, PART I. GENERAL HEALTH, CHAPTER 9. MANAGED CARE ORGANIZATIONS, as published in the *Pennsylvania Bulletin* this month.

I wanted to communicate my support for the proposed regulation, and to make particular comment on sections 9.678 (Primary Care Providers), 9.683 (Standing Referrals), and 9.761 (Credentialing). I believe that these sections help to support the spirit of Act 68, specifically, the intent to enhance the access of Pennsylvania's citizens to the high-quality care provided by Certified Registered Nurse Practitioners—especially in medically underserved areas. I strongly support the final publication of these sections as written.

Thanks for your time, and have a wonderful holiday season.

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Sincerely,

R. Eric Doerfler, NP
President

1430 Bridge Street
New Cumberland, Pennsylvania 17070
Phone: 717.712.0993 Fax: 712.0994

DEPARTMENT OF HEALTH
...in pursuit of good health

January 10, 2000

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

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

Dear Mr. Nyce:

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

Sincerely,

Stacy Mitchell

Stacy Mitchell
Director
Bureau of Managed Care

ENCLOSURE

Original: 2079

MANAGED CARE ASSOCIATION OF PENNSYLVANIA

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April 25, 2000

Mr. John Jewitt
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Mr. Jewitt:

Enclosed for your review and information are materials pursuant to the Department of Health's proposed Act 68, 1998 regulations. The Association developed the materials to illustrate how the proposed regulations would affect managed care plans that are under contract with the Department of Public Welfare to enroll Medical Assistance (MA) recipients. The Association represents a number of managed care plans that participate in the MA program.

Association members are hopeful that the enclosed information will encourage the respective Departments to provide specific and cooperative regulatory guidance to managed care plans that must comply with the proposed regulations as well as MA programmatic and contractual standards.

Thank you for your time and consideration of our concerns. Please do not hesitate to contact me directly with any questions you may have.

Sincerely,

Kimberly J. Kockler
Executive Director

enclosure

MANAGED CARE ASSOCIATION OF PENNSYLVANIA

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DEPARTMENT OF HEALTH PROPOSED ACT 68 REGULATIONS & MEDICAL ASSISTANCE PROGRAM REQUIREMENTS

Purpose & Objective:

The purpose of this document is to provide additional information as to how the Department of Health's proposed regulations pursuant to managed care plans and Act 68, 1998 either duplicate or are in potential conflict with current Medical Assistance (MA) requirements, specifically within the mandatory managed care program, HealthChoices. The objective is to illustrate for regulators, legislators and others involved in the regulatory process the importance of specifically addressing duplicative or inconsistent requirements in the proposed regulations so as to:

- ✓ Provide clear regulatory guidance to health plans under contract with the Department of Public Welfare which will help alleviate potential difficulties for MA consumers and providers.
- ✓ Prevent redundant regulatory reviews of the same information which may result in different directives from different agencies and increase costs for managed care plans.
- ✓ Not interfere unnecessarily with existing MA program and/or HealthChoices contractual requirements.

The following information identifies major areas of overlap and conflict between the DOH-proposed regulations and MA/HealthChoices requirements. Also provided is an extensive list of items which managed care plans participating in HealthChoices are required to submit to the Department of Public Welfare for approval prior to use.

Areas of Conflict

- **Access standards**

The HealthChoices Southeast Request for Proposal (SE RFP) requires that travel time to a primary care physician not exceed 30 minutes (urban areas) and 60 minutes (rural). The DOH proposed standards require primary care physician access within 20 minutes or 20 miles (urban) or 30 minutes/30 miles (rural). **Most, if not all, existing MA provider networks would be invalidated under the proposed DOH standard.**

Also, the DOH regulations require that managed care plans notify DOH in the event of a network change that effect "more than 10% of enrollees." The SE RFP requires plans to notify DPW of a network change that "materially affects the HMO's ability to make available all capitated services in a timely manner."

- **Health care providers**

The proposed regulations would require that managed care plan provider directories list providers "by specialty." Managed care plan provider directories are 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 MA recipients as oftentimes such directories list providers by zip code for the ease of enrollees. The Association is asking that the phrase "by specialty" be eliminated. Its elimination 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.

- **Continuity of Care**

The proposed regulations would require that, for continuity of care purposes, there be an expedited or "less than full" credentialing process. In addition to potential quality of care and liability concerns for all HMOs in all lines of business, this presents additional issues for HMOs that enroll MA. For example, if an MA recipient chooses a provider who does not participate in the MA program and would be unable to submit encounter data as per the requirements of the HealthChoices program.

- **Complaints and grievances**

In addition to extensive complaint and grievance processes, the HealthChoices program also includes a fair hearing process. At a minimum, the respective processes should be crosswalked to identify differences and provide regulatory direction to managed care plans. A specific example of a major difference is noted below.

The proposed regulations establish a 45-day timeframe in which consumers may file initial and second-level complaints and grievances with the Departments of Health and Insurance. In addition to differing from final Act 68 regulations issued by the Insurance Department, this timeframe is different under the MA program which allows at least 30 days. HMOs participating in MA 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.

Items Requiring Department of Public Welfare Prior Approval

While not all materials requiring DPW prior approval are included in the DOH proposed regulations, many are, including: quality assurance plans, provider contracts, subcontracting agreements, and complaint and grievance procedures. **Requiring that the same information be submitted to two different agencies for approval will be administratively burdensome and**

costly. More importantly, this places plans in a precarious position if the agencies differ on approval decisions and changes to policies, procedures and contracts.

Outlined below is a comprehensive list of materials which plans participating in the HealthChoices program must submit to the Department of Public Welfare for approval prior to use:

- Member handbooks (annual approval)
- Provider directories (entire document is updated annually; supplements must be updated and distributed quarterly)
- Quality assurance plan (updated annually and in the event of any changes)
- Subcontracts between the HMO and any individual, firm or corporation or any other entity to perform all or part of the selected HMO responsibilities under their contract with the Department of Public Welfare.
- All written and oral marketing materials, including those to be used by the Independent Enrollment Assistance Program.
- Health related incentives.
- Expanded benefits.
- Reinsurance arrangements.
- Outreach and educational materials.
- Member newsletters.
- Prior authorization policies and procedures.
- Drug utilization review policy and procedures.
- Provider appeals timeline for processing denials and appeals.
- Correction action plan.
- Provider training and education plan.
- Provider manual and subsequent policy clarifications/procedural changes.
- Provider network.
- Release of QM/UM data, correspondence, corrective action plans to other plans.
- Provider agreements.
- Location of administrative offices.
- Organizational structure listing, including function of each executive and administrative member.
- Drug formularies.

The Bottom Line

The Association is seeking to minimize the regulatory and cost burden on managed care plans that are subject to the Department of Health regulations and also under contract with the Department of Public Welfare. The Association is advocating that the Departments work jointly to the extent possible to coordinate the Act 68 regulatory process and requirements with the contractual obligations of the MA and HealthChoices programs.

ITEMS REQUIRING DPW PRIOR APPROVAL

HealthChoices Program

ITEMS	CITE	FREQUENCY/IF APPLICABLE
1. Member Handbook	RFP pg. 29 & 32	Annually
2. Provider Directory	RFP pg. 32	Entire document must be updated annually. Supplements must be updated and distributed on a quarterly basis.
3. Healthy Beginnings Plus Program	RFP pg. 45	No time limit
4. Quality Assurance Plan	RFP pg. 87 4th yr. Contract, Exhibit F, pg. 3	Annually and any changes or updates.
5. Statistical and Analytical presentations	RFP pg. 88	No time limit
6. Reinsurance arrangement	RFP pg. 97	No later than 60 calendar days before the first day the HMO provide medical benefits to MA recipients. The HMO must notify the Department 30 days prior to any change in the reinsurance arrangement.
7. Sub-Contracts between the HMO and any individual, firm or corporation or any other entity to perform part or all of the selected HMOs responsibilities under their contract with the Department	RFP pg. 101	No time limit
8. Any transaction with the related party regardless of their stated purpose included but not limited to loan advances and or lease arrangements. The HMO must inform the Department that the sub-contractor is a related party at the time approval is requested.	RFP pg.101	No time limit
9. All written and oral marketing materials. Including those to be used by Benova	RFP pg. 22 and 4th yr. Contract pg. 16 RFP pg. 23	No time limit
10. Community Events 11. Contributions and/or payments made to non-	RFP pg. 23 4th yr. Contract pg. 17	30 days prior to the event

ITEMS REQUIRING DPW PRIOR APPROVAL

HealthChoices Program

profit groups in connection with health fairs and community events exceeding $2, 000. or more.	and Exhibit C, 4th Year Contract	
12. Health related incentives	RFP pg. 24	No time limit
13. Items of little or no intrinsic value not to exceed $1.00 in retail value.	4th yr. Contract pg. 17	No time limit
14. Expanded benefits	4th yr. Contract pg.17	No time limit
15. Products of value that are health related and/or prescribed by a licensed provider	4th yr. Contract pg.17	No time limit
16. Outreach and educational materials	RFP pg. 36	No time limit
17. Member newsletters	RFP pg. 36	Quarterly
18. Prior authorization policy and procedures	RFP pg. 38 4th yr. Contract pg. 22 and Exhibit D, 4th year contract	No time limit
19. Drug Utilization review policy and procedures	RFP pg. 47	No time limit
20. School district agreements	RFP pg. 51	No time limit
21. Behavioral health letters of agreements	RFP pg. 59 & 60	No time limit
22. Behavioral health /Drug Utilization review program policy and procedure	RFP pg. 59	No time limit
23. Provider Appeals timeline for processing denials and appeals	RFP pg. 83	No time limit
24. Corrective Action Plan	4th yr. Contract pg. 14	No time limit
25. Provider training and education plan	4th yr. Contract pg. 33	No time limit
26. Secondary Liability Arrangements	4th yr. Contract pg. 54	No time limit
27. Provider Manual & subsequent policy clarifications/procedural changes	RFP, pg. 73	***New RFP will require this to be completed annually
28. Provider Network	RFP, pg. 72	No time limit
29. Focused studies (three annually)	4th yr. Contract, Exhibit F, pg.20	No time limit

ITEMS REQUIRING DPW PRIOR APPROVAL

HealthChoices Program

30. Release of QM/UM data, correspondence, corrective action plans to other PH/BH-MCO's	4th Yr. Contract, Exhibit F, page 21	No time limit
31. Provider Agreement	RFP, pg. Xiii definitions	No time limit
32. Location of administrative offices	4th Yr. Contract, pg. 15	No time limit
33. Organizational structure listing, function of each executive, administrative member.	4th yr. Contract, pg. 15	No time limit
34. Formulary		
35. Children and Youth Agency Agreement	4th Yr. Contract, pg. 30	No time limit
36. CLPPP Agreements	4th Yr. Contract, pg. 30	No time limit

#2079

PENNSYLVANIA HEALTH LAW PROJECT

801 ARCH STREET • SUITE 610A • PHILADELPHIA, PA 19107-2421

FAX TRANSMITTAL

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TO: John Jewett DATE: 2/14/99

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TELEPHONE NUMBER: SENDER'S FAX NUMBER: 215-625-3879

RE: SENDER'S TELEPHONE NUMBER: 215-625-3663

☐ URGENT ☐ CONFIDENTIAL ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ FOR REVIEW

NOTES/COMMENTS:

42 CFR § 417.479

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Diagnostic Risk Adjustment for Medicaid: The Disability Payment System

Richard Kronick, Ph.D., Tony Dreyfus, M.C.P., Lora Lee, M.S., and Zhiyuan Zhou, Ph.D.

This article describes a system of diagnostic categories that Medicaid programs can use for adjusting capitation payments to health plans that enroll people with disability. Medicaid claims from Colorado, Michigan, Missouri, New York, and Ohio are analyzed to demonstrate that the greater predictability of costs among people with disabilities makes risk adjustment more feasible than for a general population and more critical to creating health systems for people with disability. The application of our diagnostic categories to State claims data is described, including estimated effects on subsequent-year costs of various diagnoses. The challenges of implementing adjustment by diagnosis are explored.

INTRODUCTION

Medicaid programs are increasingly turning to capitated managed care, not only for adults and children receiving Aid to Families with Dependent Children (AFDC) who have, to date, dominated Medicaid managed care enrollment, but also for Medicaid recipients with disability, whom health plans have little experience serving. This article has two purposes. First, we argue that risk adjustment is even more important when contracting with health plans for people with disabilities than when contracting for other populations. Second, we describe the Disability Payment System (DPS), which State Medicaid programs can use to provide financial incentives so that health plans will seek to excel in providing appropriate services for people with disabilities.

