Stacy
00-01-179

Pennsylvania Chapter of the
American College of Cardiology

Facsimile Cover Sheet

To: Stacy Mitchell
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From: Jessica Judy
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Date: 1/18/2000
Pages including this cover page: 5

Comments:

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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.

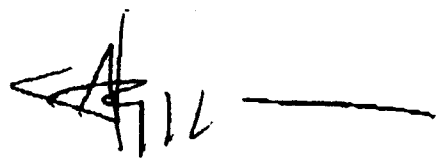
9.677 Requirements of Definitions of "Medical Necessity."

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 primarliy 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

P.01

TRANSACTION REPORT

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January 18, 2000

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

Dear Director Mitchell,

AARP, an organization representing 1.8 million Pennsylvanians over the age of 50, would like to take this opportunity to comment upon the Department of Health's draft regulations to implement Act 68 of 1998, concerning managed care organizations.

There are a number of concerns we have with the draft regulations we wish to comment upon. They are as follows:

Criteria for Getting a Certificate of Authority

We are concerned that the process for receiving a certificate of authority is not stringent. We have a particular concern that a Board of Directors with 1/3 its members being enrollees of the plan need not be in place for first 18 months of operation. We feel it is critical that managed care organizations are held accountable for their actions from their initial date of operation - any delay in this accountability is unacceptable.

No assurance of adequate network

We feel there is a lack of standards for numerous issues. Several states have passed laws and issued regulations which establish the standards that an adequate network must meet. This oversight in the draft regulations again brings up the issue of accountability - without the additional regulations which define standards there is little accountability for managed care plans.

Limited plan oversight by DOH

The review process is flawed in that there is a perception that it is not an independent review. The managed care plan should not determine the scope of external reviews - this should be an independent process directed by Department of Health guidelines. Corrective action must be guaranteed if the review finds problems, and this is not spelled out by the draft regulations. The public should also have access to these external reviews in a format which is understandable and provides a basis for consumers to compare plans.

Medical Necessity

This draft eliminates language from the Department of Health's initial draft regulations 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." AARP is insistent that the definition of medical necessity be based on national standards of practice, and that this language be included in the final regulations.

Quality Assurance Standards and Reviews

Quality is critical to managed care plans. It is fundamental that quality be defined in these regulations, but there are no specific standards or outcome measurements to define quality in these draft regulations. No standards are set relating to quality improvement and health outcomes. In addition, reviews are set at an interval of 3 years. This is far too long an interval - annual reporting is a necessity.

Drug Formulary Disclosure

Although a plan is required to disclose the existence of any restrictive drug formulary, and to disclose whether a specific drug is covered within 30 days of a written request of an enrollee, this disclosure requirement is not extended to potential enrollees. It is critical that consumers shopping for a managed care plan know what drugs are covered by that plan.

Data Collection, Review and Dissemination by DOH

Stronger data reporting collection requirements are needed. The comparison of plan data is critical to consumers. The data should include a consumer satisfaction survey, and it is also critical that the complaint and grievance information be provided in a standard format so consumers are able to compare and contrast the plans.

Lack of coordination with Insurance Department regulations

The Insurance Department issued final regulations which they have since withdrawn. Several sections of the Health Department regulations cover the same topics as the Insurance Department regulations. Despite frequent assertions that the two Departments are working closely together, however, these shared sections are drafted very differently, often with conflicts between the versions. Both the Insurance Department and the Health Department should now take the opportunity to truly work together to ensure a consistency in their regulations.

AARP appreciates the opportunity to provide these comments. Please contact Ray Landis at 717-238-2277 for clarification of any of the above comments.

Sincerely,

Ray Landis
Acting State Director

Stacy

00-01-143

3518 N. Third Street
Harrisburg, PA 17110

January 17, 2000

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

Dear Ms. Mitchell:

Thank you for the opportunity to comment on the proposed rulemaking at 28 PA. Code Chapter 9, Managed Care Organizations published in the December 18, 1999 PA Bulletin. The following comments are submitted on behalf of the Disability Budget Coalition, Pennsylvania Coalition of Citizens with Disabilities, United Cerebral Palsy of PA and the Pennsylvania Chapters of the National Multiple Sclerosis Society.

We begin with one general comment. There must be more of an effort to coordinate the Department's regulations with those of the Department of Insurance. There are several areas in the proposed regulations which are inconsistent or in which one Department includes more detail than the other. From the consumer, provider and insurer perspectives, it is critical that the regulations be consistent.

Section 9.653 Use of co-payments and co-insurance: The regulations only provide for DOH review upon request by DOI. We believe that the regulations should contain a much stronger statement about the need to limit co-payments to avoid under- treatment. PPO regulations state that co-pays over 20% can result in under-treatment and poor quality care. If the use of percentages is problematic here, another approach should be used to accomplish the same result.

Section 9.672 Emergency Services: In subsection (c), we believe that the word "may" should be changed to "shall". Application of the prudent layperson standard should not be optional. Other provisions, like those about payment for ambulances, are helpful.

Section 9.673 Plan provision of prescription drug benefits: There are a number of positive parts of this section which we support—requirements on disclosure of drugs on the formulary with time limits and recognition that disputes about exceptions to the formularly are grievances.

Section 9.674 Quality Assurance Standards: This section should be amended to include specific standards and outcome measures including consumer satisfaction surveys. It is particularly important that the regulations include measures for those with chronic illnesses and disabilities.

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Section 9.707 External Grievance Process: We support the language in subsection (f) which prohibits plans from selecting a CRE which is "affiliated directly or indirectly with the plan" to do the external review. Some clarification may be necessary regarding the nature of direct or indirect affiliation.

Section 9.709 Expedited Reviews: We strongly support the recognition in the regulations that all cases in which life, health or ability to regain maximum function would be put in jeopardy (both grievances and complaints) would be subject to expedited reviews. The regulations should additionally address how the enrollee appeals a decision to deny an expedited review.

If additional information or clarification on any of these points is needed, I can be reached at 717 234-4195 phone, 234-4146 fax or troth@paonline.com via e-mail. Thank you for this opportunity to comment.

Sincerely,

Terry Roth

Terry E. Roth, Esq.

Section 9.676 Standards for Enrollee Rights and Responsibilities: Again, it would be helpful to include more specifics. At a minimum, subsection (4) should include references to specific provisions of the law, i.e., "including, but not limited to section 2136 of Act 68 on disclosure..."

Section 9.677 Definition of Medical Necessity: Requiring that plan definitions be consistent is positive, but the regulations should go further. An earlier draft of the regulations would have required that plan definitions be consistent with industry standards, not unduly restrictive and not rely solely on the interpretation of the plan or the plan's medical director. At a minimum, such language should be put back in to this section. The previous draft also provided for the CRE doing an external review to look at whether the plan's definition is unduly restrictive. Reinserting that language would be helpful.

Section 9.678 Primary Care Providers: In subsection (e), the provider directory should also indicate pcp's who refuse to allow, perform, participate in or refer for certain health care services on moral or religious grounds (section 2121(e)(3) and 2171).

Section 9.680 Access for Persons with Disabilities: While we don't dispute the language here, which essentially tracts the Act, we would appreciate any additional language that would emphasize the Department's intent to oversee the plans, policies and procedures to ensure compliance.

Section 9.681 Health Care Providers: Subsection (c) provides for going out of network when there are "no providers available". The section should also further define in what circumstances the plan must pay for out-of-network care and the procedure for doing so.

Section 9.682 Direct Access for obstetrical and gynecological care: While the language here is better than the previous draft, it still appears to limit direct access more than the law intended. The Insurance Department's draft regulations at least give specific examples of the types of services requiring prior authorization, rather than relying, as here, on vague terms like "routine" and "non-routine".

Section 9.683 Standing Referrals or specialists as pcp's: The proposed regulation here is stronger than that of the Insurance Department. We appreciate the time limit on responding to requests and the recognition that an appeal of a denial of a request is a grievance.

