March 16, 2001

Lori McLaughlin, Esq.
Chief Counsel
Department of Health
Health and Welfare Building
Harrisburg, PA 17108

BY FAX

Dear Ms. McLaughlin:

I am writing to express the Pennsylvania Psychiatric Society's grave concern about the Department of Health's stated intention to interpret Section 9.750 (D) of the proposed Act 68 regulations in a manner that directly contradicts our understanding of the plain language of both the statute and the regulations proper.

Although we have recommended approval of the proposed regulations if the only choice at this time is approval or disapproval in their entirety, we urge you to amend Section 9.750 if the regulations are withdrawn or tolled for changes to the utilization review section.

Both Act 68 and Section 9.750 (D) of the regulations stipulate that only a physician (or, in limited circumstances, a psychologist) may deny payment for a service as medically unnecessary. Our support for Act 68 was predicated on the understanding that this language would require that a physician actually review the patient's clinical situation and the service under consideration. Otherwise, "physician denial" is a euphemism.

Although the regulatory language tracks the statute, in the published commentary (page 478) the Department asserts its intention to deem automated system denials, based on "decision logic," as meeting the requirements for physician denial if the Medical Director has approved the clinical criteria on which the decision logic is based. In other words, the physician "issuing" the denial will have neither reviewed the record nor discussed the case with the plan's employee, the treating physician, or hospital staff making the request. Indeed, his only connection to the decision to deny will have occurred prior to the request for service, and prior to the entry into the system of the patient's clinical status.

When a physician's connection to a review is so attenuated, and indeed occurs prior to the request for approval, we do not believe that it meets the plain and common-sense interpretation of the statutory and regulatory language.

If the Department has the ability to reverse this decision in the regulations themselves, the following amendment might suffice:

To § 9.750, add the following new subsection (E), and renumber current subsections E, F, and G accordingly:

(E) A UR DECISION TO DENY PAYMENT MADE BY A PHYSICIAN OR APPROVED LICENSED PSYCHOLOGIST, AS

(F) REQUIRED IN § 9.750 (D), SHALL INCLUDE THE PHYSICIAN OR PSYCHOLOGIST'S ACTUAL REVIEW OF THE CURRENT CLINICAL INFORMATION SPECIFIC TO THE PATIENT AND THE SERVICE WHICH ARE THE SUBJECT OF THE DENIAL.

When a request for authorization fails a screening mechanism, it should be reviewed by someone with the ability to understand and apply the subtleties of the particular clinical facts involved. People and illnesses vary. The practice of medicine requires clinical judgment that a "cookbook approach" cannot provide.

If the Department does not have the legal ability to add this or similar language at this point in time, we would certainly urge that it to reconsider its intention to allow such denials as meeting the requirements of the regulation.

Sincerely yours,

Gwen Yackee Lehman
Executive Director

cc: Jeremy S. Musher, MD, President
Robert L. Nyce, IRRC
The Honorable Dennis O'Brien
The Honorable Harold Mowery

govt/Act 68 LM

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

Original: 2079

March 16, 2001

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

Dear Mr. McGinley:

The Hospital & Healthsystem Association of Pennsylvania (HAP) on behalf of its members—the more than 225 acute and specialty care hospitals and health systems in the commonwealth—appreciates the opportunity to comment on the Department of Health's final-form rulemaking for the Quality Health Care Accountability and Protection Act (Act 68) and revisions to the state's HMO regulations.

Hospitals and health systems supported the enactment of Act 68 as a first step in assuring improved managed care accountability for patients. Implemented appropriately, managed care can help ensure that patients receive the right care, in the right setting, at the right time. Over the past several years, HAP has worked with the legislature, the Insurance Department, the Department of Health, and other stakeholders during the implementation of Act 68. We believe the Department of Health's final-form rulemaking, as submitted, will benefit managed care subscribers—patients—by fostering coordination and cooperation between health care plans and health care providers.

We recognize that, pursuant to Act 68, the department's final-form rulemaking:

- Uses consistent definitions with the Insurance Department regulations for emergency services, direct access to obstetrical and gynecologic care, and continuity of care;
- Standardizes and implements fair and responsible utilization review requirements for licensed insurers and managed care plans;
- Provides clear guidance on plan communication with providers on the rationale for the denial of payment such that the provider will understand the clinical reasons and thus be able to improve care;
- Requires denials to be issued by licensed physicians;
- Grants providers the ability to obtain written consent from patients at the time of treatment to file grievances on their behalf with a managed care plan;
- Clarifies access to care requirements for HMOs;
- Articulates that an informal dispute process between a managed care plan and a health care provider can coexist with the grievance process required by Act 68, thus enable opportunities for providers and plans to settle disputes without involving the patient; and
- Requires plans to apprise providers in advance of contract or policy language changes.

In addition, the act clearly differentiates which components apply to licensed insurers and which components apply to licensed insurers and managed care plans. In particular, the act states in

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Section 2151(e) "A licensed insurer or a managed care plan with a certificate of authority shall comply with the standards and procedures of this subdivision but shall not be required to obtain separate certification as a utilization review entity." The Department of Health has appropriately interpreted the act in the development of its regulations by requiring licensed insurers and managed care plans to comply with the utilization review standards. It should be pointed out that similar language is included in Section 2166 of Act 68 regarding prompt payment and the final-form regulations promulgated by the Insurance Department require all licensed health insurers and managed care plans to adhere to prompt payment requirements.

The utilization review standards developed by the Department of Health are consistent with those used by national health plan accrediting agencies, therefore their implementation should pose no additional burdens on insurers and managed care plans. The standards establish uniform processes that will benefit patients by assuring care decisions are made timely and fairly and will standardize utilization processes across the many licensed insurers and managed care plans that pay for health care in Pennsylvania. This was a major goal of Act 68 and the Department of Health's regulations fulfill that statutory objective.