The research described in this article was supported by grants from the Robert Wood Johnson Foundation, the Pew Charitable Trusts, the Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, and the National Institutes on Disability and Rehabilitation Research, U.S. Department of Education. The research also depended on data generously provided by the Medicaid programs of Colorado, Michigan, Minnesota, Missouri, New York, Ohio, and Wisconsin. Richard Kronick and Lora Lee are with the Department of Family and Preventative Medicine, University of California, San Diego (UCSD). Tony Dreyfus is with the Boston University School of Public Health. Zhiyuan Zhou was with UCSD when this research was performed, and is now with Upjohn Pharmaceuticals. The opinions expressed herein are those of the authors and do not necessarily reflect the views of the UCSD, the Boston University School of Public Health, Upjohn Pharmaceuticals, or the Health Care Financing Administration.

Need for Risk-Adjusted Payment

Advocates of managed competition have long argued that risk-adjusted payments are required to make a competitive health care system function properly (Enthoven, 1988). As we shall see, the argument is much more powerful for people with disabilities.

In any year, a small number of people account for a large portion of health care expenditures. If a health plan can avoid these costly people, it can reap large, undeserved profits. Management of competition by public or private purchasers may limit the more egregious tactics used to avoid high-risk enrollees, but without adequate risk adjustment, plans will at best try to stay "in the middle of the pack." That is, no plan will seek to excel in serving high-risk people, lest it attract a larger share of costly members who would force the plan to lose money or raise premiums. Yet people with serious illness, even more than others, can benefit from the creative efforts of health plans to improve their care (Master et al., 1996). If we want plans to excel in caring for those most in need, sufficient dollars must be allocated to the plans that take on this challenge.

97

The Insurance Federation of Pennsylvania, Inc.

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February 10, 2000

Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
333 Market Street
Harrisburg, PA 17120

Re: Act 68 - Health Department's proposed regulation

Dear Mr. Nyce:

Yesterday, I had a conference call with your team handling this regulation, and one question we discussed was the propriety of the regulation's repeated requirement of the Health Department's prior approval of contracts of managed care plans. It came down to two questions - whether Act 68 (or some other provision of law) gives that general power to the Health Department; and if it does, how should that power be exercised.

Your team recommended I put the thoughts we discussed in writing to buttress the arguments we raised in our January 18 letter - so here goes.

1. Authority for prior approval

The Health Department's proposed regulation asserts, without any specific or express legislative grant, prior approval of a number of contracts - those covering managed care-IDS contracts (Section 9.601), the delegation of medical management (Section 9.675), and all plan and provider contracts (Section 9.722).

Prior approval in the insurance laws is an exception, not the rule. Granted, it is commonplace in the regulation of insurance, as it applies to a wide array of contracts, forms, rates, transactions and investments. But it is always an express grant of statutory authority to the regulator.

These express grants of prior approval authority are found not only throughout Pennsylvania's insurance laws generally, but also throughout the Insurance Company Law specifically. Within the Insurance Company Law, the grants do not come as a general power enjoyed by the regulator, but as individual grants pertaining to specific areas of contracts, forms, investments and the like. Further, in regulations under the various provisions of the Insurance Company Law, I cannot think of provisions requiring prior approval without specific mention of it in the underlying provisions of the law.

Act 68 is an amendment to the Insurance Company Law. Its provisions relating to the regulation of managed care plans constitute a new article within that law - but deal with the same type of subject matter found throughout that law. This holds true even with the dual regulation of managed care by the Insurance and Health Departments, an area already covered with respect to preferred provider organizations (a subset of managed care plans) under Section 630 of the Insurance Company Law - and an area where the General Assembly expressly granted the power of prior approval to both Departments with respect to certain contracts and operations of PPOs.

For all the detail of Act 68, it does not grant express authority for prior approval in the areas where that authority is being sought by the Health Department in this regulation. That runs afoul of the general rule of statutory construction, followed in Pennsylvania, of "expressio unius est exclusio alterius" - where certain things are designated in a statute, all omissions should be understood as exclusions. Commonwealth v. Charles, Pa.Super., 411 A.2d 527 (1979); Latella v. Commonwealth, Unemployment Compensation Board, Pa.Cmmwlth., 459 A.2d 464 (1983).

A regulation can only go as far as the underlying statute. In this case, Act 68 did not expressly grant the Health Department the power of prior approval in the above-noted areas. Given the legislative awareness of prior approval, and the express grant of it throughout the Insurance Company Law, the Health Department cannot now assert it as an implied power, either, or as something intended - albeit not provided - by the General Assembly in Act 68.

Further, the power of prior approval sought by the Health Department is not essential to its ability to regulate under Act 68. As we noted in our January 18 letter, the option of information filings - commonly used in the regulation of insurance - is sufficient.

2. The exercise of prior approval

The Health Department compounds the problem of prior approval by not providing any timing in its exercise of this. Section 9.722 is a prime example: It requires managed care plans to submit their provider contracts to the Health Department for prior approval, with detailed provisions as to what must be in the contracts. But for all that detail, there is no mention of the time in which the Health Department will review those filings.

That open-ended timing is in marked contrast to the time requisites set forth throughout the Insurance Company Law where prior approval is expressly granted. One relevant contrast is Section 630 of the Insurance Company Law, setting forth the Insurance and Health Department's joint jurisdiction of PPOs: Subsection (f) expressly sets forth areas of prior approval, and includes a time limit of 60 days for that approval to be exercised. A regulation that asserts prior approval as an implied power should at least match the definitiveness of statutes that expressly grant this power in similar instances.

Absent such deadlines, managed care plans run the risk of being put on hold indefinitely. That raises constitutional concerns - as it is tantamount to a deprivation of due process.

As a final point, I note that the General Assembly has, over the last five years, enacted several bills lessening the prior approval requisites imposed on insurers - in areas including workers compensation rates, commercial liability rates and forms, and health insurance rates (including those of at least some entities that qualify as managed care plans).

That is further evidence of the legislative awareness of the prior approval requisite in the regulation of insurance - and evidence that the General Assembly is interested in reducing this where it has previously existed. The Health Department's proposed regulation goes against this clear legislative trend, as well as the principles of statutory construction, in claiming the implied power of a prior approval over certain contracts; it compounds this by failing to provide any deadlines on that prior approval.

That about covers what we discussed yesterday. Please call with any questions or comments.

Sincerely,

Sam Marshall

Samuel R. Marshall

FAX

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Date 2/10/00

Number of pages including cover sheet 5

To: Mary Lou Harris	From: Sam Marshall

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REMARKS:

FYI:
Additional Q&A regarding Act 68
-1/22/99

Pennsylvania Department of Health
Managed Care
(717)787-5193

Additional Consumer Rights Issues

(Note: some of these questions may appear elsewhere in the questions and answers relating to Act 68 implementation. Because of expressed consumer concerns over the specific issues regarding complaints and grievance, the Department has addressed these questions and answers in greater detail.)

Q. Act 68 and the Department of Health's Statement of Policy appear to have resulted in a decrease in consumer rights in certain critical areas relating to consumer complaints and grievances, when compared with HMO standards previously in effect in these areas. For example, HMOs are not required to provide consumers with essential information about their decisions and the decision making process. Is this correct?

A. HMOs and managed care plans are in fact required to provide consumers with descriptions of the appropriate complaint and grievance processes and appeal rights under Act 68. These descriptions will be found in amendments or revisions to enrollee subscriber contracts, being reviewed and approved by the Insurance Department, and likewise may appear in other forms of enrollee literature, including, for example, member handbooks, marketing materials, etc. The Departments have toll-free numbers for consumers to call with questions; HMO and managed care member services are available to answer questions; and the Departments are working on distribution of a consumer education pamphlet, a copy of which is already posted on this Web Site (See New Managed Care Brochure). Experience of all parties -- consumers, providers, managed care plans, state agencies-- will be utilized to help determine how specific Act 68 regulations will need to be in addressing these and similar issues.

Q. Why is there not "adequate" consumer representation on the complaint and grievance committees, especially when contrasted with prior requirements that 1/3rd of the membership be HMO plan enrollees?

A. Since the HMO Act is non-specific on the details of a consumer grievance system, when the Department published the 1983 HMO regulations, it did in fact establish a standard that 1/3rd of the membership of a grievance committee be HMO enrollees. Act 68 of 1998 however is much more specific and detailed in nature, including composition of the new complaint and grievance committees established thereunder. This composition includes, for the 2nd level complaint review committee, 3 or more individuals who did not participate in the initial review, at least one third of whom shall not be employed by the managed care plan. For the 2nd level grievance review committee, one or more persons selected by the managed care plan who did not previously participate in the

decision to deny payment for the health care service, with a requirement that the review 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 Department believed, given the level of specificity in the Act, that it would be inappropriate in a statement of policy to attempt to go beyond apparent legislative intent to include consumer representation on these committees. The Department is willing to reconsider the issue during its development of formal regulations on Act 68, and to hear pros and cons on the issue, including whether it can, in fact, through regulation, go beyond the specificity of the Act, to require consumer representation on these committees.

Q. Why did the Statement of Policy not include a clear statement, previously made by the Department of Health, that requires impartiality of the members of the complaint and grievance committee?

A. The Department of Health's August 1991 document, "HMO Grievance systems: Operational Standards for Fundamental Fairness for HMO Members", which did not have the force of law or regulation and which was not formally published even as a statement of policy, but was rather made available to plans to represent guidance on the attributes of a grievance system which the Department could find to be fundamentally fair and acceptable under the HMO Act, does contain the guideline that, "(Second level grievance review) Committee members must have the ability to be fair and impartial." The Department continues to have a reasonable expectation, as do managed care plan enrollees, that the new complaint and grievance committee members under Act 68 will be impartial in their consideration of enrollee and/or provider appeals. It is the intent of the Department to include a specific standard to this effect in its proposed Act 68 implementation regulations. It is likewise the expectation of the Department that managed care plans, in implementing the new Act 68 complaint and grievance procedures, will utilize the general guidance provided in the cited "Operational Standards", where it is not inconsistent with Act 68 or the Department's statement of policy, to develop, operate and maintain fundamentally fair complaint and grievance systems for enrollees and providers filing grievances with the written consent of enrollees.

Another issue addressed in the "Operational Standards" but not in Act 68 or the statement of policy relates to disclosure to consumers about decisions made by the managed care plan and its committees at each step of the appeals process. The "Operational Standards" go into great detail providing guidance on fundamentally fair procedures, including information that should be provided to consumers in order to assist them in understanding the process, the basis for decisions at each appeal level, and rights to appeal to the next level.

<u>These "Operational Standards", to the extent they were not preempted by Act 68, are to be read as consistent with the implementation of Act 68 and remain in effect.</u>

Once again, the Department's expectation is that each managed care plan will maintain its new Act 68 complaint and grievance procedures in a manner so as to

provide enrollees with a fundamentally fair dispute resolution process, consistent with the general guidance provided in the "Operational Standards." The Department will determine the extent to which the guidelines contained in the "Operational Standards" should be incorporated into Act 68 implementing regulations, including, for example, any necessary clarification of "burden of proof" issues, another concern raised by consumers.

Generally, it is the Department's belief that since 1991, given the monitoring by the Department, its hearing of grievance appeals, and its in-depth review of grievance case files, HMOs have operated a fundamentally fair consumer grievance system, with adequate consumer safeguards, and that HMOs and managed care plans will continue to do so under the revised provisions of Act 68. Failure to provide fundamentally fair procedures in accordance with the Act will be monitored and corrective action required.

Q. Won't consumers suffer because of the failure to have an expedited process for medically pressing denials?

A. Act 68 only specifies a procedure for an expedited internal review by a managed care plan. It is silent on what the next step should be if the consumer and/or provider is dissatisfied with the decision and wants to appeal further. The statement of policy does not go beyond Act 68, but the Department has urged plans to provide specific details regarding this process to consumers and providers. Most plans submitting compliance materials have indicated that the next logical step in the process is to proceed directly to the internal 2nd level grievance committee; in other words, the internal 48 hour expedited grievance appeal takes the place of the lst level grievance committee review and decision, thereby cutting the review process by 30 or more days. Again, based on actual implementation experience and input from all parties, the Department intends to address this issue in its draft Act 68 implementation regulations, and sooner, if necessary.

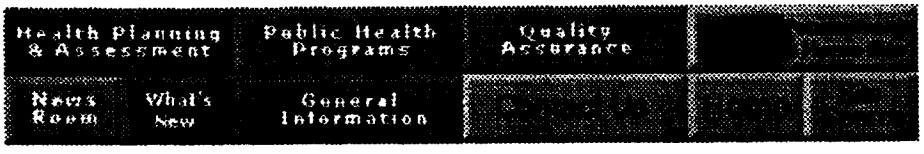
Q. Why are consumers not permitted to file oral grievance requests, as they where under the old grievance system?

A. The language of Act 68, Section 2161(a), uses the phrase, "...shall be able to file a written grievance regarding the denial of payment for a health care service." (Emphasis added.)

Q. Why are providers not required to explain to consumers, when obtaining their written consent to file a grievance, that by doing so consumers lose their right to appeal directly?