Section 9.702 Complaints and Grievances: Subsection (c)(3) is a welcome recognition of the need for Departmental intervention when the enrollee believes that the plan has mis-classified the appeal. Language should be added to provide for disclosure of this right.

P. 01

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RACE FOR THE CURE®
National Council of Jewish Women
1620 Murray Avenue
Pittsburgh, PA 15217
412-521-CURE • 412-421-1121 FAX
http://race4cure.lm.com - Race web site
http://trfn.clpgh.org/bcis - Breast Cancer Info Service
Race4Cure@aol.com

5K Run/Walk and 1 Mile Fun Walk to benefit breast cancer screening, education, research and treatment

Mother's Day

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Support RACE FOR THE CURE® as a volunteer throughout the year

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For details on special events and educational forums, call the Race hotline, ext. 25 or check the Race web site

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Breast Cancer Information Service (BCIS)
http://trfn.clpgh.org/bcis

Date: 1/17/00
To: Stacy Mitchell
From: Laurie Moser
Re: Act 68
# of pages (inc. cover): 4

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The Susan G. Komen Breast Cancer Foundation
PITTSBURGH RACE FOR THE CURE.
Presented by JCPenney

January 17, 2000

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

Re: Proposed Regulations to Implement Act 68

Dear Ms. Mitchell:

We at the Komen Pittsburgh RACE FOR THE CURE, a member of the Consumer Health Coalition, are concerned with the proposed regulations to implement Act 68 as published by your office in the December 18, 1999 edition of the Pennsylvania Bulletin.

The most problematic issues are as follows:

Medical Necessity

The DOH has eliminated language from the draft that "a plan shall adopt and maintain a definition of medical necessity which is consistent with national and industry standard definitions of medical necessity, is not unduly restrictive and does not rely on the sole interpretation of the plan or plan's medical director."

OB/ GYN Access

The draft eliminates 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 PB/GYN services considered "routine" but allowing plans to require prior authorization for any "non-routine" procedures.

Health Care Provider Contracts

- The draft 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.

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The Susan G. Komen
Breast Cancer Foundation
5005 LBJ Freeway, Suite 370
Dallas, TX 75244
972•855•1600
972•855•1680 FAX

- In addition, it permits financial disincentive to serve and treat expensive patients by permitting plans to base economic incentives and disincentives on non-risk adjusted factors.
- There is 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.
- Health care providers are deselected at will.
- The new plan 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.

Complaint and Grievance Process

The Fundamental Fairness Guidelines for HMOs previously issued by the Department and currently in place have many excellent consumer protections that are inexplicably not present in the proposed regulations. Listed below are but a few of the concerns:

- The regulations no longer require that plan members be given at least 15 days advanced written notice of the second level complaint/grievance committee hearing
- The regulations do not require plans to make available to the consumer all documentation relating to the consumer's dispute.
- The regulations no longer detail a fair, uniform plan for how compliant and grievance hearings are conducted
- The regulations do not provide for expedited review of complaints, even if the enrollee's life, health or ability to regain maximum function would be placed in jeopardy.

Disclosure of Consumer Rights:

The proposed regulations no longer require plans to advise members of their rights to receive current, complete information from their physician regarding diagnosis and treatment; to emergency services; to receive technical communications which are written in " plain language;" and to request and receive the credentials of any "hands-on" health care provider.

Lack of knowledge if a right negates a person's ability to exercise that right, which effectively eliminates the right.

It is the strong recommendation of the Komen Pittsburgh RACE FOR THE CURE that the regulations be redrafted to reflect the concerns listed above and others raised by the Pennsylvania Health Law Project.

Sincerely,

Laurie S. Moser
Executive Director

Stacy
CC-01-140

TUCKER ARENSBERG, P.C.
ATTORNEYS

Jeffrey Culley (412) 594-5520

January 17, 2000

Stacy Mitchell
Director
Bureau of Managed Care
Pennsylvania Department of Health
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Dear Ms. Mitchell:

Pursuant to the instructions outlined in the Pennsylvania Bulletin, Vol. 29, No. 51, December 18, 1999 regarding rule making for Act 68 of 1998 (the "Act"), we are submitting the following comments on behalf of the Pennsylvania Physical Therapy Association ("PPTA") whom we represent.

Initially, we renew our previous comments regarding the issue of "medical necessity" made to the Department of Health ("Department") on May 28, 1999. In the proposed rule making of December 18, 1999, the Department has required each plan to simply be uniform in the use of its own version of the term medical necessity without providing some guidance on standards that may be referred to in establishing the plans definition of medical necessity.

Analogizing this to the Public Utility Law, it was established so that the utility companies operating in all 67 counties of the Commonwealth could not establish different regulations and rules regarding utility service in those 67 counties. The Public Utility have made these rules uniform to avoid a chaotic application of utility regulations. In the matter of health care, however, it is suggested in these rules that each health plan in Pennsylvania can have its own definition of medical necessity so long as it acts uniformly in applying such definition. How many health care plans are covered by this law?

This will mean that adjacent plans in urban areas in serving the same population could have different definitions of medical necessity and what may be medically necessary in one plan will not be in another plan in the same area. What are consumers to do, shop around based on the most liberal definition of medical necessity? the situation is very problematic because the Act has no definition (despite repeated efforts) of medical necessity. The PPTA believes strongly that even without a specific definition in the Act, the Department has adequate statutory basis with the term medical necessity as used in the Act to establish at least some standards of reasonableness which would apply to each plan's definition in order to promote fairness and some degree of uniformity without a specific statutory provision. It appears that the proposed language of the April 1999 draft rule for Act 68, in fact, went further than the proposed rules for medical necessity of December 18, 1999. If nothing else, at least preserve the guidelines set forth in the draft.

With respect to Section 9.683 dealing with Standing referrals, it appears that the Department has set forth certain guidelines and standards to attempt to achieve some degree of uniformity in this area. The PPTA was concerned in reviewing the April 1999 draft that plans

had no guidance on dealing with this issue. These standards will now be required in establishing the plans policy on standing referrals still leaving the final decision to the plan on any request. One note however, the PPTA believes that the 45 day time limit in which the plan can act as suggested by the proposed rules, should be shortened to 30 days. There is no time set forth in Section 2116(6) of the Act. Based on the need and circumstance of the enrollee, there is no reason why such decision can be made by the plan in 30 days. Early intervention relating to physical rehabilitation, for example, not only promotes timely recovery, but cost saving as well.

A further comment by the PPTA relates to the Grievances under Section 2161 of the Act. The Act provides for the inclusion of either a physician or licensed psychologist at the first and second level of review together with either one or more or three or more individuals, respectively, chosen by the plan. Because the basis for any grievance decision made at these levels must provide the "basis and clinical rationale for the decision" (Section 2161(B)(3) and 2161(C)(4)), which decisions under the definitions of "Grievance" relate to medical necessity and appropriateness, it is very appropriate that a same licensed peer of any health care provider either requesting review or involved in the enrollee's request, to participate in the review. How else can a decision be made requiring the "basis and clinical rationale" without the same licensed peer being involved in the review? It seems clear that that decision made with appropriate input of a clinician of the same license involved in the review would, as a practical matter, provide a better basis to defend a plan's position if appeals were taken. The use of the same license peer would, in most cases, should actually limit appeals saving cost to the system, if the enrollee or provider believed the decision involved deliberation by the same licensed specialty. Further, there is nothing in the statute that would exclude the use of same licensed clinicians in the review process. The proposed rules on grievance review accordingly should be revised to provide such plan standards for individuals participating in the grievance reviews to be chosen by the plan.

Also relating to the grievance procedure proposal, Rule 9.703, is it the intention of (b) to prohibit the provider with obtaining routine advance consent to file a grievance if the consent was not a condition precedent to care? This should be clarified since most providers would normally seek advance consent on such a matter before treatment, but in a way that does not make treatment conditional on obtaining the consent? By having consent to file a grievance on file with the other information covered in this proposed rule, would certainly save time and costs in having the provider track down the enrollee if the provider believed a grievance should be filed.