HAP believes that the Department of Health's regulations represent a balanced approach in fulfilling the Department of Health's obligation to protect and promote public health and safety to the citizens of the commonwealth. The final-form rulemaking responsibly address the many concerns raised during the public comment on behalf of the insurers, providers, and patients. Therefore, HAP supports approval of the Department of Health's final-rulemaking pursuant to Act 68 and the revisions to the state's HMO regulations.

If you have any questions about our comments, feel free to contact me at (717) 561-5344.

Sincerely,

Paula A. Bussard

PAULA A. BUSSARD
Senior Vice President
Policy and Regulatory Services

/mg

c: The Hon. Robert S. Zimmerman, Secretary of Health
The Hon. Dennis M. O'Brien, Chair, House Health and Human Services Committee
The Hon. Frank L. Oliver, Minority Chair, House Health and Human Services Committee
The Hon. Harold F. Mowery, Chair, Senate Public Health and Welfare Committee
The Hon. Vincent J. Hughes, Minority Chair, Senate Public Health and Welfare Committee
The Hon. Nicholas A. Micozzie, Chair House Insurance Committee
The Hon. Anthony M. DeLuca, Minority Chair, House Insurance Committee

Original: 2079

GOOD SHEPHERD

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Allentown, PA 18103-3296
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March 16, 2001

John R. McGinley, Jr.,Chairman
Independent Regulatory Review Commission
14th Floor, Harristown 2
333 Market Street
Harrisburg, PA 17101
Via Fax: (717)783-2664

Dear Mr. McGinley:

With more than two-thirds of Pennsylvania's hospitals and health systems losing money on patient care, it would be inappropriate to delay implementation of the Department of Health's final regulations to Act 68 requiring HMO's to adhere to standards that would ensure greater health plan accountability. Effective implementation of these regulations can benefit patients and healthcare systems alike by fostering greater coordination and cooperation between health plans and health care providers in caring for patients.

Good Shepherd administrators commend the Department of Health for:

- Ensuring consistency of Department of Health standards with the Insurance Departments regulations;
- Establishing fair and responsible utilization review standards that hold licensed insurers and managed care plans accountable for utilization review decisions;
- Ensuring that providers may advocate for patients and may obtain written consent to do so at the time of treatment; and
- Balancing the interests of patients, health care providers and health plans in the development of these regulations.

I urge you to consider adopting the final Department of Health regulations as an important first step in providing health plan accountability that will ultimately have a positive impact on health care delivery.

Sincerely,

James E. Sok

James E. Sok
Executive Vice President Health Care
Senior Vice President Institutional Advancement & Communications

Original: 2079

GREATER HAZLETON HEALTH ALLIANCE

Hazleton General Hospital

Hazleton-Saint Joseph Medical Center

Hazleton Healthcare Foundation

Franciscan Skilled Care Center

Healthy Beginnings Plus

Hi-Tech Home Care

Occupational Health Services

Primary Care Centers

Rehabilitation and Fitness Center

March 16, 2001

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

Dear Mr. McGinley:

I am writing on behalf of the Board and Administration of the Greater Hazleton Health Alliance to support adoption of the final Department of Health Act 68 regulations.

The Department of Health should be commended for balancing the interests of patients, health care providers and health plans in the development of these regulations.

Effective implementation of these regulations can benefit patients by fostering greater coordination and cooperation between health plans and health care providers in caring for patients. With more than two-thirds of Pennsylvania's hospitals and health systems losing money on patient care, it would be inappropriate to delay implementation of regulations that establish fair and responsible oversight of managed care plans.

Thank you for your prompt action on this matter.

Sincerely,

Bernard C. Rudegeair

Bernard C. Rudegeair,
President/CEO

Hazleton-Saint Joseph Medical Center
687 North Church Street, Hazleton, PA 18201 (570) 459-4444

Original: 2144

IRRC

From: Richard Dale [rdale@caiu.org]
Sent: Friday, March 16, 2001 12:28 PM
To: irrc@irrc.state.pa.us
Subject: Chapter 14

pub comment to St Board.doc

Dear IRRC Members:

I have attached public comments which I presented to the Council of Basic Education of the State Board of Education on 14 March 2001 regarding revisions to Pennsylvania's special education regulations at 22 Pa. Code Chapter 14. It is my understanding that you will be reviewing a resubmission of these regulations in the near future.

I would appreciate your support of Chapter 14 as it is presented to you by the State Board. My reasons are explained in the attached document. While my preference would have been for the State Board to resubmit the regulations without revisions, I strongly support the version which they have agreed to resubmit.

Thank you in advance for your consideration in this matter. Please do not hesitate to contact me if you have any questions.

Sincerely,

Richard E. Dale, D.Ed.
Director of Special Services
Capital Area Intermediate Unit
55 Miller Street PO Box 489
Summerdale, PA 17093-0489
717-732-8400 ext. 504
717-732-8414 (fax)
rdale@caiu.org
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CAPITAL AREA INTERMEDIATE UNIT
CAIU

Providing Educational Services to the Capital Region

Division of Special Services • 55 Miller Street • P.O. Box 489 • Summerdale, PA 17093-0489
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Public Comment to the State Board of Education on 3-14-01

Good afternoon. My name is Richard Dale. I am the Director of Special Services for the Capital Area Intermediate Unit. My comments today represent my views as both a private citizen and as a special education administrator.