A. Act 68 does not provide specific details concerning the form or content of an acceptable written consent. The Department has received expressions of concern from all parties, including health plans, providers and consumers with regard to written consent. Based upon actual implementation experience, the Department, if necessary or desirable, will address this issue in its draft Act 68 implementation regulations. Pending the regulations, the Department expects that providers, at

the time a managed care plan enrollee presents for treatment, may obtain written consent to file a grievance for the limited purposes of obtaining reimbursement. The Department likewise expects that providers will clearly disclose to the managed care plan enrollee that by signing the consent the enrollee gives up his or her ability to file a grievance directly, for the limited purpose of obtaining reimbursement for the provider.



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APPLICABLE SECTIONS OF PROPOSED DOH MANAGED CARE REGULATIONS INDICATING RESPONSIBILITY OF DOH & INSURANCE DEPARTMENTS FOR REGULATORY OVERSIGHT OF HMO/MCO CONTRACTS WITH PHARMACY BENEFIT MANAGEMENT COMPANIES. (PBMS)

SUMMARY OF RULEMAKING SECTION OF PROPOSED REGULATIONS

Subchapter G. HMOs

p. 6412, Sec. 9.635 Delegation of HMO operations.
p.6412 This section acknowledges there is "A growing industry trend of managed care organizations delegating certain functions to a contractor with expertise in performing the function" and that "the Department must have the same ability to oversee the contractor performing functions for which the HMO is responsible as it would the HMO itself, if the functions were still performed directly by the HMO."

Subchapter J. Health Care Provider Contracts

p. 6418 Section 9.721. Applicability. "The Department is proposing this subchapter, relating to health care provider contracts, under its authority to promulgate regulations relating to the contractual relationships between the managed care plan and health care providers under Act 68, the HMO Act and the PPO Act.
Section 2111(1) of Article XXI requires a managed care plan to assure availability and access of adequate health care providers to enable enrollees to have **access to quality and continuity of care**".
"The PPO Act requires the Insurance Department consult with the Department in determining whether arrangements and provisions for a PPO **which assumes financial risk which may lead to undertreatment or poor quality care** are adequately addressed by quality and utilization controls as well as by a formal grievance system."

p. 6418 Section 9.724(c)(5). IDS provider contracts. This section "would reinforce the fact that the HMO, as the regulated entity, would be responsible at all times for the services it contracts to have provided," and "would require the IDS to agree to be subject to monitoring by both the HMO and the Department."

ANNEX
Subchapter G. HMOS

p.6427, Section 9.635, Delegation of HMO operations.
(a) "A contract for delegation of HMO operations shall be filed with the Commissioner and does not in any way diminish the authority or responsibility of the board of directors of the HMO, or the ability of the Department to monitor quality of care and require prompt correction action of the HMO when necessary."

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PENNSYLVANIA PHARMACISTS RECOMMENDATIONS RE DOH PROPOSED ACT 68 REGULATIONS

9.722 (p. 6437). PLAN AND HEALTH CARE PROVIDER CONTRACTS

Recommendation 1: New title to read: "PLAN AND HEALTH CARE PROVIDER AND PBM CONTRACTS"

Reason. Pharmacy benefit management companies were not listed as providers in Act 68. However, managed care plans are responsible for all contracts under their auspices, which would include PBM contracts.

This responsibility is noted in the Proposed Regulations on: p. 6412 (Sec.9635); on p. 6418 (Sec.9.721 and 9.724(c)(5)); on p. 6427, (Sec.9.635); and by inference on p.6437 (Sec.9.712 and 9.722) and p.6438 (9.724)

PBMs, it should be noted, play a major role in the HMO/MCO health operation. This role may include: handling all prescription claim processing, setting reimbursement levels; determining which pharmacies are in the network, and deciding which drugs are will be on the formulary.

Recommendation 2. The words "provider or PBM contract" should be used throughout Section 9.722 in the various subsections: e.g.

(a) A plan shall submit the standard form of each type of health care provider or PBM contract to the Department for review and approval prior to implementation.
(b) The plan shall submit any change or amendment to a health care provider or PBM contract...
(c) To be approved by the Department, a health care provider or PBM contract.....
(d) To be approved by the Department, a health care provider or PBM contract may not.....
(e) To be approved by the Department a health care provider or PBM contract shall include.....[also in the numbered and lettered subsections, wherever "provider" is used, the words "or PBM" should be added]
(f) To be approved by the Department, a health care provider or PBM contract shall satisfy the following: ... [the numbered subsections shall also added the words "or PBM" wherever the word "provider" is found.

(f)(1) Include the reimbursement method being used to reimburse a participating provider **"or PBM) and the PBM's reimbursement to its pharmacy providers."**

9.725. (p.6438). IDS-PROVIDER CONTRACTS.

Recommendation 1: New title to read: "IDS AND PROVIDER AND PBM CONTRACTS" (For the same reason the title of 9.722 should be expanded to include PBM contracts).

Recommendation 2: Add the underlined words:
"The health care provider and PBM contracts between the IDS and its participating health care providers or its PBM shall be submitted for review and approval to the Department.....An IDS-health care provider or IDS-PBM contract shall meet the following standards:

> [Additionally, wherever in 9.725 sub-sections the words "health care provider" occur, they should be followed by "or PBM"]

9.673 (p. 6429) PLAN PROVISION OF PRESCRIPTION DRUG BENEFITS TO ENROLLEES.

> **9.673 (b) The 30 day time allowed a MCO to respond to a formulary inquiry is too long.**
> This information is presumably readily available on a computer; and the question is apt to be time-sensitive to help a prospective enrollee to decide where to enroll, or to help an enrollee decide to commence a recommended treatment. The enrollee should receive an answer by mail within 14 days, or earlier by fax or e-mail.
>
> **9.673(c) Proposed formulary exception is commendable, add one other exception.**
> The proposed regulation will serve enrollee's health and help to contain costs. It would be desirable to extend this exception to situations where an enrollee has a condition which has been difficult to manage and finally has been stabilized on a non-formulary medication.

9.679.2(E), (p.6430) ACCESS REQUIREMENTS IN SERVICE AREAS.

The Proposed Regulations use the standard that network providers of frequently used health services should be within 20 minutes or 20 miles in an urban area.

> **Twenty miles is much too far for an enrollee to go in an urban area for frequently used services like a primary care provider, pharmacy or ob/gyn.** The result can only be to discourage enrollees from seeing providers when they need to, thus risking a worsening of enrollee's condition and future health care costs.

9.604(a)(6), (p.6424). PLAN REPORTS

The loss of some 500 pharmacies serving Health Choices Southeast networks went unreported. As indicated in a June 1999 Legislative Budget and Finance report, access to both pharmacies and prescriptions was affected. DPW, however, reported "a few pharmacies elected not to participate."

> **Plan annual reports should list not only the number of primary care providers joining and leaving the network, but also the number of pharmacies and major specialties joining and**

leaving.

9.677. REQUIREMENTS OF DEFINITIONS OF "MEDICAL NECESSITY"

The Proposed Regulations are inadequate. An excellent definition is available from The Department of Public Welfare. Additionally, the New Hampshire Insurance Department has a list of guidelines managed care companies must follow in determining their definition of medical necessity.

The Proposed Regulations also do not require the managed care companies to provide DOH with a copy of their definition (except as it might be referred to in the MCO literature). Thus the DOH is not in a position to monitor a CRE as to whether it is properly making its determinations of medical appropriateness in light of the individual MCO's definition of medical necessity.

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John:

Attached is the front page of the current issue of an industry publication which talks about risk pools. It is not permitted to be copied, but is published by Brownstone Publishers (1-800-643-8095). As you can see, risk pools involve withholding part of the capitation from a group of providers, and using it to pay for some member service or services. Distribution from the pool can be tied to anything the plan wants to put in the contract. For example, all hospital days could be paid out of the pool. This puts the prescriber in a conflict of interest position relative to the patient. (If I send my patient to the hospital, it is coming out of my pocket.) At the end of a period of time (one year for example) the profits (or losses) are calculated and distributed to the providers in the pool.

How these arrangements are constructed are very important, and can vary widely. How many (and which) providers are in the pool, how many patients are included, the services or other factors which determine the distribution, and the percentage of the capitation which goes into the pool, are all factors in determining the extent of the provider's conflict of interest. This is all out of view of the consumer or even the payer. The proposed regulations essentially say that DOH doesn't want to see the arrangement in advance, and hasn't established any safeguards other than that no more than half of the payment can be tied to patient utilization of services.

The comment is that DOH needs to take a sophisticated look at these arrangements to see if they target any particular expensive group, or create too much of a conflict. Allowing up to half of a provider's payments to be tied to utilization of services by patients can put undue financial pressure on the provider by essentially making the provider the insurer.

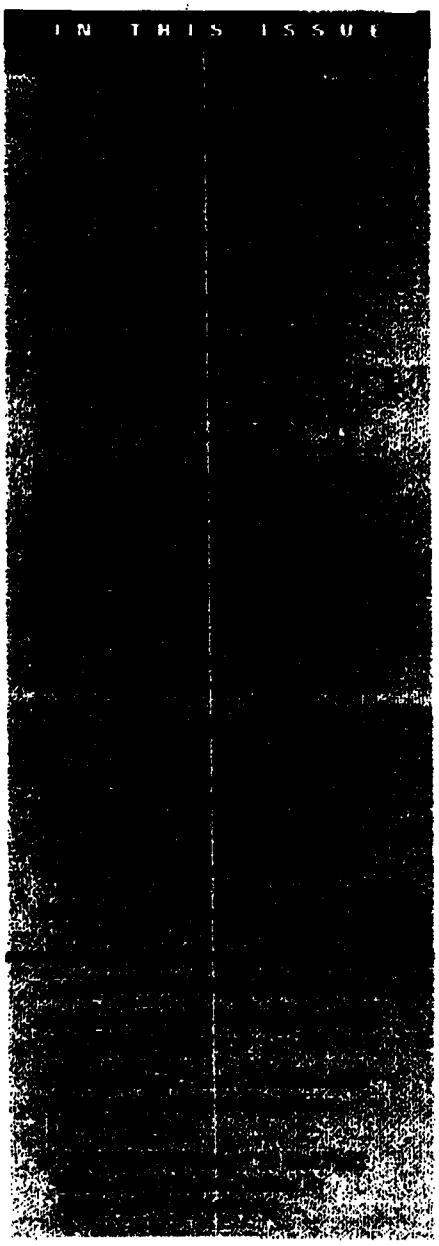
Risk adjustment as we use the term simply means paying plans according to the anticipated expense of the enrollee population, based on certain predicting characteristics (age, diagnosis, history of treatment, or whatever). If there is no risk adjustment, there is financial pressure on the plan to avoid expensive enrollees. This is accomplished in many ways: e.g. marketing, network enrollment, reimbursement practices which providers unlikely to prescribe or supply the service, and establishing barriers to care through restrictive drug formularies or complicated utilization review. In the

absence of risk adjustment, the incentive is highest for the plan to weed out expensive enrollees.

If you have further questions, please call me at 215-625-3874.

Mike Campbell

• Managed Care Contract Negotiator



Correct Six Contract Errors to Increase Risk Pool Profits

If your plan contracts include risk pools, you can make a lot of money on the surpluses in those pools. But errors in drafting a contract—either deliberate or inadvertent—may cause a plan to charge the risk pool more than it should, or to charge the risk pool when it shouldn't. That can drain surplus dollars out of the risk pool—and have a major, adverse impact on your revenues.

You can protect yourself from this problem, experts say, by learning how to recognize and fix contract errors before you sign your risk pool contract. To help you do this, we'll point out six common drafting errors and tell you how to correct them.

Errors Lead to Inappropriate Charges or Overcharges

Risk pools are becoming increasingly common in provider contracts, according to Massachusetts attorney Richard Trembowicz. In a risk pool arrangement, the plan creates one or more pools of funds to pay for certain services used by plan members. The providers (and sometimes the plan) linked to a pool contribute a predetermined amount of money to the pool. For example, the contract may require that a set percentage of a capitated provider's per member per month (pmpm) payment be automatically deposited into one or more risk pools. The money in a pool is used to pay claims for services to members—for example, for out-of-area care given to a member.

At the end of a set period, usually a year, the plan calculates whether a pool has a positive balance, called a surplus, or a negative balance, called a deficit. If there's a surplus, the providers (and the plan, if it's participating) will get a percentage of any surplus. The larger the surplus, the more money there is to distribute at the end of the year. If there's a deficit, providers are usually expected to pay back the plan to make up the deficit. "Hundreds of thousands of dollars are put at risk this way," Trembowicz says.

Usually the plan, not the provider, pays claims for member services and charges them to the appropriate risk pool. The contract sets the rules for the spending and accounting of risk pool dollars, so if you don't review it carefully, you may miss mistakes that will affect how the plan administers the pools, according to Missouri attorney Jill Rubin Hummel. "Sometimes it's just sloppy drafting, or failure to tailor your specific deal to the language in the contract," she says. Whatever the reason, when a plan overcharges a risk pool or includes inappropriate charges based on a poorly drafted contract clause, it reduces risk pool surpluses; it can even turn a surplus into a deficit. Either way, providers lose money.