Insofar as prohibiting billing for services already given under Section 9.703(d) and (e) awaiting a grievance review or a CRE decision, where is the statutory authority to make such a substantive requirement under Section 2161 of the Act or elsewhere? Aside from a lack of clear statutory basis to make such a rule, why should a provider have to be at full economic risk when, (A) the provider (with consent) has filed a grievance because, for example, the plan and/or its reviewers only approved partial payment because it believed the services should have been of shorter duration and (B) the health care system commonly requires disgorgement of

TUCKER
ARENSBERG, P.C.
ATTORNEYS

fees which were not appropriately paid if, in fact, the plans decision to not pay in full was eventually upheld. Making the provider wait through the Act's lengthy statutory appeal procedure for the ability to bill and collect for their services without a clear statutory basis similar to Act 6 of 1990, should not be permitted. Additionally, this proposed rule appears to conflict with prompt payment provisions of the Act.

Thank you for the opportunity to provide these comments.

Very truly yours,

TUCKER ARENSBERG, P.C.

J. Kent Culley

JKC:sg

cc: Paul Rockar, P.T. President, PPTA
Sandra McCuen, P.T., Insurance Reimbursement Specialist
Carol Galletta, P.T., Chair, Insurance Committee

BE-124320:0009-30188

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FAX: 717-705-0947
783-3794

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

FROM: Susan Tachau
Institute on Disabilities/UAP at Temple University
(215) 204-5396

DATE: January 17, 2000

RE: Comments on the proposed regulations to implement Act 68 of 19 [illegible].

4 ~~5~~ pages

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A Commonwealth University

Institute on Disabilities
University Affiliated Program

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January 17, 2000

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

Dear Ms. Mitchell:

Thank you for the opportunity to comment on the proposed rulemaking at 28 PA. Code Chapter 9, Managed Care Organizations published in the December 18, 1999 PA Bulletin.

Comments to the Proposed Regulations to Implement Act 68 of 1998, the Managed Care Accountability Act, published by the Pennsylvania Department of Health, presented by Pennsylvania's Initiative on Assistive Technology, a project of the Institute on Disabilities/a University Affiliated Program at Temple University.

Pennsylvania's Initiative on Assistive Technology (PIAT) is the Commonwealth's statewide, cross-age and cross-disability program under the Assistive Technology Act "AT Act". As specified under the AT Act, PIAT's priority activities include the development, implementation and monitoring of laws, policies, practices, and organizational structures to improve access to assistive technology for all Pennsylvanians with disabilities and older Pennsylvanians.

An assistive technology device is "any item, piece of equipment, or product system, whether acquired commercially off-the-shelf, modified, or customized, that is used to increase, maintain, or improve the functional capabilities of individuals with disabilities" (P.L. 103-218). Assistive technology services are "any services that directly assist an individual with a disability in the selection, acquisition, or use of any assistive technology device" (P.L. 103-218.)

Several years ago, two staff members of PIAT participated in the Special Needs Workgroup that made recommendations to the Departments of Health and Insurance and the Governor regarding managed care within Pennsylvania. The Special Needs

Workgroup was comprised of people representing a broad and diverse spectrum of interests. We are disappointed that the proposed regulations issued by the Department of Health do not adopt more of the recommendations that were built by the consensus of the Workgroup. The final recommendations included: a standard definition of medical necessity, a sound quality assurance plan, disclosure of consumer rights and responsibilities as well as consumer protections, and adequate provider access.

Please note that we support the comments outlined by the Pennsylvania Health Law Project as well as those of the Disability Budget Coalition. Our comments, however, are centered upon the proposed regulations in the above four areas.

1. Requirements of definitions of "medical necessity". The Department of Health removed language that we believe is important from the first draft of the regulations. The first draft required that ("a) A plan shall adopt and maintain a definition of medical necessity which is consistent with national and industry standard definitions of medical necessity, is not unduly restrictive and not rely on the sole interpretation of the plan or plan's medical director. "

That language should be adopted, as well as "Plans must consider information provided by the enrollee, the enrollee's family, the primary care practitioner, as well as other providers, program, and agencies that have evaluated the individual." In addition, any definition of "medical necessity" should at least reference the "medical necessity" definition as employed under HeathChoices.

The previous draft of the regulations also provided for the (Certified Utilization Review Entity) CRE performing an external review to examine whether the plan's definition is unduly restrictive. That language should be reinserted.

2. Health plans are required to have a quality assurance process, but the proposed regulations have no specific standards or outcome measurements. We recommend that all health plans have a quality assurance process and that they are acceptable to the Department of Health. In addition, "The quality assurance plan must include regularly updated standards for health promotion, early detection of disease and injury prevention for all ages, systems to identify special chronic and acute health care needs at the earliest possible moment. These standards shall be made knowr to providers and enrollees. The quality assurance plan must be regularly update with the involvement of providers and members." (PA Health Law Project.) This section should also be amended to include consumer satisfaction surveys.

3. Disclosure of Consumer Rights and Responsibilities as well as Consumer Protections. The proposed regulations no longer require the health plan to provide and notify members of rights such as: the right to get current, complete information on

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 services. The proposed regulations also 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.

Additionally, the regulations should address how the enrollee appeals a decision to deny an expedited review.

4. Provider Access Requirements. The proposed regulations retains the current requirement that hospitals, primary care providers and frequently used specialists be available within 20 minutes or 20 miles in urban areas, and 30 minutes or 30 miles in rural areas. There is no definition of "frequently used specialists", and there are no standards for "less frequently used specialists". There are no standards for providers who are not hospitals, primary care physicians, or specialists -- such as durable medical equipment providers, home health agencies, drug stores.

The proposed regulations must set the same requirements in both urban and rural areas (time and/or mileage) for access to the necessary providers of assistive technology devices and services. Access to these important services should be considered the same as a "frequently used specialist".

We appreciate the opportunity to comment on the Department's proposed regulations to implement Act 68 of 1998, the Managed Care Accountability Act. We hope that our comments will be incorporated into the final draft. We also hope that the two Departments -- Health and Insurance -- will work together in developing and issuing these important regulations.

If you need any additional information or you would like any clarification on any of these points, I can be reached at 215-204-5696.

Sincerely yours,

Susan Tachau

Susan Tachau

Pennsylvania Psychiatric Society

The Pennsylvania District Branch of the American Psychiatric Association

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January 17, 2000

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

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

Dear Ms. Mitchell:

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

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

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

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

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

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§ 9.653 - Use of copayments and co-insurances in HMOs. We appreciate the Department's deletion of the current, confusing regulations in this area. We request, however, that the Department retain the right to establish maximum co-insurance and co-payment amounts. The current wording in this section of the proposed regulations does not seem adequate for carrying out the Department's quality assurance role, since it only allows the Department to "review" proposals for patient payment amounts, and then only at the request of the Department of Insurance. Inasmuch as insurers and plans sometimes set co-insurance amounts as high as 50% for any outpatient mental health treatment, specifically for the purpose of discouraging patients from seeking services, this section of the proposed regulations is an important one and should be re-written to ensure that its stated goals will be met.

§ 9.678 - Primary care providers - If plans are to be allowed to use CRNPs as primary care providers, plans should be required to allow patients to choose a primary care physician, rather than a CRNP, as their primary care provider.

Standards for psychologist reviewers - the relationship of subchapter K, on CREs, to § 9.706, 9.707, and 9.708, is unclear. We assume that a plan must meet the requirements of subchapter K in order to provide review services that may result in the filing of either internal or external grievances. If this is the case, then the reference in § 9.706 (c) (3) (i) to an "approved" licensed psychologist should refer to § 9.743 (d) (2). Alternatively, the language of § 9.743 (d) (2), which describes the statutory limitations on the use of psychologists as reviewers, should be repeated in § 9.706, § 9.707, and § 9.708.