I would like to commend the State Board of Education and the Pennsylvania Department of Education, particularly the Bureau of Special Education, for their efforts to revise Pennsylvania's special education regulations and standards. Your approach has, from the outset, been focused on regulating minimally so that those of us in the field can **direct our limited resources to serving kids.** From the outset, crafting a minimal set of regulations by adopting the federal regulations by reference and adding a limited number of Pennsylvania-specific requirements has been the right thing to do, because less regulation allows those of us in the field to **direct our limited resources to serving kids.** You can imagine my shock and dismay when I learned that the Independent Regulatory Review Commission (IRRC) disapproved the final-form regulations. Not only did the IRRC ignore Governor Ridge's Executive Order 1996-1, but also it jeopardized over $200 million in federal Individuals with Disabilities Education Act (IDEA) funds, and potentially delayed the onset of needed regulatory relief in special education.

It is my fervent hope that the State Board will decide to proceed with promulgation of the chapter 14 **without** revision. Toward that end, I have brief rebuttals for each of the points the IRRC made in its disapproval order.

1. Regarding the inconsistency of the definitions of "early intervention services" and "mutually agreed upon written arrangement" [sic][1] between Chapter 14 and Act 212 of 1990, while I am not convinced there is truly legal inconsistency in the definitions, this is a technical issue which surely could be corrected in the publication process by the Legislative Reference Bureau. Please don't delay promulgation of this regulation over such a trivial technical matter, so that the relief in Chapter 14 becomes available and we can then **direct our limited resources to serving kids.**

2. Regarding the issue of foster parents, there is no need to regulate in this area in order to provide clarity. Any needed clarity can be provided via a BEC or other written PDE guidance. Please don't delay promulgation of this regulation over clarity which does not need to be in regulations, so that the relief in Chapter 14 becomes available and we can then **direct our limited resources to serving kids.**

3. Regarding the definitions of itinerant, part-time, and resource, I agree that the terms may be considered "vague" by non-practitioners, but, rather, flexible. As you may know from my previous testimony and letters, I would advocate that we do not need any caseload or class size limitations at all. Accordingly, I would prefer "flexibility" in these terms because it provides us with increased ability to **direct our limited resources to serving kids.**

[1] I note that even the IRRC did not bother to get the latter term correct, since it is hyphenated in Act 212 of 1990.

4. Regarding class size, a Winter 2001 research synthesis in CEC's research journal, Exceptional Children, stated:

> ...no identifiable caseload practice has consistently produced positive outcomes for students with disabilities.... The extant research provides few clear empirical directions for policymakers, administrators, and educators attempting to formulate consistent caseload policies. A myriad of complicating factors, which include inclusionary settings, cross-categorical models, and IDEA reauthorization, steer a complex problem into still murkier waters.

Trying to regulate caseload and class size is bureaucratic folly: it only serves to protect jobs and provide litigation fodder, while hamstringing administrators. The IDEA contains more than enough individual procedural protections for children with disabilities. Please leave the caseload and class size language as is, so that we can **direct our limited resources to serving kids.**

On a related note, I must mention my disappointment in the apparent credence which the IRRC has given to single, anecdotal horror stories from advocates about the disastrous outcomes which would result from eliminating the class size requirements. Where is the data to support their predictions? I would again point out that the Capital Area Intermediate Unit currently operates three autistic support classrooms which we self-limit to 4 children each because it is the right thing to do for the kids. Our districts support this financially. Why should it be assumed that districts will overload classes without regulation, when we currently self-impose a limit which is half the allowable number?

5. Regarding adoption by reference, I wholeheartedly agree with the State Board's deliberative decision to do so, and I disagree with IRRC that inserting federal language verbatim will be less confusing. On the contrary, I think that such insertion will cause **more** confusion, and therefore more litigation and diversion of resources away from **directing our limited resources to serving kids.**

6. Regarding 2-year reevaluations for eligible young children, the IDEA would allow us to reevaluate every 3 years. We already spend too much time and money on unnecessary processes and paperwork. Reevaluations can occur any time they are needed, so a more stringent cyclical requirement than required in the IDEA is unnecessary. Additionally, good practice demands that preschool special education providers collect evaluative data on children in an on-going fashion in order to drive decisions about specially designed instruction. This practice reduces the need to conduct formal reevaluations, whose main purpose is to make sure programs are effective. Please leave the 2-year reevaluation requirement for eligible young children undisturbed so that we can **direct our limited resources to serving kids.**

Thank you for your time and attention. Again, I hope that you will decide to proceed with promulgation of Chapter 14 **without** revision. If I can be of any assistance to the Board in this matter, please do not hesitate to contact me.

Carlisle Hospital and Health Services™

Original: 2079

March 16, 2001

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

Dear Mr. McGinley:

I am writing to you regarding the Department of Health, Act 68 regulations. Carlisle Hospital and Health Services supports adoption of the final Department of Health regulations as an important first step in providing health plan accountability. Effective implementation of these regulations can benefit patients by fostering greater coordination and cooperation between health plans and health care providers in caring for patients. With more than two-thirds of Pennsylvania's hospitals and health systems losing money on patient care, it would be inappropriate to delay implementation of regulations that establish fair and responsible oversight of managed care plans.

The Department of Health should be commended for:

- Ensuring consistency of Department of Health standards with the Insurance Department's regulations;
- Establishing fair and responsible utilization review standards that hold licensed insurers and managed care plans accountable for utilization review decisions;
- Ensuring that providers may advocate for patients and may obtain written consent to do so at the time of treatment; and
- Balancing the interests of patients, health care providers and health plans in the development of these regulations.

Should you have any questions concerning this matter please do not hesitate to contact me.