(continued on p. 2)

PENNSYLVANIA HEALTH LAW PROJECT

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HEALTH MAINTENANCE ORGANIZATION GRIEVANCE SYSTEMS OPERATIONAL STANDARDS FOR FUNDAMENTAL FAIRNESS FOR HEALTH MAINTENANCE ORGANIZATION MEMBERS

ORIGINAL: 2079/BUSH
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I. INTRODUCTION

The Pennsylvania Department of Health (hereinafter referred to as the Department) has developed Health Maintenance Organization (HMO) Grievance System Operational Standards and is distributing this explanation of its expectations in order to:

- Assist HMOs in the Commonwealth to comply with provisions of the HMO Act and Department of Health Regulations (28 PA Code Chapter 9);
- Help ensure that the HMO member receives a fundamentally fair process for resolving grievances;
- Maximize the use by a member of internal HMO grievance systems and procedures before involving regulatory agencies;
- Maximize thorough investigation and documentation of substantive issues regarding a member grievance by HMOs themselves, so as to ensure creation of adequate records upon which appeals to the Department by an HMO member may be judged;
- Minimize the potential for the Department overturning HMO second level Grievance Review Committee (as specified in 9.73(s)) decisions based on failure to follow proper administrative procedures, and/or to provide adequate fundamentally fair grievance resolution;
- Develop and promote uniformity in the reporting of grievances to enhance the potential for tracking trends and comparative analysis of grievance resolution and member satisfaction not only by the Department but by purchasers and consumers of HMO services; and
- Ensure prompt expedited review by both the HMO and the Department of grievances alleging HMO denial of urgently needed care.

Each licensed HMO is to submit, not later than the date specified in the covering letter accompanying this document, for Department review and approval, member grievance resolution procedures complying with the provisions of the HMO Act and regulations and Department expectations regarding compliance set forth herein.

II. BACKGROUND

During the course of the external quality review process, Department staff identified many deficiencies in the methods by which HMOs define, process and resolve disputes with their members. The Department identified the need for improvement and standardization of grievance procedures in quality improvement plans of many HMOs.

In many of our meetings with HMO CEOs, Medical Directors and other staff to discuss preliminary quality improvement plans and short-term quality assurance work plans, the Department indicated that it was working on a uniform set of grievance guidelines/operational procedures, and would be distributing them in the near future.

In addition, the Department recently has been receiving an increasing number of appeals of HMO members from the decisions of HMO second level Grievance Committee determinations. We could not help but notice in reviewing the files/records underlying these grievance appeals, various significant deficiencies in HMO grievance procedures.

For example, we found such deficiencies as:

1. A record which included three separate claim denial letters from the HMO, including one signed by the HMO Medical Director. None of the denial letters mentioned the grievance process or the member's right to appeal an adverse decision. When the member wrote to the Department for assistance, the indication was that all appeals within the HMO had been exhausted. Yet, when we contacted the HMO, despite the fact that the claim had been more than nine months old and been formally denied three times, the HMO initially argued that the member would have to go back to the first level Grievance Committee Review, since a formal grievance had never been filed.

2. Second level Grievance Review Committee decisions by committees not containing the one third subscriber member representation required by the Department's regulations, and containing HMO staff members who had previously denied the grievance at the first level.

3. Decisions which were not clearly supported by specific findings on critical substantive issues in dispute. For example, a recorded two sentence decision and summary of a second level Grievance Review Committee's determination that a grievance regarding payment of an out-of-plan emergency claim be upheld because the member failed to obtain approval of the primary care physician (PCP), with absolutely no consideration in the record of the critical substantive issue of whether or not a true emergency may have existed.

The Department hopes that by issuing this indepth clarification of its expectations in the form of operational standards, fewer member appeals from HMO second level Grievance Review Committee decisions will be questioned on fundamental fairness/due process grounds, and that the grievance records furnished to us as part of the appeal process will address all of the important and essential substantive issues involved in each grievance. Grievance decisions which afford fundamental fairness/due process and which adequately address all substantive issues involved will be beneficial to all parties concerned, the HMO, the HMO member and the Department.

III. DEFINITIONS, REPORTING AND MEMBER NOTIFICATION OF GRIEVANCE RIGHTS

The Department's quarterly and annual HMO reports require submission of statistics on grievances. Section IV of the quarterly report, "Grievance Data", states, "List the number of formal grievances filed with the plan this quarter. Attach a summary of each."

It is the Department's intent and you are hereby advised to change Section IV of the quarterly report to require reporting of four statistics:

1. List number of first level grievances filed with the plan this quarter: _____

2. List number of first level grievance decisions by the plan this quarter: _____

   a. Number decided in favor of member: _____

   b. Number upholding HMO's position: _____

3. List number of[1] second level grievances filed with/appealed to the Plan's second level Grievance Review Committee consisting of at least one third subscriber members, this quarter:

   _____

4. List number of second level grievance decisions by the plan this quarter: _____

   a. Number decided in favor of member: _____

   b. Number upholding HMO's position: _____

HMOs, in reporting these statistics, should utilize the definitions contained below. It is the Department's intent during its periodic on-site visits to review the complaint log and files of complaints, and to review first and second level grievances to ensure proper classification and handling.

To provide HMOs with sufficient time to revise internal reporting procedures, this change in reporting grievance data will be effective for the fourth quarter of 1991, October - December.

Inquiry: An inquiry is any member's request for administrative service, or information, or to express an opinion. Whenever specific corrective action is requested by the member, or determined to be necessary by the HMO, it should be classified as a complaint.

Complaint: A complaint is an issue a member presents to the HMO, either in written or oral form, which is subject to informal resolution by the HMO within a thirty-day period. All HMOs

---

[1]Based on 28 PA Code Chapter 9 Section 9.97 Exceptions: With required Department of Health approval, a plan may choose to limit its grievance system to one level. Be advised that if this option is elected, the composition of the Committee must be the same as for a second level Grievance Committee, i.e., one third subscriber members. In addition, all procedures governing second level Grievance Committee reviews must be adhered to and the option must be consistently utilized. An HMO choosing this option must request approval from the Department prior to implementation.

must establish and maintain an effective complaint resolution system, including a written log of each complaint and its disposition. Failure to render a decision within the thirty-day timeframe automatically results in the complaint being upgraded to a grievance.

Grievance: A grievance is a complaint which cannot be resolved to the member's satisfaction or when the member requests formal grievance consideration during the thirty-day period. All grievances shall be committed to written form either by the member or the HMO prior to processing.

Department of Health Expectations Regarding Complaints and Inquiries

Each HMO must maintain written documentation on all such phone calls or letters classifying them by type in a complaint and/or grievance log for the purpose of tracking adverse trends or patterns and for assuring timely resolution of all complaints and grievances.

Each HMO also must ensure an appropriate referral process for concurrent medical service issues as described herein. The HMO should adopt a policy to routinely advise dissatisfied members of their rights under the complaint/grievance system over the telephone and advise them how to file a written grievance. Members must be informed of their rights under the grievance process (in writing) at each point in which a potential dispute regarding claim denial is identified by an HMO.

Each HMO must establish a reasonable timeframe for informal resolution. Such a reasonable timeframe appears to be thirty days for all non-medically pressing retrospective issues or disputes. Medically pressing concurrent issues require a different approach and the grievance procedure may not be used as a barrier to needed care.

Such disclosures will assist HMOs, since fully informed members are likely to use the proper grievance procedures rather than contact regulatory authorities directly with matters which should properly be handled within the HMO's grievance process. Regulatory consideration is reserved as the last step in the grievance process.

The Department has noted that many HMOs are not specific in their disclosures to members. For example, general references in claim denials, such as "if you have a question concerning this claim denial, call us" or "refer to your subscriber contract if you have any questions" are insufficient. References should be specific to the grievance process, for example: "If you are dissatisfied with this claim denial, you should call member services. Member services will then attempt to informally resolve the matter. If the matter has not been resolved to your satisfaction in thirty days, you may then file a formal grievance with the Plan."

Since deficiencies have been noted in this area, HMOs should ensure that all letters from the Medical Director and/or quality assurance/utilization review departments denying coverage, also contain notification of the grievance process. For example, a letter from a Medical Director to a subscriber, stating that he has reviewed the applicable medical records and determined that the care provided was not medically necessary or not a true emergency, should contain a clear notification that the member has a right to contact the Plan for informal resolution or to file a formal grievance.

The process of routine claim review does not constitute a first-level grievance review as it is generally an administrative process that may occur off-site and often occurs apart from the medical and management decision process. For example, a missing piece of information may often be the basis for claim denial. The grievance process is an administrative procedure that requires a higher level of detail and objectivity.

IV. DEPARTMENT EXPECTATIONS REGARDING FUNDAMENTAL FAIRNESS AT THE FIRST LEVEL GRIEVANCE REVIEW

The first level Grievance Review Committee is to be made up of one or more employees of the HMO (Medical Director, Q.A. staff, etc.). The Committee should not include any person whose decision is being appealed or who made the initial determination denying a claim or handling a complaint. This first level review may be in the form of a phone conference, staff meeting, or polling of experts by telephone. The first level review should be held within thirty days of receipt of the grievance.

We recommend that, whenever possible, the HMO afford the member the opportunity to present his case, but the member does not have the right to attend or to have representation in attendance at this stage. The member does have the right to submit written material and to have an uninvolved staff person assist him, and the HMO has the obligation to assure that these rights are made known.

Official record of the review is not necessary by the HMO with the exception of issuance of a written decision, at the earliest possible time following the hearing, **but not more than ten working days after the date of the hearing.** In addition, a record of those persons participating in the decision must be maintained. In all cases where the member is not upheld completely, and the possibility exists of the member going to the second level review, the content of the written decision is most important and must contain:

1. Description of committee's understanding of member's grievance as presented to grievance committee, e.g., dollar amount of the disputed issue, medical facts in dispute, etc.;

2. Committee's decision in clear terms and the contract basis or medical rationale in sufficient detail for member to respond further to HMO's position, e.g., did not contact PCP, non-emergency service as identified in the medial record, or not covered by subscriber contract;

3. Evidence or documentation used as the basis for the decision should be referenced in the letter, e.g., Paragraph 1.1 of subscriber agreement, ambulatory medical records, etc.; and

4. Statement indicating:

    a. decision is binding unless the member appeals to the second level;

    b. a description of the process on exactly how to appeal to the second level Grievance Review Committee; and

c. the written procedures governing appeal including any required timeframe for appeal.

The HMO should provide a minimum of thirty days to appeal and such timeframes should not exceed sixty days unless there are extenuating circumstances.

Upon receipt of a request of an appeal to the second level grievance committee, the HMO shall provide the member requesting the appeal, a brief disclosure of procedures regarding the appeal and hearing. A sample disclosure is attached as **Exhibit 1.**

As stated in Section III, a plan may choose to limit its grievance system to one level based on 28 PA Code Section 9.97 Exceptions, provided the procedures governing the second level Grievance Committee reviews are utilized and the required approval by the Department is obtained prior to implementation.

V. DEPARTMENT EXPECTATIONS REGARDING FUNDAMENTAL FAIRNESS AT THE SECOND LEVEL GRIEVANCE REVIEW

The second level review is to be conducted by a committee, one third of which must be actual HMO members appointed by the Board of Directors of the HMO. The Department recommends that subscriber board members serve as the required subscriber members on the grievance committee. This committee may not include anyone previously involved in the grievance. For example, the Medical Director or member services supervisor, unless they have had no prior involvement in the case, should not serve on the Committee. Committee members must have the ability to be fair and impartial. Moreover, it is the Department's suggestion that there be some continuity of HMO Grievance Committee membership so as to facilitate a knowledgeable and consistent approach to grievance resolution.

The Committee must have written procedures approved by the Department for investigating and conducting hearings relative to second level grievances. The procedures shall include general provisions regarding member rights as well as specifics concerning the HMO's responsibilities in assuring due process and the steps to be taken in that regard. At a minimum, the procedures must include:

<u>General Provisions Regarding Member Rights</u>

1. The member always has a right to attend the second-level hearing and to present his case, and has the right to be assisted/represented by a person of his choice.

2. The member may again submit written material in support of his claim. Formal rules of evidence are not appropriate, and the member may arrange for a physician or other expert to testify on his behalf.

3. The member has the right to question HMO staff concerning the dispute.

4. The member's right to a fair and equitable hearing may not be made conditional on his appearance at the hearing. Regardless of the members presence or lack of, the hearing must be conducted in the same manner.

5. The HMO is responsible for insuring that hearings are held at mutually convenient times. The member shall be notified in writing, at least fifteen days in advance, of the date and time of the hearing, which should be held within thirty days of receipt of the appeal. Requests for hearing postponement by a member (for just cause) must be considered.