Use of psychologist reviewers - the proposed regulations should clarify that psychologists performing medical necessity review can only deny services provided by or proposed to be provided by a non-physician provider. Although the statute and the regulations specify that they may not review grievances involving inpatient treatment or prescription medicines, we would note that a physician's decision to treat a mental health patient without a prescription is based on the same analysis of the patient's clinical state, including laboratory tests, prescriptions prescribed by other physicians for other conditions, or the patient's desire to avoid medication if possible - all of which complicate the prescribing picture. In other words, a physician's treatment of a patient almost always involves the potential for prescribing medications, the need for which is constantly under examination. As psychologists do not have medical training, their denial of a physician service on medical necessity grounds is outside of their scope of practice, and is an intrusion into the physician's responsibility to determine whether or not medication is appropriate at any one time. For a physician, the decision not to prescribe is as dependent on medical training and experience as the decision to prescribe.

§ 9.708 (d) - this paragraph dealing with reviewer qualifications for external reviews is confusing because it seems to allow a lower standard for external reviews than that required for internal reviews. Specifically, it would allow, in (d) (2), a physician practicing ANY specialty, if he or she is in active clinical practice, to deny care proposed by a physician in a dissimilar specialty. Inexplicably, this is provided as an option to (d) (1), which would require not only that the reviewer be in the same specialty, but be board-certified. We believe, based on discussions with people involved in drafting the bill, that the problem stems from a simple but critical drafting error. We believe that the statute was intended to offer as an alternative to board certification in the same or similar specialty a combination of active clinical practice and the same or similar specialty, without board certification. Such an alternative would make this section consistent with the standards for internal grievances, which, in § 9.706.(c) (3), requires same or similar specialty at both the first and second level. The addition, rather than the substitution, of active clinical practice for external reviews is the only interpretation that makes sense to us, both in relation to the internal reviews and the external review option provided in § 9.708 (d) (i).

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

Sincerely yours,

Gwen Yackee Lehman/dnd

Gwen Yackee Lehman
Executive Director

Facsimile Cover Sheet

To: Stacy Mitchell, Director
Company: Bureau of Managed Care – DOH
Phone: 717-787-5193
Fax: 717-705-0947

From: Gwen Yackee Lehman
Company: Pennsylvania Psychiatric Society
Phone: 717-558-7750, ext. 1473
Fax: 717-558-7845

Date: January 17, 2000
Pages including this cover page: 4

Comments:

Fed Ex

Stacy
CO-01-119

Pennsylvania Coalition of Nurse Practitioners
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Berks County NPs
Bucks/Mont. Counties NPs
Central Pennsylvania NP Association
Ches./Mont. NP-PA Group
DelVal NAPNAP
Lehigh Valley NP Group
Mid State NP Association.
Northeast Pennsylvania Coalition of Primary Care NPs
Northwestern Pennsylvania NP Association
NPs of South Central Pennsylvania
NP Association of Southwest Pennsylvania
Philadelphia Area NP Association.
Three Rivers Chapter of NAPNAP

January 17, 2000

Stacy Mitchell, Director
Bureau of Managed Care
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17109-0090

Enclosed are the comments of the Pennsylvania Coalition of Nurse Practitioners regarding proposed rulemaking for the Department of Health-28 PA Code Ch 9 Managed Care Organizations.

The Pennsylvania Coalition consists of the thirteen Nurse Practitioner organizations in the Commonwealth of Pennsylvania. They are:

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Sandusky
Wyatte

Berks County NPs
Bucks/Mont. Counties NPs
Central PA NP Association
Ches./Mont. NP-PA Group
DelVal NAPNAP
Lehigh Valley NP Group
Mid State NP Association
Northeast PA Coalition of Primary Care NPs
Northwest PA NP Association
NPs of South Central PA
NP Association of Southwest PA
Philadelphia Area NP Association.
Three Rivers Chapter of NAPNAP

Sincerely,

Jan Towers

Jan Towers, PhD, CRNP
Chair

JFT/mln

Comments on Proposed Rule Making

Department of Health-28 PA Code Ch 9

Managed Care Organizations

Subchapter F. GENERAL

Section 9.602 Definitions

Emergency Services: We endorse the proposed definition of Emergency Services that includes the provision of ambulance services based on prudent lay person judgement.

Gatekeeper: Stated in the manner of the proposed rule, this definition at first blush broadens the ability of the program to refer or approve services . However it is not clear how the reverse situation would play out in the area of denial of referrals or services without the input of a health care provider. Should not the gatekeeper at least be a health care provider as defined in this section?

Grievance: Given the separation of complaint and grievance characteristics later in the proposed rule, it would seem prudent to remove the word "solely" from section (i), so that patients or providers who file grievances that might contain complaints or other issues will not be denied the grievance process because the grievance is not "solely" concerning medical necessity. While this obviously is not the intent of the language of the proposed rule, there is the potential for misuse of this rule the way it is currently stated.

Primary Care Provider: While we would prefer to see the words "nurse practitioner" listed in this definition, we accept the language as you have proposed it.

Section 9.604 Plan Reporting Requirement

(6) We notice that you are requiring a statement of the number of physicians leaving and joining the plan, but do not include any other group of providers. It would seem that keeping track of all primary care providers and specialists, if not all health care providers, would be needed in the annual report.

In addition, it was our understanding that HEDIS outcome criteria would be used for evaluation purposes, but we see no evidence of such criteria in the proposed rules. Likewise the reporting of complaints and grievances seems to be missing. Will this information reach the Health Department Records through other processes and therefore not be required in annual or quarterly reports?

Section 9.678 Primary Care Providers

(d) We endorse the language regarding the inclusion of CRNPs as primary care providers in managed care plans. This will make significant contributions in the areas of access, quality of care and cost effectiveness.

(b) (4) The language appropriately allows for alternative arrangements for admitting an enrollee "approved by the plan". What protections are provided so that plans cannot discriminate against a provider under these circumstances?

Section 9.706 Enrollee and provider grievance system

(3) (I) It unclear why the grievance committee requirements do not include the inclusion of a peer of the health care provider sponsoring the grievance as well as a physician or a psychologist. While it is acceptable to have these members of the health care team as a part of the committee, it would also seem that professional peers would be useful for the fair and equitable execution of decisions brought to the grievance committee and would reduce the potential for discrimination if the grieving provider is not of the same professional orientation or specialty as the designated physician or psychologist.

Section 9.707 External grievance process
(I) There seems to be a biased disincentive to health care providers to seek an external grievance in this section, since their ability to assume the payment of fees and costs associated with an external grievance (unless very minimal) will be far less than managed care programs if they are not the prevailing party. This needs to be examined to determine a more equitable penalty process.

Section 9.708 Grievance reviews by CRE
(d) (1) Again the absence of provider peer review is evident and should be corrected. A health care provider with the same professional preparation should be included in this group.

(d) (2) This section poses the same problem and should include an actively practicing health care provider with the same preparation as that individual who is grieving.

In both cases above, the physicians or psychologists could still make up the majority of the committee, but representation from the grieving provider's profession would also be present for input. This should diminish, at least, any possible bias based on the grieving party's professional preparation in the decision making process in each case being reviewed.

Section 9.743 Content of an application for certification as a CRE

(d) This section is unclear in light of the previous proposed regulations regarding committee decisions and does not reflect the input of peer review of the health care providers grievance.

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Pennsylvania Community Providers Association

Fax

To	Stacy Mitchell Department of Health	**From:**	C. Lu Conser, MPH Director of Government Relations
Fax:	705-0947	**Pages:**	3
		Date:	01/18/00

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PENNSYLVANIA COMMUNITY PROVIDERS ASSOCIATION
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January 17, 2000

Stacy Mitchell, Director
Bureau of Managed Care
Pennsylvania Department of Health

MESSAGE BY FAX
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Dear Ms. Mitchell:

Thank you for this opportunity to offer comments on the proposed rulemaking at 28 PA Code Chapter 9, Managed Care Organizations, published in the December 18, 1999 PA Bulletin. The following comments are submitted on behalf of the Pennsylvania Community Providers Association, a trade association representing over 200 community-based agencies that provide mental health, mental retardation, substance abuse, and other human services to almost 1 million Pennsylvanians every year.