Sincerely,

CARLISLE HOSPITAL AND HEALTH SERVICES

Michael J. Halstead
President and CEO

MJH/cao

246 Parker Street • P.O. Box 310 • Carlisle, PA 17013-0310 • 717-245-5110

Original: 2079

620 HOWARD AVENUE
ALTOONA, PA 16601-4899

814/946-2223
Fax 814/946-7808

JAMES W. BARNER
PRESIDENT/CHIEF EXECUTIVE OFFICER

altoona hospital
CENTER FOR MEDICINE

March 16,2001

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

Dear Mr. McGinley:

This is to affirm that Altoona Hospital, along with most in the Commonwealth, supports the adoption of the final Department of Health "Act 68" regulations. We believe strongly that implementation of these regulations can benefit patients by fostering greater coordination and cooperation between health plans and health care providers.

At a time when this Hospital has a significant operating deficit and loses money on patient care, a condition faced by two thirds of the hospitals in the state, we feel it would be inappropriate to delay implementation of regulations that establish fair and responsible oversight of managed care plans.

We commend the Department of Health for balancing the interests of patients, health care providers, and health plans in the development of these regulations. We believe that they serve to establish fair and responsible utilization review standards, ensure their consistency, and ensure that providers may advocate for patients.

We urge the Commission to proceed with the full complement of the regulations without delay.

Sincerely,

James W. Barner
President/Chief Executive Officer

altoona hospital
CENTER FOR MEDICINE

620 HOWARD AVENUE
ALTOONA, PA 16601-4899
PHONE: 814/946-2223 FAX: 814/946-7808

Facsimile Cover Sheet

Date: 3/16/01

Attention: Mr. McGinley

Company:

FAX No: 717-783-2664

Total Pages: 2

(Including this Cover Sheet)

From: James W. Barner

Altoona Hospital Administration
Altoona, PA

FAX No: 814/946-7808

Subject:

Comments:

Please call 814/946-2223 if the telecopy you received is incomplete or illegible.

Original: 2079

620 HOWARD AVENUE
ALTOONA, PA 16601-4899

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JAMES W. BARNER
PRESIDENT/CHIEF EXECUTIVE OFFICER

altoona hospital
CENTER FOR MEDICINE

March 16,2001

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

Dear Mr. McGinley:

This is to affirm that Altoona Hospital, along with most in the Commonwealth, supports the adoption of the final Department of Health "Act 68" regulations. We believe strongly that implementation of these regulations can benefit patients by fostering greater coordination and cooperation between health plans and health care providers.

At a time when this Hospital has a significant operating deficit and loses money on patient care, a condition faced by two thirds of the hospitals in the state, we feel it would be inappropriate to delay implementation of regulations that establish fair and responsible oversight of managed care plans.

We commend the Department of Health for balancing the interests of patients, health care providers, and health plans in the development of these regulations. We believe that they serve to establish fair and responsible utilization review standards, ensure their consistency, and ensure that providers may advocate for patients.

We urge the Commission to proceed with the full complement of the regulations without delay.

Sincerely,

James W. Barner
President/Chief Executive Officer

Alliance of Health Care Providers

757 Poplar Church Road ▪ Camp Hill, PA 17011

Original: 2079

March 16, 2001

Robert Nyce, Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown 2
333 Market Street
Harrisburg, PA 17101

Dear Mr. Nyce:

The Alliance of Health Care Providers (Alliance) includes associations of most non-physician health care providers, including chiropractors, dentists, nurses, nurse anesthetists, optometrists, podiatrists, psychologists, and community mental health, mental retardation and drug and alcohol providers. I am writing on behalf of the Alliance concerning the proposed regulations to Act 68. The Alliance has actively followed the development of Act 68 and the creation of the Department of Health's regulations. Individual member organizations have submitted or will submit additional comments to IRRC. The Alliance wishes now to submit comments reflecting its general concerns.

The Alliance believes that the regulations contradict the letter of Act 68 and must be rejected. First we will review the ways in which these regulations contradict Act 68 by allowing for inadequate access to services. Then we will review other ways in which these regulations can be improved. The specific sections of the proposed regulations that we will comment on are 9.604 (Plan Reporting Requirements), 9.677 (Medical Necessity Definition), 9.722 (Health Provider Contracts), 9.744 (External Review Process), 9.751 (Utilization Reviews), 9.761 (F) (Credentialing Process), and 9.761 (a) (10) (Out-of-Network Access Limits).

However, our first comments concern Section 9.679 (D) (H) and (J), which deal with access requirements.

Lack of reasonable access to services

These proposed regulations violate the provisions of Act 68 and IRRC must reject them. Specifically, Act 68 requires that managed care plans "Assure availability and accessibility of adequate health care providers in a timely manner, which enables enrolles to have access to quality care and continuity of health care services" (Section 2111 (1)). However, the proposed regulations violate that provision of Act 68.

Let me explain the problem in more detail.

Regulations for Act 68

Section 9.679 (D) of those regulations must be read in conjunction with 9.679 (H) and 9.681 (C). Section 9.679 (D) states that

> Except as otherwise authorized in this section, a plan shall provide for at least 90% of its enrollees in each county in its service area access to covered services that are within 20 miles or 30 minutes travel from an enrollee's residence or work in a county designated as a metropolitan statistical area (MSA) by the Federal Census Bureau, and within 45 miles or 60 minutes travel from an enrollee's residence or work in any other county.

Section 9.679 (H) states that

> For infrequently utilized health care services, such as transplants, a plan may provide access to non-participating health care providers or contract with health care providers outside of the approved service area.

Section 9.681 (C) says that

> A plan that has no participating health care providers within the approved service area available to provide covered health care services shall arrange for and provide coverage for services provided by a nonparticipating health care provider. The plan shall cover the nonnetwork services at the same level of benefit as if a network provider had been available.