6. The member shall receive a description of the Committee's procedures so as to permit him to be prepared for the hearing.

7. The member should also be re-advised of his rights to have a non-involved staff person to assist him in preparing for the grievance hearing.

Provisions Regarding the Hearing Process

1. The written decision of the first level Grievance Committee shall be the basis for deliberation. The objective is to keep the hearing informal and impartial so as not to be intimidating to the member.

2. Matters brought before the Grievance Committee should not be discussed by the Committee prior to the meeting.

3. Committee members should be introduced to the HMO member filing the appeal, and there should be clear identification of the subscriber member and HMO staff serving on the Committee.

4. There should be a clear recognition on the part of all members of the Committee, subscriber members and HMO staff alike, that their responsibility is to impartially hear and consider the dispute based solely on the material and presentations made during the hearing.

5. If any attorney representing the HMO is present at the hearing, the primary purpose of the attorney should be to represent the interests of the impartial Grievance Review Committee in insuring that a fundamentally fair hearing takes place and all issues in dispute are adequately addressed. The attorney should not argue or represent the HMO staff position in the dispute.

6. If the HMO desires to have an attorney present to represent the interests of the HMO staff, it also must make available an attorney to represent and assist the Grievance Committee.

7. Written minutes or a tape recorded record of the second level hearing is required. A verbatim transcript is optional, but desirable from the Department's position, particularly for those cases likely to be the subject of further appeal. The lack of complete documentation of evidence presented, may create the need to hold additional hearings at

the Department level or increase the possibility of the Department ordering the case to be re-heard. It is strongly recommended that dispute of cases involving substantial funds (more than $5,000) have a written transcript prepared.

8. A member of the HMO staff previously involved in and knowledgeable about the grievance should present and summarize for the Committee, the HMO staff's rationale for recommending that the denial be affirmed by the second level Grievance Committee.

9. The Committee should be permitted to ask questions of the HMO staff.

10. The HMO member or his representative should be given the right to present his side of the dispute, and ask questions of the HMO staff person(s) presenting the HMO side of the dispute.

11. The Committee must render a decision no more than **ten working days** following the Grievance Committee meeting.

12. The member must be advised, in writing, of the outcome of the Committee's deliberation. The written notice shall contain:

    a. a statement of the Committee's understanding of the nature of the grievance and of all pertinent facts;

    b. committee's decision and rationale;

    c. evidence or documentation supporting such conclusions; and

    d. a statement of the member's right to appeal to the Department of Health with the phone number and complete address of the Department. The address and phone number to be used is:

Bureau of Health Financing and Program Development
Pennsylvania Department of Health
Room 1026, Health and Welfare Building
P.O. Box 90
Harrisburg, Pennsylvania 17108-0090
Phone: 717/787-5193

Appeals to the Department of Health should be filed by the member within thirty days of the notification to the member of the decision unless extenuating circumstances are involved.

NOTE: 28 PA Code Chapter 9, Section 9.73, "Subscriber Grievance Systems", indicates that second level appeals may be made to either the Insurance Department or Health Department, "depending upon the nature of the grievance." The Health Department has coordinated with the Insurance Department, and the Departments have agreed that all grievance appeals **should go to**

the Department of Health. (Based upon experience, the vast majority of appeals deal with medical necessity or medical management issues appropriate to the Health Department, rather than to pure contract interpretation issues.) The Department of Health will review the appeal, and seek appropriate opinion/advice from the Insurance Department on issues which warrant Insurance Department input.

HMOs should immediately revise second level grievance decisions to include only the name, address, and phone number of the Health Department. Within one year, or the next time subscriber contracts are amended, all grievance procedure descriptions contained in HMO subscriber contracts should be amended to include reference only to the Health Department.

SPECIAL NOTE: It is particularly important that the second level Grievance Review Committee carefully consider and make particular findings of fact on all key factual disputes. For example, if the grievance involves a factual dispute between a member and a PCP, the Grievance Committee should not automatically assume that the physician is correct and the member is incorrect. The Committee has a responsibility to carefully weigh the accounts of both physician and member, and make an independent judgement on whose account is more credible.

For example: Assume the grievance involves payment of an out-of-plan emergency which the Plan has previously rejected because the member did not first contact his PCP and because the condition, in the opinion of the HMO, was not a true emergency. The claim was denied on the basis of the Medical Director's judgement that a true emergency did not exist. The member presents a letter from the admitting physician justifying why he believed the condition warranted emergency treatment. It is insufficient for the second level Grievance Review Committee to automatically assume the HMO Medical Director is correct and the other physician is incorrect. The Committee must make an independent assessment and include in its findings of fact, which physician's judgement it chose to accept and why.

VI. DEPARTMENT HEARINGS

The Department may at its discretion, particularly in those cases in which the formal grievance record submitted by an HMO is insufficient or inadequate, order the HMO to re-hear the grievance and address specific ambiguities in the record. Alternatively, the Department may hold its own hearing and gather independent testimony on the grievance from the HMO, member and other applicable parties.

VII. DEPARTMENT EXPECTATIONS REGARDING FUNDAMENTAL FAIRNESS IN PROMPTLY REVIEWING MEDICALLY PRESSING ISSUES

An HMO may not use the timeframe or procedures of the HMO grievance process to avoid the medical decision process or to discourage or prevent the member from receiving medically necessary care in a timely manner. When the dispute is recognized by the HMO or the member as involving care which is alleged to be medically necessary and pressing, but not yet rendered, the HMO must render a written decision within a reasonable time (48 hours). This decision must be signed by the Medical Director. If the member appeals this decision, the review may begin at the second level and does not have to be re-heard by an internal committee of staff.

Moreover, the availability of this expedited review process must be made known to all members in all written descriptions of the grievance process.

If a member contacts the Department directly, Department staff will immediately contact the Plan and request an expedited review of the case by the Plan's Medical Director.

VIII. GRIEVANCE RIGHTS FOR SELECT SUBGROUPS OF MEMBERS, INCLUDING FEDERAL EMPLOYEES, MEDICARE RISK CONTRACT MEMBERS, AND MEDICAID MEMBERS

The Department is currently in the process of researching potential conflicts between special grievance procedures which may be applicable to each of these special groups, versus Pennsylvania specific requirements.

Supplemental instructions will be issued at a later date. HMOs should continue to handle grievances for these members as they currently do.

The Department's preference is that there be one uniform grievance process, complying with these expectations, applicable to all HMO members, and any differences in handling or appeal rights occur only at the end of the Pennsylvania specified grievance procedures, after the Department of Health has made a determination on a second level grievance appeal.

IX. SPECIAL PROCEDURES FOR INVOLUNTARY DISENROLLMENT

Because of the infrequent, and serious nature of involuntary disenrollment of a member by an HMO, no such involuntary disenrollment shall occur without an HMO first providing a member so affected with adequate opportunity to utilize the grievance system to contest the disenrollment. If the member contests the disenrollment through the grievance process and appeals the decision of the second level Grievance Committee to the Department, the disenrollment shall not be effectuated until the Department has issued a decision on the appeal. The one exception to this requirement is if there is adequate documentation that the member poses a serious threat to the safety of the HMO and/or its providers, and the HMO finds that immediate disenrollment is necessary for its protection and/or the protection of its staff and providers. In such cases, a disenrolled member shall still be entitled to use the grievance mechanism to challenge his disenrollment.

X. GRIEVANCE REPORTING

The Department expects that any grievance identified by an HMO, will be the basis for quarterly and annual reporting to the Department of Health. Complaints and inquiries should be maintained for tracking purposes, but these incidents are not to be reported to the Department of Health. First and second level grievances should be identified and reported to the Department on a quarterly basis, pursuant to the instructions contained herein.

Finally, patient confidentiality should also be considered when reporting grievance information to the Department in quarterly and annual reports, which are considered public documents. Patient codes rather than names should appear in these reports.

XI. MISCELLANEOUS OVERVIEW

In conclusion, more specific information is presented in a question/answer format regarding grievance administration to reinforce some of the major points presented.

Question: Is a phone call complaining about inability to get referral or inability to reach PCP a complaint, a grievance or simply a phone inquiry?

Answer: It is a complaint - it does not immediately become a grievance until it is not resolved by the HMO during an initial thirty-day period or unless the member requests formal consideration of a grievance. However, if the matter cannot be resolved to the member's satisfaction within thirty days, the HMO must assist the member, if requested, by completing a grievance form, taking all necessary information over the phone and initiating the grievance review process. The HMO may choose the option of sending the member a grievance form to complete, in order to access the HMO grievance system. At the time of the HMO's contact with the member, the HMO shall describe the grievance process and procedures including the member's rights to have non-involved HMO staff member assist them and their right to submit written documentation relevant to the dispute.

Question: Must all complaints that are received in writing be considered a grievance?

Answer: No, if it can be resolved to the member's satisfaction by staff informally, it is not a grievance, even though it is received in writing. Complaint logs should clearly indicate when a complaint has been received/resolved. Grievance forms should be mailed to the member automatically at the end of the thirty day period or in those instances where the complaint has not been resolved to the member's complete satisfaction.

Question: Are all written or telephone complaints concerning denied claims automatically considered a grievance?

Answer: Not necessarily, if for example, the member's claim needs further research, this can be accomplished under the complaint definition. If, however, after thirty days of additional research, the matter is not resolved and the member is still dissatisfied, the member must always be afforded the opportunity to file a grievance.

Further, if due to the circumstances at hand, it is determined that additional informal review will not be productive, then the matter shall immediately be considered a grievance at the member's request or at the HMO's determination. At all times, a member has a right to the formal grievance system and the HMO may not require an informal period of attempted resolution unless the member agrees. At the point where a complaint is considered unresolvable, when thirty days elapse or when the member so requests a grievance, that is the point when all such matters should be identified and treated by the HMO as a formal grievance.

XII. DESCRIPTION OF GRIEVANCE PROCEDURES TO APPEAR IN SUBSCRIBER CONTRACTS

One of the problems the Department has identified is the large variability in the structure and content of grievance descriptions. While the Department of Health is responsible for reviewing and approving grievance procedures, they appear in group subscriber contracts and certificates, which are subject to approval by the Insurance Department.

Apparently some HMOs make changes in the grievance procedure descriptions in the subscriber contracts without obtaining prior approval of the Department of Health.

To help ensure compliance with Department requirements, an acceptable grievance procedure description has been prepared and is attached as **Exhibit 3**. HMOs using this standard description in filed subscriber contracts will receive prompt review and approval by the Insurance Department. Any deviation, however, will not be approved by the Insurance Department until the Health Department has first reviewed and approved the proposed changes.

Each submission for approval of descriptions of grievance procedures which deviate from the attached example must contain a detailed explanation of the HMO applicant's reasons for the proposed deviation as well as a description on how the deviation will serve to improve fundamentally fair processing of member grievances.

HMOs also are reminded of their responsibilities at least once a year to provide members with a separate and additional notification of their rights under the grievance system. This is generally accomplished through publication in the HMO member newsletter.

XIII. FILING REQUIREMENTS

Each licensed HMO, not later than the date specified in the cover letter accompanying this document, shall submit to the Department, member grievance procedures which address these operational standards. Included in this submission should be:

1. Copy of formal grievance procedure language to be included in all subscriber contracts. Currently used grievance procedure language in subscriber contracts should be reviewed and revised to comply with these operational standards and the example contained in **Exhibit 3**.

2. Copies of sample generic claim denial letters, for example:

    a. Sample claim denial forms/letters routinely used by the HMO amended to include specific reference to member right of appeal under the grievance procedures;

    b. Sample denial letter issued by the first level Grievance Committee containing appropriate language informing the member of his right to appeal to the second level Review Committee; and

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The NH Insurance Department Instructs MCOs to Define Medical Necessity

By Kirsten Singleton

In early December, the NH Insurance Department issued a bulletin instructing managed care companies to "publish, maintain and follow a written definition of medical necessity." This bulletin was a result of HB 1336, which passed last session. The 7-page bulletin was quite detailed in its instructions to the managed care companies doing business in NH.

Managed care companies objected strenuously to the bulletin, and according to Alex Feldvebel, Heath Policy Analyst at the Insurance Department, this bulletin is likely to be converted into a proposed rule. With this change, the language of the bulletin will now be subject to 2 public hearings at which the managed care companies can lobby to have the language modified. NHPA will be present at these hearings so that our voice can be heard. This medical necessity language would be a vast improvement; it would be excellent for consumers in this state. Following is a summary of the proposed language. If anyone would like a complete copy, please contact NHPA. We may need psychologists to testify at the hearings. If you are willing to do this, please let us know.