General Comments
We urge that the Departments of Health and Insurance withhold final rulemaking until such a time as they have more closely coordinated their separate regulations. The current regs offered by the two Departments have a number of inconsistencies and conflicts, and may set up a regulatory minefield through which it will be difficult to navigate.

We are very concerned that Section 9.39 (*Standards for Provision of Mental Health and Substance Abuse Services)* of the draft regulations as issued in 1999 (my copy is dated April 30, 1999) has been deleted from the current regulations. Behavioral health services have always a problem for managed care entities because of their chronic nature, communication difficulties, prejudice, and the need for experienced providers of service. We urge the Department in the strongest terms to reinsert Section 9.39 in the final regulations.

The Department of Health's regulations seem to focus more on process than outcome, and we believe that this does not serve Pennsylvania's citizens. Rather than setting standards, the Department has set up procedures such that, if followed by a managed care entity, will place the plan in compliance. This does not address the need to set standards or invoke already existing national standards or benchmarks. We urge the Department to be more proactive in assuring that quality services will be provided, not just that procedures will be followed.

Specific Provisions
Section 9.672 Emergency Services: In subsection (c), we believe that the word "may" should be changed to "shall". Application of the prudent layperson standard should not be optional.

Section 9.674 Quality Assurance Standards: This section should be amended to include specific standards and outcome measures, including consumer satisfaction surveys. Nationally recognized standards are available, and it is imperative that the state provides a benchmark for plans to meet. It is particularly important that the regulations include such measures for those with chronic illnesses and disabilities.

Section 9.677 Definition of Medical Necessity: This definition is the sieve through which managed care decisions are filtered, therefore, it is important that this be clearly defined. An earlier draft of the regulations required that the plans' definitions be consistent with industry standards, not unduly restrictive, and not based solely on the interpretation of the plan or the plan's medical director. At a minimum, such language should be put back in to this section. The previous draft also provided for the CRE doing an external review to look at whether the plan's definition is unduly restrictive. Reinserting that language would be helpful.

Section 9.680 Access for Persons with Disabilities: We urge the Department to add language that would emphasize its intent to oversee the plans' policies and procedures to ensure compliance. The Pennsylvania Community Providers Association's members serve persons with mental and physical disabilities. Persons, particularly those with understanding or communication difficulties, must be assured an equal and adequate access to healthcare. The Department's active oversight in this area is essential.

Section 9.681 Health Care Providers: Subsection (c) provides for going out of network when there are "no providers available". The section should also further define the circumstances under which the plan must pay for out-of-network care and the procedure for doing so.

Section 9.709 Expedited Reviews: We strongly support the recognition in the regulations that all cases in which life, health, or ability to regain maximum function are put in jeopardy (both grievances and complaints) must be subject to expedited reviews. The regulations should additionally address how the enrollee appeals a decision to deny an expedited review.

The Pennsylvania Community Providers Association appreciates the Department's efforts on behalf of the citizens of the Commonwealth, and we hope that these comments will help to improve the safeguards that Act 68 was designed to assure. If you wish any additional information, please contact me.

Sincerely,

C. Lu Conser

C. Lu Conser, MPH
Director of Government Relations

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Pennsylvania Community Providers Association

Fax

To	Stacy Mitchell Department of Health	**From:**	C. Lu Conser, MPH Director of Government Relations
Fax:	705-0947	**Pages:**	3
		Date:	01/18/00

Stacy
00-01-197

NAMI Pennsylvania

Pennsylvania's Voice on Mental Illness

Formerly The Alliance for the Mentally Ill of Pennsylvania

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January 17, 2000

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

RE: Comments on the Proposed DOH Regulations to Implement Act 68 of 1998

Dear Ms. Mitchell:

In this correspondence, we are registering our grave concern and objections to the Proposed Regulation to Implement Act 68 of 1998, the Managed Care Accountability Act.

It is unconscionable that the State of Pennsylvania will turn its back on its citizens with these most egregious proposed regulations. The State shall not walk away from its regulatory and oversight responsibilities in such a laissez faire manner. We have significant concerns with the following:

It appears that there is very limited oversight of the plan by DOH and that DOH will depend on external review by a firm or accrediting body hired by, paid for by the plan with plan determining the scope of the review. (9.674) The proposed regulation does not specify the Utilization review shall be performed by a certified utilization entity.

DOH appears to require only a "process" not actual standards that ensure quality. DOH is not involved in the determination of quality standards or in the evaluation of quality. (9.674)

There is no requirement for a plan to provide treatment "outcome" measures. DOH does not require what those "outcome measures" are to be. Without a means to establish quality "outcome", how do you ensure quality? (9.674)

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There is no requirement for the definition of "medical necessity" that is consistent with national and industry standards. (9.677)

The Proposed Regulations fail to ensure timely access to specialists for both acute and long-term disease management of brain diseases such as schizophrenia, affective disorders, psychotic disorders, etc. "Best Practice" standards require access to an array of medically necessary medical and rehabilitative treatments. The proposed regulations do not require the plan to notify or seek DOH approval of its policy, procedure, and clinical criteria and any amendments for referral. There is no provision for an expedited review of denial of specialists. (9.683)

Disclosure of Drug Formulary and the process to obtain prior authorization or an exception shall be extended to both potential enrollees and enrollees. For potential enrollees, classes of disease specific medications shall be provided immediately upon request, verbal or written. Marketing material must clearly state potential restrictions, requirement for prior authorization, and the procedure for exception. Current enrollees shall receive the same information upon verbal or written request. (9.673)

There should be provision for an expedited review process for matters which do not involve issues of medical necessity, but which, if not resolved more quickly would jeopardize the members life, health or ability to regain maximum function.

Under the pre-Act 68 DOH Operation Standards, disputes regarding denials of care which as alleged to be necessary and pressing were required to be decided by the plan in 48 hours, regardless of whether the issue was one of medical necessity. This member protection needs to be included in the DOH regulations.

The Definition for Enrollee is too narrow and fails to include representatives of those members who are incapacitated or incompetent to be able to act on an enrollees behalf to file a grievance or complaint, receive information on drug formularies (9.673), for requesting a referral and standing referral or a specialist as PCP (9.683), and to be able to act on an enrollee's behalf to obtain continuity of care (9.684).

The Definition for a Grievance should include the word "solely".

Fails to require disclosure of basic services to potential enrollees. (9.652)

Fails to review and monitor copayments, to set maximum limits, and to periodically update and disclose copayments to potential enrollees and enrollees.

In summary, we do not support the proposed regulations as written and, in view of the number and seriousness of our objections (of which, there are many more than stated in

the above), we strongly recommend an extensive rewrite and second submission for public comment. Thank you for the opportunity to comment.

Sincerely,

Mary Ellen Rehrman

Mary Ellen Rehrman
Director of Policy

cc: Senator Harold F. Mowery
Senator Vincent J. Hughes
Senator Tim Murphy
Representative Dennis M. O'Brien
Representative Frank L. Oliver

NAMI Pennsylvania is the largest family-based mental health membership organization in Pennsylvania. Our mission is to improve the quality of life and quality of services for mental health consumers and their families. More than 6,000 individuals are members of NAMI Pennsylvania from more than 60 affiliates throughout the Commonwealth.

000117

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January 17, 2000

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12:33 p.m.

Stacy Mitchell, Director
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Pennsylvania Department of Health
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Harrisburg, PA 17108-0090

Re: Proposed Managed Care Organization Regulations

Dear Ms. Mitchell:

This firm has been engaged to represent five health systems operating in the Delaware Valley area (collectively, the "Systems") and The Delaware Valley Healthcare Council of The Hospital & Healthsystem Association of Pennsylvania ("DVHC"). We appreciate this opportunity to comment on the Pennsylvania Department of Health's (the "Department") proposed Managed Care Organization Regulations published in the *Pennsylvania Bulletin* on December 11, 1999.