In addition we need to draw attention to Section 9.679 (E) which states

> A plan shall at all times assure enrollee access to primary care providers and other health care facilities and services necessary to provide covered benefits . . .

And Section 9.679 (J) which states that

> if there is a therapeutic reason to arrange for services at a distance greater than the travel standards in subsections (d) and (f), whether for frequently or infrequently utilized health care services, the plan may make arrangements necessary to provide access to quality health care services.

Problems with the Proposed Regulations

The proposed regulations create four major problems that limit the access to services required in Act 68. First, the proposed distance to travel to access a health care professional is too large. Second, the proposal that only 90% of the beneficiaries have to fall within the specified range of travel substantially even further reduces the ability of beneficiaries to access their health care benefits. Third, the regulations fail to define "infrequently used services" adequately, and thus allow managed care companies to restrict patient access to treatment even further. Finally, the regulations contain a "therapeutic reason" exception that creates another loophole that allows plans to circumvent the availability of health care professionals.

This distance is simply too large to allow enrollees to access their health care services. The Alliance suggests that if an enrollee is unable to access an appropriate network provider within 20 minutes/20 miles (urban) or 30 minutes/30 miles (rural), the enrollee may access an appropriate non-network provider without penalty (i.e. usual co-pay). This arrangement would seem to benefit both the enrollee and the plan. It benefits the enrollee by providing access. It benefits the plan by providing flexibility in meeting county-wide service responsibilities, and in servicing enrollees when networks become too limited or are under temporary appointment pressures.

Furthermore, Section 6.79 (H) permits waivers of this standard for "infrequently utilized" services and Section 9.679 (J) includes another loophole that managed care companies can use to restrict provider panels if necessary "to provide access to quality health care services." The net effect is that enrollees will have to travel long distances to get the health care services they need. Understandably, many enrollees cannot make these long trips and will have to lose the opportunity to use their health care benefits.

These Sections of the proposed regulations violate one of the basic provisions within Act 68. The distances that enrollees have to travel to access services are too large, and even then these distance requirements have to apply only to 90% of the beneficiaries covered by a plan. In addition, the regulations allow broad loopholes for "infrequently" used services (which are not defined clearly in the regulations) and for "quality" services. Consequently, we have no choice but to recommend that IRRC disapprove these proposed regulations to Act 68.

Additional concerns with Act 68 regulations

We have several additional comments on Act 68 regulations, including the filing for point-of-service plans, plan reporting requirements, enrollee rights, medical necessity definition, reimbursement for out-of-network services, health care contracts, external review process, utilization reviews, the credentialing process, and a provision that appears to limit out-of-network access.

Clarifying Plan Reporting Requirements

We support the plan reporting requirements that are included in Section 9.604. We have found this information helpful in tracking some indices of the performance of managed care plans. We are particularly pleased to see that the proposed regulations require the reporting of complaints and grievances.

We would also like this Section to require managed care companies to conduct and report the results of patient satisfaction and quality assurance studies. Also, one of our members has noted the advantages of reporting on psychiatric hospitalizations.

Definition of *Medical Necessity*

Section 9.677 only requires that an HMO has a definition of *medical necessity* that complies with Act 68. It sets no parameters on what should be included in that definition. We believe that the regulations for Act 68 should include such a definition. The purpose of Act 68 is to establish standards that will increase the likelihood that plan enrollees receive medically necessary and appropriate health care. That is difficult to achieve without a definition of "medically necessary." Act 68 does not prohibit DOH from establishing such a definition when it requires each plan to adopt a definition. Just as individual companies often have

stricter environmental requirements than DEP or EPA standards call for, so may a plan establish its own definition of "medical necessity" that is stricter than that which DOH might establish.

We also note that Act 68 implicitly gives a definition of medical necessity when it refers to "medical necessity and appropriate health care consistent with the degree of learning and skill ordinarily possessed by a reputable health care provider practicing according to appropriate legal standards of care" (Section 2113 (c) (1)).

Because contract, not staff model, plans are the norm, a plan contracts with many individual providers or groups of providers. Also providers may contract with many plans. Without a common definition of medical necessity, each provider must try to keep in mind which plan has which definition and which treatment might or might not pass muster under this patient's plan for his/her condition. External reviewers must also keep in mind under which definition of medical necessity and which interpretations of this definition, must this particular grievance be reviewed. Then DOH, in monitoring and reviewing the external grievance reviewers' adequacy of decisions, must also switch back and forth between each different plan's definition when it evaluates the reviewing entities' reviews.

This system is haphazard at best. It is unfair to both enrollees and providers and burdens reviewers and DOH. We recommend a definition of medical necessity that is consistent with the definition currently used by Health Choices.

Health Care Provider Contracts

We note that under Section 9.722 (c) (4) that health care provider contracts may not contain language that prohibits providers from advocating for medically necessary services, filing grievances on behalf of an enrollee, and for other reasons. We believe that contracts should also be prohibited from disenrolling providers for filing prompt payment claims under Section 2166.

External Review Process

We note that Section 9.744 (a) (4) (iii) requires external review organizations to include the "applicable generally accepted practice guidelines developed by the Federal government, National or professional medical societies, boards, and associations." This is very important as DOH could not be expected to monitor the quality of the review without knowledge of the relevant standards that are being applied.

Time Frames for Utilization Review

Section 9.751 deals with the time frames required for utilization review decisions. These provisions require the UR decision to be made within one business day "of the receipt of all supporting information reasonably necessary to complete the review" for concurrent UR decisions and two business days for prospective decisions.

However, some providers report that these reviews take weeks or sometimes even months. The UR decision is simply delayed because the supporting documentation is not received. Section 9.751 needs to include a provision that requires the UR entity to inform the provider of what additional supporting information is necessary to complete the review within one business day of receiving the request. If the

regulations fail to include this provision, then the intent of this section is vitiated and it becomes meaningless.