In the bulletin's introduction, the Insurance Commissioner states: "The concept of medical necessity has become a major tool for controlling health care expenditures in a time of increasing costs. Though the concept of medical necessity is central to managed care, there is little consistency among health carriers in the way it is defined, interpreted and applied. A 1994 study by the General Accounting Office revealed substantial variation in denial rates for lack of medical necessity. There is also little predictability as to when an insurance or health plan administrator will determine that a service or supply is medically necessary. This is because the definitions of medical necessity appearing in health insurance contracts are vague and subject to widely varying interpretations. Because of this vagueness, the information provided to enrollees about what services are covered under the plan is sometimes misleading. For example, a schedule of benefits might state that the plan covers up to 20 outpatient mental health visits per year, when the actual practice of the insurer might be to deny all visits after the fourth unless the covered person files a grievance.

Chapter 329 was intended to create greater uniformity and predictability of medical necessity determinations. Accordingly, the Department will not approve medical necessity definitions that contain terms that are excessively vague or imprecise or that have the potential to mislead the consumer as to what health services, supplies or drugs will be made available. The goal is to reduce vagueness and introduce greater uniformity in the way medical necessity is defined and used so that consumers will have greater certainty about what they are buying. The following guidelines are intended to aid carriers in drafting definitions that will merit Insurance Department approval."

After the lengthy introduction, the Insurance Department lists guidelines that managed care companies must follow in determining their definition of medical necessity. They include:

1. Managed care companies must make a specific filing to the Insurance Department with their definition of managed care. It must be filed within 60 days of the adoption of this bulletin/rule.

2. The definition must be very specific and must contain all of the factors that the health carrier actually uses in making medical necessity determinations."

3. It must be a single definition of medical necessity for the insurance carrier. It cannot vary from plan to plan that is sold. Furthermore, the bulletin states: "Similarly, if the approved definition of medical necessity includes treatment which prevents deterioration of the covered person's physical health when recovery from the underlying condition is not expected to occur, then the carrier must use this definition of medical necessity for mental health purposes and cover maintenance treatment for chronic mental conditions."

4. The definition must be absolutely clear about what is covered or not covered and "to what end" medical necessity serves. The carrier must specifically list 11 stated goals and state whether medical necessity is intended to include or exclude those goals. Examples of those 11 goals: "Promote recovery or healing from an illness, injury, or infection" and "Prevent a physical or mental disability."

6. The definition must clarify what is meant by "appropriate care." The managed care company must be "concrete and quantitative in this clarification."

7. The definition must clarify what is meant by "cost-effective" in the definition of medical necessity. The bulletin reads: "For example, a medical necessity definition might state that a proposed intervention in a particular situation will be considered to be cost-effective if there is no other available intervention that offers the desired clinical benefit at a lower cost."

8. Regarding "Evidence-Based Standards of Medical Necessity," the bulletin says: "Nationally, there is a growing trend among carriers to include in medical necessity definitions the requirement that any proposed intervention be 'evidence-based.' Usually, this means that an intervention will not be approved unless it has been the subject of well-controlled studies that provide clear clinical proof of effectiveness. The problem with this approach is that many commonly used practices will fail this criterion because they have never been evaluated with well-controlled studies. Indeed, the current research infrastructure is not sufficient to evaluate all services, supplies and drugs. The performance of clinical trials is hindered by such factors as the expense of conducting a proper study and shortage of funds, difficulty attracting and retaining participants, and ethical and other feasibility issues. Low prevalence diseases are particularly unlikely to be studied. Women, children, people of color, and the elderly historically have had more limited involvement as research subjects. The absence of a study, then, does not mean the service is outside the accepted standards of the medical community. Nor does it mean

that the service, supply or drug is not effective... A strict requirement of documentation of effectiveness is therefore an unrealistic standard, and any definition containing such a requirement will not be approved."

9. Objective standards must be met. The bulletin reads: "The definition of medical necessity must provide an objective standard against which any individual judgment about medical necessity can be measured.... Any definition that states or implies that an intervention is medically necessary only if the carrier determines it to be so will not be approved. The carrier can, of course, establish utilization review procedures whereby approval for a proposed intervention is given only after the carrier has made a determination of medical necessity against an objective standard. What the carrier cannot do is to define medical necessity in such a way that what is medically necessary is nothing more than what the carrier determines to be medically necessary."

10. The process used to determine medical necessity must be described, and the decision-maker must be identified.

11. The managed care company must list categories that are automatically considered medically unnecessary.

12. Adverse Determinations: "Chapter 216 (laws of 1998) (SB 371) requires that if a consumer or health care provider acting on behalf of the consumer requests, the health carrier must provide a written explanation of any adverse determination, including the relevant clinical rationale used to make the adverse determination. Any such clinical rationale must include detailed reference to the carrier's approved definition of medical necessity and must cite that portion or portions of the definition which the health carrier's medical director or designee is relying upon in making the adverse determination."

Hearings on the language of this medical necessity will begin in January.

(NHPA Meets With MCC, Continued from Page 1)

A second case described extreme rudeness on the part of a care manager, and he expressed a lot of concern about this situation. Dr. Witte said that psychologists who feel that they are being treated disrespectfully should make this known. The overall manager of care at Holyoke is Michele Hills, and she should be called when a serious problem like this takes place. A final, more positive e-mail talked about how some of the basic complaints from the summer, outlined above, have seemed to diminish. This feedback was also given to Dr. Witte.

We were then shown around the office only after we signed a release related to our possibly seeing confidential information on a computer screen or desk. There are 8 "care managers" working at Holyoke. These are people with clinical backgrounds (mostly social workers and nurses) who do the utilization review after 8 sessions. There are 2 care managers specifically assigned to New Hampshire. He said that calls to care managers should be returned within 24 hours.

Mark and Kirsten reiterated to Dr. Witte that Healthsource has a history of problems with their mental health benefits management firms (Medco, CMG) and that the therapists here in NH are used to having to fight back hard against the steady stream of abuses. It was pointed out that it was most discouraging to see MCC come to NH and bring in many of the same problems that have been encountered in the past. We suggested that MCC create a Provider Advisory Panel with members representing the professional associations. Dr. Witte seemed very interested in this idea and mentioned that MCC is going to have a staff person based at Healthsource in NH who might be able to be a local contact person for such a group.

After the meeting, a report was made to the NHPA Board of Directors, which was greeted with considerable skepticism. Given the few negative e-mails providing more recent examples of difficulties, Mark and Kirsten were startled to experience so much discontent. It had been their experience that the meeting had been productive, useful, and positive.

Given this experience, Mark Peterson had a conference by phone with Brad Witte giving him the feedback that the level of discontent was higher than we had realized when meeting with him. He was told that much more work was going to have to be done to reverse the discontent and animosity that has been created. He was responsive and concerned.

On Monday, December 7th NHPA attended another meeting with MCC executives in Concord. This meeting was held with the Alliance of the Mentally Ill and Citizen's Alliance. Several executives from Healthsource and MCC were in attendance. The meeting was a follow-up to a meeting held in July to air the concerns. The promised report of the statewide meetings with therapists was reviewed at this meeting.

Much of the information presented at this meeting paralleled what Dr. Witte had reported to Mark and Kirsten during the meeting held the week before. Additional information was provided concerning what happens when care is denied. It was reported that there are approximately 1000 requests per month for treatment authorizations (i.e. sessions over 8 being requested). Dr Witte reported that of these 1,000 requests, there are only four denials per month. This low number seems hard to believe, but he was very specific about it. He said that MCC looks for creative care options (i.e. options that don't cost money) such as community support, so that there is no such thing as a blanket denial. He said that all denials are reviewed to make sure there was nothing further that could be done for the patient.

It should be noted that the NH Insurance Commissioner's office is beginning its investigation of MCC. This is expected to last about ten weeks. In order for us to keep on top of this, please communicate with Kirsten with regard to any events which take place which you feel will help us to know how MCC is handling their management of the care of NH citizens, as well as how you are being treated in the process.

PENNSYLVANIA HEALTH LAW PROJECT

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January 18, 2000

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

Dear Ms. Mitchell:

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

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

Sincerely,

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

Positive Aspects and Areas for Improvement Regarding DOH's Proposed Regulations on Act 68

PHLP's analysis of the proposed regulations reveals the following:

Criteria for Getting a Certificate of Authority

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

- only requires description of what the plan intends to do;
- no standard for ownership's background in health care management, previous experience, etc., i.e. virtually anyone can own and operate an HMO
- allows foreign HMO to operate in the state by obtaining a waiver of PA's managed care requirements from DOH without notice to the public or an opportunity for comment
- no mandatory on-site inspection by DOH
- no readiness review by DOH to see if what the applicant said they intend to do (e.g. adequate staff, quality assurance, phone system, etc.) is in place before they enroll members and provide health care services
- Board of Directors with 1/3 enrollees need not be in place for first 18 mos. of operation. No prohibition against enrollee board members being employees
- eliminates review of the HMO's process of Board selection to assure an appropriate, balanced Board
- eliminates requirements for an HMO to describe its cost control incentives and that they be reasonable
- eliminates requirement that HMO detail qualifications and authority of its Medical Director
- no requirement for the plan to use generally accepted medical standards for utilization review
- no standards for quality assurance

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

- no definition of what an adequate network is
- no definition of what specialties must be covered (including whether pediatric & adult)
- elimination of enrollee/provider ratios provided in current HMO rules
- no access standards for appointments
- no review of travel time to appointments
- elimination of requirement that plan have a DOH approved procedure for referring to out-of-plan specialists

C. Very limited plan oversight by DOH in that:

- no QA external review by anyone for first 18 months of HMO operation and then only by a firm hired and paid by the plan with plan determining the scope of review
- no requirement of corrective action, etc. if external review finds problems;
- no public access to external review;
- no assured further external review needed for 3 years even if serious problems.
- no requirement that DOH regulators ever step foot in a plan- permits DOH to rely exclusively on external reviewers hired and paid for by the plan to do any external reviews.
- no standards of scope of review required by the external reviews and no requirement that compliance with Act 68, HMO Act and accompanying regulations be reviewed

DOH Investigations of Plans

- Places financial business of the plan off limits for DOH investigations, precluding an inquiry into whether reimbursement decisions impact quality of care and access to services.
- Does not allow DOH to investigate information found in provider appeals and enrollee grievances as well as in complaints

DOH Review of Plans' Financial Incentives

- Applications for Certificate of Authority require a detailed description of the types of financial incentives that a plan may use, rather than a detailed description of the actual incentives that a plan will use.
- Eliminates requirement that HMO detail any financial incentives provided to its Medical Director

Approval of Plans

- Does not permit deemed approval of plans if DOH fails to act on application for Certificate of Authority within 90 days. Plans must demonstrate that they meet DOH standards in order to gain a certificate of authority.
- Establishes DOH standards for approval of point of service options by HMOs

Copayments

- Eliminates confusing copayment language contained in current regulations
- Does away with limits on copayments, and provides that DOH will review the impact of copayments on access, continuity of care, quality and cost effectiveness, only upon request by the Department of Insurance.
- Goes beyond the Act by permitting consideration and approval of coinsurance

PCPs

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

Medical Necessity.

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

Quality Assurance Standards.

- Health plans are required to have a quality assurance process but no specific standards or outcome measurements are mentioned. As long as the plans have a process and follow that process, DOH won't look behind it to see if the process actually results in quality care. This section does not really set out quality assurance STANDARDS at all.
- Does not provide for the development of a uniform member satisfaction survey to be made available to the public, as recommended by DOH workgroup.
- Fails to establish QA standards that include a system to identify special, chronic and acute health needs quickly, a mechanism for inform providers and enrollees of updates and changes, and maximum appointment waiting times

Quality Assurance Reviews

- Generally requires that external quality assurance assessments be done by an entity appointed by the plan, but extends the initial assessment from one year to 18 months after the plan has been in business (and every 3 years thereafter) to study the quality of care being provided and the effectiveness of the plan's Quality Assurance program.
- Does not set standards relating to quality improvement and health outcomes, to be the basis of the assessments and does not require assessment to include review of Act 68, HMO Act and accompanying regulations

- Reduces the scope of external reviews by no longer requiring a review of a statistically significant sample of medical records

Restricted Networks

- Allows plans to make only part of their network of providers available to enrollees, upon adequate disclosure to potential enrollees. Does not require disclosure to current enrollees, and does not set minimum standards for disclosure, such as inclusion of language in provider directory and/or marketing and enrollment materials.
- Permits networks without a single provider for a covered service as long as the service is otherwise arranged for-giving enrollees no choice in the matter
- Permits limited networks for those within a "reasonable travel distance" without defining that standard
- Allows an HMO to restrict access by limiting some enrollees (the poor? those who are higher risk?) to a potentially inadequate network

Drug Formulary Disclosure

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

OB/GYN Access

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

Access to Emergency Services

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

Provider Access Requirements

- Retains the current requirement that hospitals, PCPs and frequently used specialists be available within 20 minutes or 20 miles in urban areas, and 30

minutes or 30 miles in rural areas. No definition of frequently used specialists. No standards for less frequently used specialists. No standards for providers who are not hospitals, PCPs or specialists (such as drug stores, home health agencies or durable medical equipment providers).