The Systems and DVHC fully support the comments to the proposed regulations submitted by The Hospital & Healthsystem Association of Pennsylvania ("HAP"). We believe that it is of utmost importance for the Department to adopt HAP's suggested modifications so that the resulting regulations properly reflect the meaning and intent of the Quality Health Care Accountability and Protection Act of 1998 (also known as "Act 68") the Health Maintenance Organization ("HMO") Act, and other laws governing managed care plans and HMOs in the Commonwealth. In particular, we wish to emphasize the critical nature to the Systems and DVHC of two issues raised by HAP:

1. Proposed §§ 9.672 (Emergency services) and 9.681 (Health care providers)/Coverage for Services Provided by Nonparticipating Providers

There are significant inconsistencies between the proposed regulations and comments made by the Department in its introductory summary of the proposed regulations that must be rectified in the preamble to the final-form regulations.

Proposed § 9.672 requires a managed care plan to cover medically necessary emergency services provided by a health care provider that does not participate in the plan's network "at the same level of benefit" as that provided by a participating provider. However, the Department's summary suggests that under this section, the plan must pay for services provided by a non-participating provider "at the same rate" as it pays to a participating provider.

The Department's summary comments completely misinterpret the regulatory requirement and Act 68's intent. The regulatory requirement appropriately requires that enrollees receive the "same level of benefit," i.e., the same type of coverage, at a nonparticipating provider as is provided within the network. The Department's comments address a different issue -- the rate paid to a nonparticipating provider for an emergency services. In effect, the Department suggests the creation of a "default rate" for non-participating providers, a notion which is unworkable, unfair, and not authorized by statute. A "default rate" assumes that only a single payment rate for emergency services exist. However, every participating provider may negotiate a different contractual rate with a given plan. Requiring the establishment of one payment rate would undermine the plans' and providers' ability to freely and fairly negotiate rates and other contract conditions. It also prohibits institutions that are not under contract with a plan from appropriately billing their charges, without statutory authority.

There is a similar error in the Department's comments to proposed § 9.681. That section requires a plan to cover services provided by a nonparticipating provider which are not available through the plan's network "at the same level of benefit" as those provided by a participating provider. According to the Department's comments, this section requires that a plan provide coverage for health care services that are not available within the network and are provided by a nonparticipating provider "according to the same terms and conditions" as those provided by a participating provider.

The language of § 9.681 clearly intends that if an enrollee is required to seek services out-of-network, he or she will receive the same type of coverage as would be provided by a participating provider. In the summary, the Department's phrase "the same terms and conditions" suggests that something more or other than benefits are at issue. In particular, the phrase could be construed to apply to payment terms and to create another "default rate" for nonparticipating providers. As with the Department's interpretation of the § 9.672 discussed above, this interpretation would be untenable for providers.

For the above reasons, the preamble to the final-form regulations must clarify that neither §§ 9.672 nor 9.681 addresses the rates of payment to nonparticipating providers.

2. Proposed § 9.703 (Health care provider initiated grievances)/Enrollee Consent

Proposed § 9.703(a) states broadly that a provider may file a grievance if it obtains the enrollee's consent. The regulation must provide more guidance in this area, which is of extreme importance to providers.

This section must state clearly that a provider may obtain consent at the time of treatment. It is common for a provider to render a service, which is subsequently determined by the plan to not be medically necessary, and payment is denied. If the provider has not obtained a consent to file a grievance from the enrollee at the time of treatment, it may be difficult, if not impossible, to obtain one after treatment. Without the consent, the provider is unable to challenge the denial through the grievance process.

Also, the section must include the contents of a proper consent to file a grievance form and a statement that a provider may use any consent that contains the appropriate elements. Plans maintain varying consent form requirements. Some plans are rejecting consent forms created by the provider. This forces the provider to obtain a new consent from the enrollee, thereby confusing the enrollee and delaying the resolution of the claim. A list of required elements for a consent form would obviate this problem.

The Systems and DVHC believe that the foregoing changes, and all others raised by HAP, are necessary to the implementation of effective Managed Care Organization regulations pursuant to Act 68, the HMO Act and other pertinent laws.

Sincerely,

Harry Madonna/mcb

HARRY MADONNA

Stacy
00-01-14

HIGHMARK

January 17, 2000

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Ms. Stacy Mitchell, Director
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PO Box 90
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Re: Proposed Managed Care Organization Regulations

Dear Ms. Mitchell:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

C. M. (Candy) Gallaher
Regulatory Affairs Director

CMG:cjp

Attachment

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

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

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

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

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

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

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

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

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

05511

TO: Stacy Mitchell, PA Department of Health
FROM: Janet Schlesinger, Consumer Health Coalition Board
RE: Implementation of Regulations of Act 68

As a member of the CHC Board, Chair of the Health Care Committee of the League of Women Voters of Greater Pittsburgh and involved in the field as teacher and advocate, I have reviewed the recent proposals inplementing Act 68 and have concluded the following:

Serious questions arise regarding both the language and process of the act, in such areas as -

1) Basic Definitions
2) Conflicts of Interest
3) Complaint/Grievance Procedures
4) Disclosure of Patient Rights
5) Subcontracting
6) Coordination with Other Agencies
7) Implementation
8) Standards
9) Review Procedures
10) Public Access to Records

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Sandusky
Wyatte

The comments below illustrate, in part, the omissions and shortcomings of the most recent regulations.

1) Basic Definitions
"Medical Necessity", a major concept, must be as precise and clear as possible, not open to confusing interpretations. Other uncertainties exist in defining an 'adequate network' or specialties, whether adult or pediatric. Importantly, there should be a requirement to include all critical input from the patient, PCP and other providers in formulating the level of necessity. No definition of "adequate network".

2) Conflicts of Interest
The health field is rife with opportunities to maximize or minimize care to the financial advantage of caregivers. The rules do not explicitly limit or deny such impropriety. The boards of HMO licensees can tap their own employees to receive a certificate of authority.

3) Complaint/Grievance Procedures
Previously-accepted Fundamental Fairness Procedures, are not included, e.g. availability of all documents. and 15 day advanced written notice of second level hearing.

4) Disclosure of Rights
Serious omissions permit the plans to avoid advising patients to get complete and current information from physicians on diagnosis, treatment, emergency service, non-technical notes, and the credentials of direct providers.

5) Subcontracting
The absence of controls on subcontracting is especially troublesome. Almost all functions can be assigned to unlicensed organizations or service providers. This invites uneven quality control. Licensed HMOs can subcontract many functions to an unlicensed entity, putting it at risk with minimal protections for important functions such as credentialing and quality assurance.

6) Coordination With Other Agencies
DOH will review the impact of copayments on access, continuity of care, quality and cost-effectiveness, only on the request of the Department of Insurance. Legislative and executive rulings also differ according to varieties in governmental structure and functions. Insurance Dept. regs have been withdrawn with duplication of some DOH rules, notably in access to obstetrical and gynocological care, standing referrals on PCPs, specialists, and continuity of care. .

7) Implementation
Lack of DOH readiness review on intention, staff adequacy, quality assurance or communication before enrollment. No access norms for appointments. Importantly, delegation of general medical management upon prior approval by DOH, but without explicit standards for utilization review in an integrated delivery system,

8) Standards
No standard for ownership related to experience or management
No on-site inspection by DOH, adequacy of network, outcome measurements, quality improvements or minimal PCP training.

9) Review Procedures
General absence of verification of adherence to time lines, no expedited complaint review or HEDIS data,

10) Public Access to Records
Weak regulations on details of tracking formularies, complete health charts and staff credentials, Particular problems related to complaint and grievance openness and access for patients, families and public or non-profit groups.

January 15, 2000

Stacy
00-01-211

EASTON HOSPITAL
A member of Valley Health

January 15, 2000

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

ORIGINAL: 2079
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Sandusky
Wyatte

Dear Ms. Mitchell:

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

The Administration and Board of Trustees at Easton Hospital would like to commend the Department of Health for the following requirements established in the proposed regulations:

- Establishing plan reporting requirements that will help ensure effective oversight as well as provide the public with data on plan practices.
- Requiring that all definitions of medical necessity by a health plan be the same across all documents (e.g., marketing literature, patient handbook. provider contracts. etc.) to ensure uniformity and consistency of medical decision making.
- Enabling managed care plans to create mechanisms for routine procedural errors and denials to be addressed between the plan and the provider without the need for enrollee consent.