Greater Information Needed on the Credentialing Process

9.761 (F) includes data that plans have to submit to the Department of Health regarding the credentialing process.

If DOH gathered data on the credentialing process, then it could better determine if reasonable efforts were being made to develop and maintain adequate access to services. We recommend that the data required should include data from subcontractors and the number of active providers currently within the panel. This data should help DOH monitor whether or not the managed care company has the panel needed to provide covered services.

Allow Out-of-Network Access

We would recommend the deletion of Section 9.761 (a) (10), which reads that "the credentialing system shall include policies and procedures for the following: . . . (10) enrollee access to only those providers who have been properly credentialed." This section appears to prohibit point-of-service plans and appears to prohibit enrollees from going out of network when there are no in-network providers available as is permitted or at times even required under Section 9.679 (F). This internal contradiction can be avoided by eliminating Section 9.671 (a) (10).

Summary

Act 68 is explicit in its requirement that managed care companies have to provide adequate access to services. These proposed regulations would circumvent the letter and intent of Act 68 and therefore, IRRC must reject them. In addition, we have noted other ways that these proposed regulations could be improved. Thank you for the opportunity to respond to these proposed regulations.

Sincerely,

Thomas H. DeWall, CAE
On behalf of the
Alliance of Health Care Providers

cc: House Insurance Committee
House Health and Human Services Committee
Senate Banking and Insurance Committee
Senate Public Health and Welfare Committee
Stacy Mitchell, Department of Health

Original: 2079

Waynesboro Hospital
an affiliate of Summit Health

THE PEAK OF GOOD HEALTH

March 15, 2001

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

Dear Sir:

We at the Waynesboro Hospital, Summit Health, offer our support of the final regulations embodied in Act 68. As a small rural hospital we struggle with the bureaucracies of the managed care environment. We firmly believe that payments to our facility are delayed without regard to the patient's well being or our facility's means to provide care to our local community.

We particularly support legislation that would ensure coverage for non-participating providers at no less than the network level of benefit when no participating provider is available in the network. We also support provider contracts that permit informal dispute resolution between the plan and providers without requiring patient consent. Often times the patient has no responsibility to pay, (nor is the provider able to pursue the patient for payment), based on certain administrative denials of claims. Therefore, there is no vested interest on the part of the patient to provide consent, not to mention the burden on the provider to acquire it.

We support the efforts being made to ease these significant burdens, and we are hopeful that such efforts will somewhat help to ensure the continued viability of our small healthcare facility.

Sincerely,

Rita C. Brizzee
Vice-President, Chief Operating Officer

Original: 2079

NASON HOSPITAL

105 NASON DRIVE • ROARING SPRING, PA. 16673 • (814) 224-2141 • FAX (814) 224-6236

March 15, 2001

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

RE: DEPARTMENT OF HEALTH ACT 68 REGULATIONS

Dear Mr. McGinley,

Nason Hospital supports adoption of the final Department of Health regulations for Act 68 as an important first step in providing health plan accountability. Effective implementation of these regulations can benefit patients by fostering greater coordination and cooperation between health plans and health care providers in caring for patients. With more than two-thirds of Pennsylvania's hospitals and health systems losing money on patient care, it would be inappropriate to delay implementation of regulations that establish fair and responsible oversight of managed care plans.

The Department of Health should be commended for:

- Ensuring consistency of Department of Health standards with the Insurance Department's regulations;
- Establishing fair and responsible utilization review standards that hold licensed insurers and managed care plans accountable for utilization review decisions;
- Ensuring that providers may advocate for patients and may obtain written consent to do so at the time of treatment; and
- Balancing the interests of patients, health care providers and health plans in the development of these regulations.

Thank you for hearing our concerns.

Sincerely,

Garrett W. Hoover
President/CEO

Original: 2079

IRRC

From: Carocci, Vince (CBC) [Vince.Carocci@CapBlueCross.COM]
Sent: Thursday, March 15, 2001 9:08 AM
To: 'irrc@irrc.state.pa.us'
Subject: DoH Act 68 regs

please accept this testimony as the comments of capital blue cross on the Act 68 regulations promulgated by the dept. of health. written copies to be delivered this morning. thank you. any questions, pls call--541-6650.
<<TestimonyAct68(Feb21)5thdraft_.doc>>

Original: 2079

WRITTEN TESTIMONY

On

ACT 68 Department of Health Regulations

from

I. Steven Udvarhelyi, M.D.
Senior Vice President and Chief Medical Officer
Independence Blue Cross

Presented to:

PENNSYLVANIA HOUSE
HEALTH AND HUMAN SERVICES COMMITTEE
And
INSURANCE COMMITTEE

The Honorable Dennis O'Brien, Chairman
The Honorable Nicholas A. Micozzie, Chairman

March 15, 2001

Good afternoon Chairman O'Brien, Representative Oliver, Chairman Micozzie, Representative DeLuca, distinguished committee members, staff, ladies and gentlemen. My name is Steven Udvarhelyi and I am pleased to be able to offer testimony regarding Act 68 regulations from the Department of Health. I am here today in my capacity as Senior Vice President and Chief Medical Officer for Independence Blue Cross (IBC). I am also a Board Certified Internist, a member of the board of Directors of the National Committee on Quality Assurance (NCQA), a member of the Board of Directors of the American Association of Health Plans (AAHP), Chair of AAHP Committee on Quality Health Care, and I have previously served on the faculty of Harvard Medical School. With me today is Mary Ellen McMillen, Vice President for Legislative Policy at Independence Blue Cross.