- Provides only a vague access requirement that an HMO show it "has an adequate number and range of providers
- Fails to require HMOs to provide access to a provider within 24 hours for urgent care

Access for Persons With Disabilities

- Requires a plan to assure ADA compliance on physical accessibility and communication.
- Does not establish specific standards to be monitored and enforced by DOH.
- Does not clarify DOH will review and determine the adequacy of HMO's procedures, plans and policies to ensure its providers can communicate with members with sensory disabilities
- Does not require special needs units.
- Does not require QA plans contain a focus on delivery of services to special populations

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

- Section 2136 of the Act requires plans to provide: "(5) a description of how the managed care plan addresses the needs of non-English-speaking enrollees." However, the DOH proposed reg does not specify a plan for addressing needs but only requires: "Instructions as to how non-English speaking and visually-impaired enrollees may obtain the information in an alternative format."
- Fails to require accommodation of non-English speaking members in grievance/complaint process regarding notices and interpreter services

Disclosure of Enrollee Rights and Responsibilities

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

- No longer requires the health plan to routinely tell dissatisfied members of their rights under the complaint/grievance system and how to file a complaint/grievance at each point in which a potential dispute with the HMO is identified.

Continuity of Care

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

Health Care Provider Contracts

- Fails to place any limits on conflict of interest between health care provider and patient, but instead permits huge financial incentives to providers to limit care. Bonus, withhold pools, etc. based on low utilization can constitute 49% of the total health care provider payment by the plan. Although gag clauses are banned by the regulation, these regulations permit huge financial incentives which can in and of themselves make physicians feel constrained to limit communication with patients.
- Permits financial disincentive to serve and treat expensive patients by permitting plans to base economic incentives and disincentives on non-risk adjusted factors.
- No objective standard to determine if the financial incentive compensates a health care provider for providing less than medically necessary and appropriate care to an enrollee, as prohibited by Act 68 (For instance HCFA defines substantial financial risk which could influence provider judgment as 25% of potential payments for covered services.)
- Authorizes DOH to require re-negotiation of subcontracts between an HMO and its subcontractors for delegated duties
- Permits plans to get around Act 68 protections by deselecting health care providers at will. Although the regulations prohibit HMO-provider contracts from containing language which permits the plan to sanction, terminate or fail to renew a provider's contract for advocating for necessary health care, filing grievances, etc., the HMOs may deselect physicians after the end of the contract year. There is no requirement that the contracts provide a reason for non renewal and no opportunity for health care providers to appeal, if the HMO has sanctioned, terminated or failed to renew a contract for an impermissible reason.
- Permits licensed HMOs to subcontract all functions except soliciting and enrolling members and the grievance and complaint process to any unlicensed person, corporation or other entity and put that entity at risk for providing all health care services with minimal protections. DOH has no direct regulatory authority over these entities who are performing such important plan functions as credentialing providers, contracting with providers, quality assurance, etc.
- Inadequate contract reporting requirements to allow HMOs and DOH to provide oversight of Integrated Delivery Systems (IDS)

Utilization Review

- Fails to specify the timeframes within which a URE must conduct utilization reviews and provide notice of their decisions
- Fails to require utilization review entities to comply with the requirements of the Act. The regulations request a description from each applying URE of how and whether it could meet the requirements but do not actually require that the URE comply with the Act. Also doesn't require all UREs to disclose any business relationship they might have with a plan for whom they are doing utilization review
- Permits licensed insurers to conduct utilization reviews for anyone without needing to be certified as a CRE
- Fails to require DOH to inquire into the licensure and standing in the medical profession of a CRE applicant
- Fails to establish uniform standards for utilization review by CREs which will result in inconsistent decisionmaking
- Must provide that DOH will have access to books, records, staff, facilities and any other information it needs to determine CRE applicants as well as existing CREs are complaint with the Act and must clarify that DOH will review decisions rendered by the CRE
- Does not provide DOH will oversee all CREs for Act 68 compliance, including those accredited by a nationally recognized body
- Must clarify that as part of its review of CRE compliance with the Act, DOH will review decision rendered by the CRE

Enrollee Dispute Resolution Process

The "take-aways" listed are from the DOH Fundamental Fairness Guidelines for HMOs which have been in place since 1991.

Expedited Review

- The opinion of a physician or nurse PCP that the enrollee's life, health or ability to regain maximum function would be placed in jeopardy by delay occasioned by the review process in this chapter shall be conclusive to require the plan to make expedited review available at any stage of a grievance review
- Does not provide for expedited review of complaints (matters involving issues other than medical necessity, such as coverage), even if the enrollee's life, health or ability to regain maximum function would be placed in jeopardy

General Complaint and Grievance Procedures .

- As a positive, prohibits administrative procedures, time frames, or tactics that discourage enrollees from, or disadvantage enrollees in using the procedures
- Positively, requires that copies of an HMO's complaint and grievance procedures be submitted for review and approval by DOH
- Fails, however, to provide a mechanism for addressing the fairness of an HMO's procedures or tactics as they are applied to an individual complaint or grievance
- Auditing or surveying HMO reporting of complaints and grievances should be a required part of DOH's monitoring process rather than an option
- The right to complain should be extended to former and potential enrollees who have contractual and legal rights for which there may be no recourse but to file a complaint
- Fails to require plans to accept an oral grievance from an enrollee and reduce it to writing
- No longer requires that first level complaint and grievance decisions contain: a description of the reviewer's understanding of the member's dispute; clear terms and in sufficient detail for the member to respond further; references to the evidence and documentation used as a basis of decision; a statement that the decision is binding unless the person appeals
- Fails to require plans to identify the identity, position and credentials of the individual(s) who make its decisions despite the enrollees right to have a decision rendered by a properly credentialed person
- Does not require plans to make available to the enrollee all documentation relating to the issue in dispute.
- Does not require that if the HMO fails to act on a complaint or grievance within the timeframes established by the regulations, the relief sought by the member must be granted automatically by the plan
- Does not require acknowledgment of a complaint or grievance from the plan to establish the date of receipt and to clarify the plan's characterization of the appeal
- Allows plans to send notification of decisions to either the enrollee or provider, contrary to Act 68, which requires notification to both.

Second level Reviews of Complaints/Grievances

- No longer requires that members be given at least 15 days advance written notice of the second level complaint/grievance committee hearing and their right to appear, be given a description of the Committee's procedures to prepare, and be re-advised that they can be assisted by an uninvolved HMO staff person if they need help preparing.
- No longer requires that the second level review committee (for complaints and grievances) be made up of at least 1/3 HMO members, and that the consumer attending be told which of the Committee is staff and which members
- Does not require plans to make available for questioning, at the second level review, those persons who made the determination in dispute.
- Does not require the entire second level review hearing to be transcribed by the HMO and fails to guarantee the enrollee the right to record/transcribe the proceeding
- Does not prohibit the second level review committee from basing a decision against an enrollee on a reason not specifically raised in the first level review decision
- No longer requires that an HMO staff person knowledgeable about the grievance/complaint be present at the second level review to present the HMO's view of why the denial should be upheld, and that the staff person may be questioned by the member and by the Committee
- No longer requiring that if an HMO attorney is present, they cannot argue the HMO's case and instead must assist the committee to assure a fair hearing and that all issues are properly addressed. No longer requiring that an HMO may only have an attorney present to represent their staff if they provide another attorney to represent the Committee
- No longer requires all second level grievance/ complaint committee members to be present at the hearing and instead allows physician members to participate in the hearing and in the decision by a written report
- No longer requires that the second level grievance/complaint committee base their decision solely on materials and testimony presented at the hearing.
- Does not require the second level complaint/grievance decision to articulate a detailed basis, including reference to the standard used and the evidence considered.

Appeal of Complaints to DOH or DOI

- Should require in enrollee appeals to DOH or DOI that the Departments will assist the enrollee in identifying and gathering information and material necessary to proceed with the appeal
- Fails to require a process for DOH and DOI to determine the appropriate agency for review of an appeal that includes timeframes for reaching the decision and communicating it to the parties

External Grievance Process

- Fails to require the HMO to provide notice to the enrollee as well as the provider when a provider files an appeal
- Should only require enrollees to send along with their appeal correspondence they have available, other correspondence and documents should be submitted by the plan
- Fails to require the plan or entity that conducted the initial review to forward the decision, supporting information and a summary of the issues not only to the CRE, but also to the enrollee and/or provider
- Is cumbersome in routing communication to the enrollee through the plan, rather than directly from DOH and the certified review entity.
- To avoid unnecessary delay and loss, should permit enrollees to send new information directly to the CRE rather than through the HMO
- Must require DOH to automatically distribute information about the CRE's accreditation rather than waiting for the enrollee requests it
- Fails to define a process for either party's objecting to a CRE including the grounds needed and to whom the objection is addressed
- Fails to require that if the plan is successful on an enrollee filed complaint, the plan must still pay the cost of the review, as required by Act 68.

Data Collection, Review and Dissemination by DOH

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

Delegation of Medical Management

- Allows the delegation of virtually any aspect of medical management (utilization review, quality assurance, case management, etc.) upon prior approval of the contract by DOH. Does not provide explicit standards for delegation of these functions except for utilization review and when an integrated delivery system is involved.

Provider Credentialing

- Fails to establish minimum provider credentialing standards for education, training, experience, record keeping, equipment, facility, etc. Fails to require review of practitioner's substance abuse history, board certification, malpractice history, etc.
- Fails to require HMOs to comply with the credentialing systems they establish and fails to establish DOH oversight of an HMO's credentialing system or process
- A copy of the HMO's credentialing requirements should be automatically provided to enrollees and providers

Lack of coordination with Insurance Dept. regs. The Insurance Dept. issued final regs which they have since withdrawn. Several sections of the Health Department regs cover the same topics as the Insurance Dept. regs. However, despite frequent assertions that the two Departments are working closely together, these shared sections are drafted very differently, often with conflicts between the versions of the 2 Departments. Some of the topics where Health and Insurance regs conflict are:

Section 9.682. Direct access for obstetrical and gynecological care;
Section 9.683. Standing referrals or specialists as primary care providers and;
Section 9.684. Continuity of care.

Gelnett, Wanda B.

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

DOH comments 1.4.00.doc

DOH bullets.doc

Please add to the file for #2079.

Thanks!

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

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

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

Sincerely,

Alissa Halperin
(215)625-3897

The Insurance Federation of Pennsylvania, Inc.

1600 Market Street
Suite 1520
Philadelphia, PA 19103
Tel: (215) 665-0500 Fax: (215) 665-0540

January 18, 2000

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

Re: The Department of Health's proposed rulemaking with respect to managed care organizations

Dear Ms. Mitchell:

The Insurance Federation, on behalf of its members and its national counterpart, the Health Insurance Association of America, submits the following comments on the Department of Health's regulation of managed care organizations proposed in the December 18 **Pennsylvania Bulletin**.

Subchapter F - General

Section 9.601 - Definitions

"Ancillary service plan:" We recommend this be limited to managed care plans, not any individual or group health insurance plan. This seems a clarification, as the substance of the regulation does not pertain to vision or dental insurance that is not offered through a managed care plan.

"IDS - Integrated delivery system:" We recommend this be limited to entities that enter into contracts with HMOs, not any managed care plans. While the Department has the authority to regulate contracts between an HMO and an IDS under the HMO Act, it does not have similar authority for all

managed care plans under Act 68. As Act 68 is the only act that even mentions managed care plans, we believe it is the sole source of authority for any regulation of those plans by the Health Department.

"POS plan - Point-of-service plan:" We recommend the Department clarify how this definition differs from that of a gatekeeper PPO, as we do not see a substantive difference. If there is one, it should be explained; if there is none, the definitions should be merged.

"Utilization review entity:" While the preamble refers to this, as did the Department's earlier draft, it is missing here and should be added.

Section 9.604 - Plan reporting requirements

As a general objection, we question the Department's authority to extend these requirements from HMOs to all managed care plans. Section 2111 of Act 68 sets forth the general responsibilities of plans and provides the Department with reporting authority. The requirements in this section, however, go past the areas covered in Section 2111, and we recommend the requirements be modified consistent with Section 2111.

As to specific reporting requirements:

(a)(1): We recommend deletion of the reference to county disenrollment data. The plans we represent do not keep that data; nor would it be useful to monitor compliance with Act 68. In any event, this is only mentioned as an example, not a requirement - and I am not sure how county information relates to product lines.

(a)(11): We recommend deletion of this subsection, or a change that the Department may request other information only through revising this regulation. This regulation correctly details the items to be reported, with each item open to public comment and IRRC and legislative review.

This subsection, however, thwarts (or at least contradicts) all that - as it gives the Department unfettered authority to make up the reporting rules as it wishes.

Section 9.605 - Department investigations

Subsections (b) through (e) outline the powers the Department intends to exercise in the course of any investigations it performs under subsection (a). Subsection (a), however, applies to all plans, while the remaining subsections apply only to HMOs.