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

- Clarifying standards for ensuring that enrollees receive the same benefit level for either emergency services provided by non-participating providers or services for which there are no participating health care providers capable of performing the needed service. These standards should not dictate provider payments in these situations. The way theses provisions are described in the preambic goes beyond the scope of both the HMO Act and Act 68. Establishing payment standards would interfere in the contracting processes between health plans and health care providers

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

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

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

Sincerely,

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

Fed Ex

00-01-133

AIDS Law Project of Pennsylvania

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a non-profit,
public interest
law firm

January 17, 2000

Stacy Mitchell, Director
Bureau of Managed Care
Pennsylvania Department of Health
911 Health and Welfare Building
7th and Forster Streets
Harrisburg, PA 17108-0090

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VIA FEDERAL EXPRESS

RE: Proposed Regulations to Implement Act 68

Dear Ms. Mitchell:

On behalf of the Working Group on HealthChoices and HIV, a coalition of almost 50 AIDS service organizations in Southeastern Pennsylvania, I am writing to voice our very strong concerns regarding DOH's proposed regulations to implement Act 68.

We believe that these proposed regulations will endanger the lives of all Pennsylvanians enrolled in managed care. Act 68, the Managed Care Accountability Act, was enacted as a way of protecting Pennsylvanians from poor health care from managed care plans. The proposed regulations remove these protections and instead establish policies that will almost certainly ensure poor care.

People with AIDS who receive care from experienced practitioners live twice as long as those who do not. The regulations as proposed will effectively diminish the ability of people with AIDS to receive life-prolonging care.

Listed below are those regulations which we believe present the greatest risk to people living with AIDS and other medically vulnerable populations.

Specifically:

* The regulations do not require PCPs to be trained and experienced in primary care medicine. People with HIV are highly susceptible to a variety of opportunistic infections, many of which are life-threatening if not treated promptly. If a provider, not trained in primary medicine, fails to diagnose or properly treat one of these infections, the consequences can literally be deadly.

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* Physicians may now receive up to 51% of their total payment in bonuses and other compensation which can be linked to low utilization. This puts the physician in a conflict of interest with his or her own sick patient.

* HMOs are no longer required to inform current members that the list of available providers has been strictly limited. Consequently, members will not know whether they have access to doctors who may be more expensive but who could be of greater help.

* HMOs are not required to inform potential members that the list of drugs available to them will be strictly limited. Patients could unknowingly enroll in a plan that does not cover life-saving medication that they take regularly.

* The regulations contain no maximum doctor/patient ratio. In the absence of a ratio, it would be permissible for one physician to treat 5,000 patients.

Accordingly, we request that DOH revise the proposed regulations to render them consistent with Act 68's original intent of accountability and oversight. We welcome the opportunity to provide additional comment and hope DOH will heed our suggestions in the interest of securing the best healthcare for all Pennsylvanians.

Sincerely,

Ronda B. Goldfein
Senior Staff Attorney

On behalf of the Working Group on
HealthChoices and HIV
(membership list attached)

Organizational Participants in the Working Group on HealthChoices and HIV

AARP, State Legislative Committee
ActionAIDS
AIDS Activities Coordinating Office, Philadelphia Department of Public Health
ACT UP/Philadelphia
AIDS Information Network
AIDS Law Project of Pennsylvania
APM (Associacion de Puertorriquenos en Marcha)
ASIAC (AIDS Services in Asian Communities)
BEBASHI (Blacks Educating Blacks About Sexual Health Issues)
Cancer Patients Legal Advocacy Network
Ches-Penn Health Services
Children's Hospital of Philadelphia
CHOICE
Circle of Care
Colours Organization, Inc.
Community Behavioral Health
Congreso de Latino Unidos
Critical Path AIDS Project
CVS ProCare
Esperanza Health Center
Family & Community Services of Delaware County
Family Service Association of Bucks County
Family Services of Chester County
Family Services of Montgomery County
GALAEI (Gay and Lesbian Latino/a AIDS Education Initiative)
Health Federation of Philadelphia
Inglis Innovative Systems
Jonathan Lax Treatment Center
Minority AIDS Project of Philadelphia and Vicinity
North Philadelphia Health Systems
Office of Mental Health and Mental Retardation, Philadelphia Department of Public Health
Philadelphia Association of Retail Druggists
PCASO (Pennsylvania Coalition of AIDS Service Organizations)
Philadelphia Community Health Alternatives
Philadelphia EMA Planning Commission
Philadelphia FIGHT
Planned Parenthood of Chester County
Project Hope
Project TEACH
St. Christopher's Hospital for Children
St. Joseph's Hospital for Children

Temple University Hospital
The Philadelphia AIDS Consortium
Unity, Inc.
Valley Forge Medical Center
We the People with HIV/AIDS of the Delaware Valley

8001163

PENNSYLVANIA
CHIROPRACTIC
ASSOCIATION

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January 14, 2000

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

RE: Comments of Pennsylvania Chiropractic Association to Proposed Rulemaking
Re: Managed Care Organizations, Saturday, December 18, 1999
Volume 29, Number 51

Dear Ms. Mitchell:

Please be advised that I serve as Executive Vice President of the Pennsylvania Chiropractic Association, a nonprofit organization established for the purpose of advancing the interests of doctors of chiropractic and the health care of Pennsylvania residents. We have had an opportunity to review the proposed rulemaking set forth in the Pennsylvania Bulletin on December 18, 1999, and pursuant to the invitation to submit written comments in response to those proposed regulations, we ask that you accept the following as the suggestions and objections of the Pennsylvania Chiropractic Association ("PCA").

Initially, the PCA wishes to compliment the Department for amending its definitions of gatekeeper, health care provider and primary care provider. The doctor of chiropractic has long been a portal of entry, direct access health care providers who evaluate, diagnose, refer and/or treat without necessity of a gatekeeper, a process that has been in place since the early part of the preceding century. Chiropractors are indeed well trained in the art of diagnosis, evaluation and assessment, yet the doctor of chiropractic brings a completely unique and clinically proven supplemental benefit to the health care delivery system; i.e., the chiropractic adjustment or manipulation. The efficacy of chiropractic has been established by studies unwritten by the federal government, studies undertaken in various states, and studies conducted by a host of nonprofit/unbiased research entities and foundations. No other health care profession provides a scintilla of education or clinical training dealing with the application of chiropractic adjustment or manipulation. Conditioning enrollees' access to chiropractic care *de facto* restricts unreasonably enrollees' rights to receive immediate and necessary care which, in many cases, if not obtained, results in a slower return of the enrollee to improved health and well being.

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17102

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717.232.8368

In this regard, your attention is directed to proposed Sections 9.678 relating to primary care providers and Section 9.682 relating to direct access for obstetrical and gynecological care. As to the former section (Section 9.678), the PCA respectfully requests that the Department consider including a doctor of chiropractic as a primary care provider who may serve as a supervisor and coordinator of the health care for the enrollee. Given the expansion of "primary care provider" from "physician" to physicians and others, including certified registered nurse practitioners, the Department justifiably understands that direct access providers other than physicians can and, in fact, do perform initial evaluation and management determinations. As doctors of chiropractic have long been doing this, we respectfully request that Section 9.678 be amended to include doctors of chiropractic as authorized primary care providers for purposes of these regulations.