Independence Blue Cross provides health insurance coverage for nearly 2.8 million members in southeastern Pennsylvania. Our company offers a full range of health insurance products for commercial and government customers. We have policies that range from a traditional, fee-for-service indemnity plan to a Health Maintenance Organization, Keystone Health Plan East.

I first want to take this opportunity to commend you all for your work in developing Act 68, which establishes rules that protect the rights of our members and our network providers. As many of you know, we worked closely with the House Insurance Committee, other members of the House of Representatives, other insurers and health care providers in developing and supporting Act 68. However, today we must regretfully ask that you disapprove the regulations submitted by the Department of Health

We do acknowledge and recognize that the Department of Health faced a difficult task in revising all of the existing HMO regulations and incorporating the new requirements of Act 68. We appreciate that the Department needed to balance the many, often conflicting, interests of our members, employer customers, and providers. And while we were pleased with many of the changes the Department made to the original proposed regulations and to the advance copy that was released last October, the final form regulations contain provisions that have appeared for the very first time. Also, even with revisions, the regulations still contain many administratively burdensome and costly provisions that appear to benefit no constituency and add unnecessary complexity and cost.

I want to emphasize that IBC is not opposing the regulations because we want to protect our interests at the expense of our members. The administrative costs that these regulations impose are extraordinary, and will ultimately be passed onto our customers. We do not oppose those costs that are consistent with the Act and benefit our members and our providers. We do, however, oppose the added administrative costs and burden that result from requirements that are either too complex, inconsistent with the Act, subject to dual regulation, or are simply outside the scope of Act 68. And our opposition to these regulations is based on specific objections, which I will elaborate with examples. I have also included as an appendix to my testimony a full list of almost 30 issues that we continue to have significant concerns about. Our objections are as follows:

First, the regulations do not contain a provision to "grand father" existing contracts that **already** have been approved by the Department under the provisions of Act 68 and existing Statements of Policy. IBC has long term contracts with many providers that were reached after years of negotiation, with compromises offered by both negotiating parties. To permit the Department to require changes after the fact would only serve to destabilize our network, unnecessarily increase the cost of health care coverage for our customers, and jeopardize our members' access to care. The final regulations should be applied only to new contracts.

Similarly, when applied to new contracts, there should be a 45 day "deemer" provision, such that if the Department fails to act within 45 days, the contract should be "deemed" approved. This would replace the current provision that gives the Department 60 days to review the contract, and allows them to require changes to contracts after the 60 day period expires and they have not objected to the contract. The 45 day "deemer" provision would be more consistent with Insurance Department standards.

Second, there is uncoordinated and overlapping regulation by the Department of Health and the Insurance Department.

Provider directories are presently regulated by the Insurance Department regulations. It is difficult to justify two departments regulating the same provider directory. However, if the DOH must become involved, we would ask that the Department clarify that hospital-based providers need not be included in the directory. These are providers who often do not see our members (pathologists). If we expand the directory to include every

provider in every setting, we transform it into a telephone book-sized document that will only add to health plan cost (estimated at over $2 million annually for KHPE alone) and will provide no significant member or customer benefit. In fact, the increased size and the listing of hospital based providers would simply generate member confusion, creating increased calls to providers and the plan.

Another example of overlapping regulation between the Department of Health and the Insurance Department is Delegation of HMO Operations.

Our third objection is to unnecessary or unclear requirements and guidelines that create a substantial cost burden without providing substantial benefits to our members, customers, or providers. I would like to provide examples in the areas of provider contracts, utilization review, grievances and complaints, and credentialing.

Examples of unnecessary or unclear requirements in the area of provider contracts include the following:

- The requirement that health plans send notification of potential contract terminations to the Department. Potential terminations are virtually impossible to identify and health plans are often threatened far in advance with termination by hospitals and large physician groups as a negotiation strategy. Health plans should only be required to notify the Department of actual termination notices between a health plan and a provider within 30 days of the termination date.

- The requirement for 30 days prior written notice to providers of **any** change to contracts, **policies, or procedures**. Prior written notice to contract changes is appropriate. Prior written notice to any change in any procedure, including minor changes, is unnecessary, burdensome, and could easily cost over $1 million annually, with hundreds of unnecessary notices to providers every year.

Another very costly requirement is the utilization review requirement that two written notices must be sent for each UR determination—even approvals. We agree that members should be notified in writing of any coverage disapproval. However, members are not adversely impacted by

approvals, and no notice should be sent to them. In fact, such notices would likely cause confusion, concern, and lead to increased calls to providers and the plan . For example, we initially approve payment for a defined number of days for most hospital stays. We frequently approve additional days in a hospital as part of our on going review of hospital stays, or as requested by a physician. There is no justification of written communication to our members that we have approved payment for an additional day or two in the hospital. We issue more than 1.5 million approvals to hospitals, physicians and other providers each year, and typically provide a summary notice to providers of approvals for an entire hospitalization or course of treatment. The cost to IBC of mailing letters to every member and every provider for every approval to all these providers would be almost $2 million every year. There is no benefit that justifies this cost.

There are many examples of complexity and cost without apparent benefit in the regulations on grievances and complaints. With regard to time frames, specific issues include:

- The requirement for 15 days advance notice to members for second level grievances and complaints (out of 45 total days to process these) instead of a more reasonable 7 day notice;

- The requirement to convene a three-person panel (including a non-employee of the plan) in less than 48 hours for an expedited appeal; instead of allowing the use of a committee with a single decision maker (as is done at first level expedited review).