This inconsistency should be reconciled - and not simply by extending the investigatory powers in subsections (b) through (e) to all managed care plans, as the Health Department has no need for or power to get at some of that information with respect to managed care plans generally.

Subsection (d): We recommend this be modified to require an HMO to give access to these medical records "to the extent available." For instance, an HMO that is not a staff model HMO would not have this information.

Section 9.606 - Penalties and sanctions

Subsections (c) and (d) set forth the procedures that the Department must follow in penalizing and sanctioning HMOs and managed care plans, respectively. We are not sure why there are two different subsections on procedures; the rules of administrative law and procedure should apply equally to both plans and HMOs, including the right to challenge (not just appeal) a proposed penalty or sanction - something subsection (d) suggests is not granted to managed care plans, but subsection (c) grants to HMOs.

We recommend this section be revised to provide that any penalties or sanctions imposed under subsections (a) and (b) be governed by 2 Pa.S.C. Chapter 5, Subchapter A (relating administrative law and procedure).

Subchapter G - HMOs

Section 9.633 - HMO board requirements

Subsection (a)'s reference to "undue influence" and "diverse representation" (indeed, that whole sentence) should either be deleted or defined. This type of editorial comment only opens litigation.

Section 9.634 - Location of HMO activities, staff and materials

Subsection (1): We recommend that, absent compelling reasons, the time period in which to make documents available be changed from 48 hours to 20 days, consistent with discovery timing in civil suits.

Subsection (2): We recommend deletion of the Pennsylvania licensure requirement as lacking statutory authority in the HMO Act. To the extent this subsection applies to utilization review activities of HMOs, it also goes beyond the utilization review requisites in Act 68 - as that act requires "current licenses in good standing," but pointedly does not require Pennsylvania licensure.

That issue was frequently debated in Act 68 deliberations, with the conclusion that licensure in other states is adequate (e.g., the medical director at Johns Hopkins could qualify) for utilization review in managed care plans, including HMOs. That should apply for HMO medical directors overseeing utilization review and quality assurance activities, too. This also recognizes the multi-state nature of our business, especially on issues of coverage; granted, we cover Pennsylvania enrollees - but the benefits and utilization criteria are frequently developed and apply on a multi-state basis.

Section 9.635 - Delegation of HMO operations

We recommend these contracts of delegation be listed with the Department consistent with Section 9.604, rather than

filed with the Insurance Commissioner (we also question whether this regulation should set forth filing requirements with the Insurance Department, but assume this is an editorial error).

Further, we recommend this be limited to the filing of contracts delegating the performance of covered services, as opposed to administrative functions. The former legitimately relates to quality of care functions under the Health Department's authority; the latter are corporate operational concerns.

Section 9.636 - Issuance of a certificate of authority to a foreign HMO

We have a question more than a comment here: Would this apply to an HMO licensed in another state but covering a Pennsylvania resident as part of a group plan issued in another state (e.g., a New Jersey HMO covering a New Jersey employer with Pennsylvania employees)? I assume the answer is no, but this should be clarified.

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

We recommend deletion of this section as superfluous. If the Insurance Department wants the Health Department's opinion, whether on co-payments, co-insurances or any other issue, it can ask for it and should be the one providing for it in a regulation - not the Health Department.

Section 9.655 - HMO external quality assurance assessment

We recommend this section be modified to require the Department to publish annually in the **Pennsylvania Bulletin** those external quality review organizations acceptable to it. This matches what the Department has proposed with respect to credentialing systems in SubChapter L, **infra**.

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

This section seems to allow an HMO to offer a POS option without doing so through an insurer, which we believe to be a significant change from current regulatory requirements and not allowed under current law.

We recommend this section make it clear that an HMO may only offer a POS option through an insurer. That is not just a question of semantics, as it would allow an HMO to become an insurer "through the back door" and escape requirements that are imposed on insurers but not on HMOs - as with the payment of premium taxes and Guaranty Association assessments.

Subchapter H - Availability and access

Section 9.672 - Emergency services

Subsection (c)'s reference to "adjudication related" claims makes no more sense than the earlier version's reference to "adjudicating related claims." Under Act 68, plans must (not may) apply the prudent layperson standard to the enrollee's presenting symptoms and services provided. That covers all claims submitted to the plan, with or without "adjudication."

Section 9.673 - Plan provision of prescription drug benefits to enrollees

Subsection (c) should be revised to clarify that a provider may request to prescribe and obtain coverage for these drugs, subject to the utilization review procedures and other approval requisites of the plan. Given the weak statutory authority for this provision - Act 68 requires that a managed care plan disclose information on this, but it does not mandate it - it should at a minimum have this restriction that is standard even to formulary use.

Section 9.674 - Quality assurance standards

This should be reconciled with Section 9.604. This section makes sense in fulfilling Section 2111 of Act 68 with respect to quality assurance; however, the combined reporting of this section and Section 9.604 go beyond that envisioned by Act 68 or needed to fulfill the Department's role of ensuring compliance with it.

Section 9.675 - Delegation of medical management

We recommend this section be revised to replace the prior approval requisite to one of reporting, consistent with our earlier comments on Section 9.635. While the standards themselves are reasonable, the prior approval requisite is without statutory authority - and is a requisite that should come only with express legislative authorization.

We also note the Department has imposed no time limits on its review. Generally in insurance regulation, prior approval is not only something that requires express legislative authorization, but also comes with guidelines on the agency as to the time in which it has to act. As a business matter, the open-ended nature here is impractical.

Section 9.676 - Standards for enrollee rights and responsibilities

We recommend deletion of this section. These standards are appropriately under the Insurance Department's jurisdiction under Act 68 and have been set forth in that Department's regulations. Further, the standards are unduly vague and subjective - as with subsection (3)'s requisite that enrollees be treated with "dignity and respect." Hard to argue with the concept - but what does it mean in terms of monitoring compliance?

Section 9.677 - Requirements of definitions of "medical necessity"

We recommend this section be clarified to apply only to a managed care plan's contracts and other materials covered under Act 68. As worded, it suggests an unintended extraterritorial impact.

Section 9.678 - Primary care providers

Subsection (d) and the allowance of certified registered nurse practitioners as primary care providers is inconsistent with the requisites in subsection (b), some of which could only be met by physicians (e.g., hospital admitting privileges and unrestricted licenses). Further, this subsection should be revised to clarify that a managed care plan need not accept these nurses as primary care providers - that remains an option of each plan.

Section 9.679 - Access requirements in service areas

Subsection (a) needs to reconcile the reality that a plan may cover non-Pennsylvania residents, or that some plans may allow enrollees to go outside its service area for some covered services.

We appreciate the difficulty of reconciling state regulation of plans that are, in some instances, multi-state (or, more accurately, regional) in practice. We understand the Department has been working with New Jersey and New York regulators in a "border project" that addresses these concerns, and some solutions may be found through that project.

Section 9.680 - Access for persons with disabilities

This section should clarify that it is the providers, not a managed care plan, that must comply with the ADA.

Section 6.681 - Health care providers

Subsections (a) and (b) should be deleted, as this subject matter is already covered in Section 154.16 of the Insurance Department's regulation regarding information that must be sent to enrollees. To the extent that the "written procedures" in **subsection (d)** are meant for enrollees (as opposed to internal operating documents), the same concern holds true.

To the extent the Health Department wants information above and beyond that set forth in the Insurance Department's regulation, it should work with that department to amend its regulatory requirements - not create a separate body of regulation. That will avoid regulatory conflict and confusion not just for managed care plans but also their enrollees, and not just in setting forth but also in monitoring those requirements.

Section 9.682 - Direct access for obstetrical and gynecological care

Subsection (b)'s inclusion of "related laboratory or diagnostic procedures" should be deleted as going beyond the scope of Act 68. Those services often require a referral, and they have required this - without opposition from providers - in the year since the effective date of Act 68. There is no need and no authority for their inclusion within the act's direct access mandate.

Subsection (d) should be deleted as lacking statutory authority under Act 68, especially with respect to its requirement that a plan have approval from its quality assurance committee. Nothing in the relevant section of Act 68 suggests or requires such a requirement.

Section 9.683 - Standing referrals or specialists as primary care providers

Subsection (b)(7) should be revised to clarify that the enrollee have the consent of a specialist to be a primary

care provider; this will avoid the unintended situation of the enrollee using this provision to complain about the specialist who does not want to be that enrollee's primary care provider.

Section 9.684 - Continuity of care

As with Section 9.681, this section should be deleted as already covered under Section 154.15 of the Insurance Department's regulation. Again, it is a question of clarity not just in setting forth the requirements, but in monitoring and enforcing them.

Subchapter I - Complaints and grievances

Section 9.702 - Complaints and grievances

Subsections (a)(1) and (a)(3) exemplify the objection we have with much of this subchapter: They ignore Act 68's clear instruction that complaints are under the jurisdiction of the Insurance Department, not the Health Department. A managed care plan's complaint procedure must satisfy the Insurance Commissioner, not the Secretary of Health, to satisfy Act 68. Complaints are already covered under Section 154.17 of the Insurance Department's regulation, so covering them here only invites overlapping or inconsistent regulation.

Other provisions of this section are unduly vague or arbitrary. The repeated references to "unreasonable" requirements, or requirements that "discourage or disadvantage" or are "intended to adversely effect" and enrollee should either be clarified or deleted. The time frames and requirements in Act 68 are detailed; if the Health Department envisions loopholes or other means around them, it should spell out what they are - not leave them to vague or arbitrary oversight.

Section 9.703 - Health care provider initiated grievances

As an editorial comment, we recommend this section be merged with Section 9.706, which covers these grievances.

As a substantive comment, we recommend **subsection (h)** be revised to require that the provider obtain the consent of the enrollees for each stage of the grievance process, as opposed to merely allowing the enrollee to rescind his consent. The grievance process in Act 68 is meant for enrollees, with providers only acting on their behalf; the involvement and consent of enrollees is therefore essential throughout the process. Absent that express consent, the danger is that the provider obtains a blanket consent at the outset and continues the grievance process even after the enrollee is satisfied (or no longer affirmatively wants to pursue the grievance).

Section 9.704 - Internal complaint process

We recommend this section be deleted. Complaints under Act 68 are within the Insurance Department's jurisdiction and are covered under Section 154.17 of that department's regulation. If the Health Department intends something other than what the Insurance Department has proposed, it should work with that agency to revise its regulation - not propose a new one that either overlaps or conflicts with it.

Section 9.705 - Appeal of a complaint decision

Again, this section should be deleted as already covered by the Insurance Department, both in Act 68 and in Section 154.17 of that department's regulation.

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

Again, this section should be revised to delete portions related to complaints, as they are covered by the Insurance

Department, both in Act 68 and in Section 154.17 of that department's regulation.

Subsection (a) should be further revised to change the need for a plan's grievance system to comply with Act 68, not to satisfy the Secretary of Health. This is more than semantics, as it reflects an ongoing problem throughout the regulation: The goal should be the implementation of Act 68 (and, where applicable, the HMO Act), not the establishment of policies of or powers for the Health Department.

Subsection (b) should be further revised to apply only to material changes and to require only filing, not prior approval. As noted with other prior approval requisites proposed in this regulation, this should only be allowed if supported by clear statutory authority - and none exists here (as opposed to instances throughout the regulation of insurance, where the General Assembly expressly dictates prior approval).

Section 9.711 - Alternative provider dispute resolution systems

Subsection (a)'s reference to administrative denials is confusing. Those denials are not covered under questions of medical necessity, which are the sole subject matter for Act 68's grievance process. As the alternative system allowed in Act 68 is for grievances, its subject matter should match it, not exceed it.

Subsection (c) should clarify that this requirement only applies if a managed care plan establishes an alternative system.

Subsection (e) should be revised to refer to compliance with Act 68, not satisfaction of the Secretary of Health.

Subchapter J - Health care provider contracts

Section 9.722 - Plan and health care provider contracts

Again, we object to the presumption of prior approval and recommend the filing of these contracts, not their prior approval. This is especially true for contracts between managed care plans and providers, as nothing in Act 68 suggests this requisite. While the Health Department has exercised this authority for HMOs, we also question its statutory authority to continue doing so under that act.

While we have mentioned it above, it bears repeating here: Throughout the insurance laws of this Commonwealth, prior approval is a legislative grant, not an implied authority. Further, if the Health Department intends to assert it, it should at least set forth how it intends to exercise it - as with providing time constraints on the time it has for review (e.g., 30 or 60 days, as found in various insurance statutes where prior approval is required).

We appreciate the opportunity to work with the Department, the Insurance Department, the IRRC and the Senate and House standing committees, as well as other interested parties, in the promulgation of a regulation that allows for fair and clear implementation of both the HMO Act and Act 68. These comments are submitted in furtherance of that, and I am happy to answer any questions or comments you have.

Sincerely,

Sam Marshall

Samuel R. Marshall

c: Robert Nyce, Executive Director
Independent Regulatory Review Commission