Alternatively, we believe Section 9.682 should be expanded to provide for all direct access for chiropractic services. Whereas the logic for permitting direct access for obstetrical and gynecological care makes sense and ensures prompt access for the female enrollee, enrollees' access to immediate chiropractic care is likewise appropriate. Nearly every study dealing with chiropractic care underscores strongly that chiropractic care is most beneficial immediately following the onset of injury, trauma, or other symptomatology. Indeed, it is during the acute and sub acute phases that chiropractic care can and does provide the most beneficial care, which an ailing or injured enrollee may receive. The PCA is not suggesting that the doctor of chiropractic should secure unfettered discretion in terms of his treatment of any enrollee of an HMO but only that direct access should be permitted subject to reasonable regulatory/monitoring oversight of the HMO and/or its gatekeeper and/or its delegated medical management team.

Finally, although no section deals specifically with our third comment, PCA respectfully requests that any HMO approved by the Department be required to include chiropractic as a specialty, which is available to its enrollees. Historical discrimination is clear – HMOs and other managed care entities, for reasons which are unclear to our profession, have repeatedly refused to either include access to doctors of chiropractic and/or have advised the enrollee that she (the enrollee) can receive the "same" care from an osteopathic or allopathic physician as he could receive from a doctor of chiropractic. With all due respect for the profession of osteopathic and allopathic medicine, this is simply not true as a matter of fact, historical data, actual practice, and clinical training and education. We, therefore, respectfully request that the regulations be modified to make clear that chiropractic care is a mandated care which must be made available within any HMO and that the doctor of chiropractic is the sole provider whose credentials, training, education, experience and license permit the application of the quintessential principle associated with chiropractic care (i.e., the adjustment or manipulation of the spine and related articulation).

On behalf of the PCA, I thank you for the opportunity to present these comments and suggestions. If you would like to speak further regarding our comments or request supporting data pertinent to that which is set forth above, we would be more than happy to provide that to you.

Very truly yours,

Gene G. Veno
Executive Vice President

GGV:dlm

Cc: Executive Committee

1001155

THE LEAGUE OF WOMEN VOTERS OF PENNSYLVANIA

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

January 14, 2000

Dear Ms. Mitchell,

The League of Women Voters of Pennsylvania appreciates the opportunity to submit comments on the Department of Health's Proposed Regulations to Act 68 of 1998, the Managed Care Accountability Act. The League's comments address issues related to the definition of medical necessity, quality assurance standards, enrollees' rights to information and the appeals process.

We are concerned about the proposed regulations' definition of medical necessity. The Department of Health's initial draft included the following language: "(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." This language is a commonly accepted definition for use by health plans, enrollees and providers in determining the health care services, procedures, and treatments that are covered. The League of Women Voters of Pennsylvania strongly recommends the reinstatement of the above Department of Health language in the final regulations.

Secondly, the proposed regulations' quality assurance standards refer only to requirements of process. Specific standards and outcome measurements are the essential tools of evaluating quality care and must be an integral part of the Department of Health regulations. Specific quality assurance standards should include health promotion, early detection of disease and injury prevention and the early identification of special chronic and acute health care needs. Member satisfaction surveys are also an important component of evaluation. A uniform satisfaction survey to be made available to the public and DOH should also be included in the final DOH regulations.

The disclosure of enrollee rights and responsibilities in the proposed regulations lacks specificity. While the regulations generally require plans to have policies to assure disclosure of rights under Act 68, they no longer require the health plan to provide and notify members of specific rights, such as:

- The right to get current, complete information from their physician of their diagnosis, treatment and prognosis in understandable terms.
- The right to obtain emergency services without unnecessary delay.
- The right to know the name, professional status and function of anyone providing them health services.
- Their rights under the complaint/grievance system and how to file a complaint/grievance at each point in which a potential dispute is identified.

These specific rights should be delineated and incorporated into the final Department of Health regulations.

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http://pa.lwv.org/pa/ • 73172.2754@compuserve.com

LWV THE LEAGUE OF WOMEN VOTERS OF PENNSYLVANIA

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January 14, 2000

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The Managed Care Accountability Act was developed to provide consumers with balanced, fair and effective mechanisms that will resolve differences that might arise with their health plan, provider or the institutions that serve them. Act 68 establishes a system of internal review and an independent system for external review, both essential to a fair appeals process. However, it does this by bifurcating disputes into complaints and grievances and by delineating definitions and processes under each. The complicated processes defined by the Act will be incomprehensible to most consumers and providers. Thus, the right of consumers to resolve real differences with their managed care plans is questionable due to the complexity inherent in Act 68 and proposed rules. The League recommends that the appeals processes be simplified to assure that consumers can easily understand and make use of the mechanisms available to resolve disputes that might arise.

In addition, the Department's proposed rules for the appeals process include expedited review for consumer grievances but exclude the same review for those individuals with complaints (matters involving issues other than medical necessity, such as coverage). This is the case, even if the enrollee's life, health or ability to regain maximum function would be placed in jeopardy. Without access to an expedited review for both complaints and grievances, consumers may not be able to resolve differences in a fair, balanced, and effective manner.

The Managed Care Accountability Act of 1998 extends essential rights to consumers of the Commonwealth. The recommendations made by the League of the Women Voters of Pennsylvania will enhance the Department of Health's proposed regulations and make the Commonwealth's law a true Patients' Bill of Rights.

Sincerely,

Mary Etezady

Mary Etezady, Ph.D.
President
League of Women Voters of Pennsylvania

THE LEAGUE OF WOMEN VOTERS OF PENNSYLVANIA

0001106

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FAX COVER SHEET

TO: Bureau of Managed Care

ATTN: Stacey Mitchell DEPT: _____

FAX NUMBER: 717-705-0947

FROM: LWVPA

DATE: 1-14-00

RE: _____

NUMBER OF PAGES INCLUDING THIS COVER SHEET: 3

MESSAGE: Hard copy will follow in mail.

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PMHCA

Pennsylvania Mental Health Consumers' Association

January 14, 2000

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

RE: Comments on Proposed Regulations to Implement Act 68 of 1998

Dear Ms. Mitchell:

The Pennsylvania Mental Health Consumers' Association (PMHCA) has reviewed the Department of Health's proposed regulations to implement Act 68 of 1998, the Managed Care Accountability Act. PMHCA represents individuals in the state who have in the past or are currently receiving mental health services, both within the public and private sector, and respectfully submits the following comments on behalf of our constituency.

PMHCA is seriously concerned that the proposed regulations eliminate protections of Pennsylvania citizens who are purchasers/consumers of managed care insurance. Consumers believe they have few if any rights when it comes to their healthcare, and moreover feel that their health could decline based on managed care systems. These concerns can be reflected in the following areas of DOH's proposed regulations, noted as lack of oversight, elimination of standards and information control.

Lack of oversight – It appears that the Department of Health will have little oversight in critical areas such as:

- establishing criteria and review of HMO licensing
- reviews of plans—no reviews for the first 18 months and reviews done by an entity hired by the plan; ongoing reviews not required even if serious problems are identified and no public access to external review
- inability to ascertain whether reimbursement decisions impact quality of care and service access

Elimination of standards

- no assurance of adequate network
- elminating PCP training requirements
- elimination of a definition of medical necessity consistent with national and industry standard definitions
- no specific standards or outcomes related to the quality assurance process
- no standard of development of a member satisfaction survey to be made available to the public

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- access standards not adequately defined regarding "frequently used specialists" and other needed health services
- does not ensure ADA monitoring and enforcement
- no requirements for special needs units
- no minimum standards established for education, training, experience, record keeping, etc.; fails to review practitioners substance abuse history, board certification, malpractice history, etc.

Information Control

- plans allowed to make only part of their network of providers available to enrollees; does not require disclosure to current enrollees
- no notification to prospective enrollees regarding any restrictive drug formulary
- no requirements of plan to provide and notify members of important rights
- eliminates requiring the plan to routinely tell dissatisfied members of their rights and how to file a complaint/grievance
- does not require that complaint and grievance procedure keep the enrollee informed of all data involved in the process and eliminates expedited complaint review
- annual data about the plan is not required to be made available in a user friendly format for public review

Concerns are also noted in areas of direct access for obstetrical and gynecological care and standing referrals or specialists as primary care providers.

Thank you for the opportunity to note these critical areas of concern.

Sincerely,

Shelley E. Eppley
Executive Director