Another concern with the grievance and complaint regulations is the requirement for plans to disclose, copy and provide to members all internal documents relating to an appeal. We object to this overly broad requirement that carries a significant cost burden associated with it. The regulations must be specific as to the information that must be disclosed, and should not require plans to disclose confidential or proprietary information. We also object to a requirement that we disclose information that would include the name of the external reviewer that made a medical necessity determination that led to an adverse coverage decision. The identify of the reviewer is not relevant to the decision, and it could discourage reviewers from participating if they think that an angry member could be writing angry or threatening letters or telephoning the reviewer.

Yet another concern with the regulations for grievances and complaints is the establishment of a "gag rule" on second level committee members, to prevent discussions with plan staff prior to a committee meeting. This rule has the result of restricting the plan's ability to properly inform and educate committee members about key facts, policies, and other information that is relevant and necessary to resolve the grievance or complaint.

Lastly, the regulations are contradictory in regard to who may review medical necessity decisions as part of grievances. The Act and regulations specify that a grievance should include a review by a provider in a same or similar specialty. The definition of same or similar specialty is "that which would typically manage or consult on the health care service in question." Yet the regulations prohibit a primary care physician (PCP) from reviewing any service that was not actually rendered by a PCP, even if a PCP would typically manage the condition. This is entirely too restrictive and not consistent with the act. An example is internists, who can serve as either a PCP or a specialist. A primary care internist could not review primary care services provided by another internist who is also a specialist.

Finally, with regard to credentialing, the regulations have failed to recognize the Act's effort to avoid duplicate accreditation activity. The Act provides for the Department to accept an external accreditation organization that meets the standards of Act 68, but the regulations have requirements that are inconsistent with that. The best HMOs, such as KHPE, are accredited by the National Committee for Quality Assurance (NCQA) for a three year period. The accreditation review by NCQA includes on-site representation from the Department at the review, and includes a review of credentialing policies and procedures. However, the regulations provide for review and approval of credentialing policies every two years, even though the Act clearly states that "The Department may adopt nationally recognized accrediting standards to establish the credentialing standards for managed care plans." The Department has chosen a time frame inconsistent with NCQA full accreditation. This creates duplicative oversight and cost.

The fourth major area of objection, and perhaps the most important reason from your point of view to disapprove the regulations, is that the regulations go beyond the scope of the law in Act 68.

The extension of the UR requirements beyond the scope of Act 68 is very troubling, and the most glaring example of this issue. In the Act, the definition of a utilization review entity is: "Any entity certified pursuant to sub article (H) **that performs utilization review on behalf of a managed care plan."** A Managed Care Plan is defined as "A health care plan that: **Uses a gatekeeper to manage the utilization of health care services..."** The utilization/review section only refers to a "Utilization Review Entity." The Health Department has decided through these regulations that the utilization review provisions of Act 68 will now apply to all licensed insurers, whether they are conducting utilization review on behalf of a gatekeeper managed care plan or on behalf of other products not covered by the Act, such as our traditional fee-for-service indemnity plan. We believe that this is clearly inappropriate. By itself, this inappropriate expansion of authority should be reason enough to disapprove these regulations.

The regulations also go beyond the scope of Act 68 by requiring plans to verify (and hence audit) that facilities, agencies, and organizations that employ non-physician providers adhere to the credentialing standards in the regulations. While the Department may want to oversee the non-physician credentialing activity of facilities, agencies and organization, it is beyond the scope of Act 68 and should not be included in these regulations.

In closing, let me state again that I must respectfully ask you to disapprove these regulations. As stated earlier, I have included in an appendix to this testimony a full list of the concerns we have with the final form regulations. We do appreciate the willingness of the Department to address some of these concerns through technical advisories, but these advisories would not have the force of law, as the regulations would, and could be subject to change at any time.

I thank you for your time and attention and appreciate the opportunity to present this testimony today. I welcome any questions you may have.

Original: 2079

Appendix to Testimony

from

I. Steven Udvarhelyi, M.D.

PENNSYLVANIA HOUSE
HEALTH AND HUMAN SERVICES COMMITTEE
And
INSURANCE COMMITTEE

March 15, 2001

Detailed comments on Department of Health Act 68 Regulations

1. § 9.601(d) Applicability – Federal Preemption

This section should state that the regulations do not apply to Medicare+Choice Programs where preempted by federal law, in accordance with the Social Security Act §1856(b)(3)(B).

2. § 9.605(d) - Department Investigations

In view of various state and federal confidentiality laws and the expanded purposes for Department access to medical records of enrollees under this article, this provision should be revised to state,

"TO THE EXTENT PERMITTED BY LAW, the Department shall have access..."

3. § 9.622(b) Prohibition Against uncertified HMOs; and §9.636 Certificate of Authority for Foreign HMOs

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

4. § 9.634 Delegation of HMO Operations

This section should be deleted in its entirety. The Pennsylvania Insurance Department has oversight authority for these contracts under the HMO Act, not the Department of Health. Moreover, the requirement is duplicative of the Pennsylvania Holding Company Act, under which HMOs need to file management agreements with the Insurance Department.

5. § 9.673 Provision of Prescription Drug Benefits

This provision should be revised and clarified to apply only to closed formularies, as opposed to open formularies or formularies with a tiered-copay structure where all drugs are available, but with varying copayment obligations.

§ 9.673(d)(e) – The last sentence needs to be revised as follows:

> **IF NO SPECIFIC EXCLUSION EXISTS, THE APPEAL OF A DENIAL OF A PHYSICIAN'S REQUEST FOR AN EXCEPTION TO THE FORMULARY ~~REGARDING THE COVERAGE OF OR AMOUNT OF COVERAGE FOR ONE DRUG VERSUS ANOTHER,~~ BASED ON MEDICAL NECESSITY AND APPROPRIATENESS, SHALL BE CONSIDERED TO BE A GRIEVANCE.**

Unless the language is stricken as indicated, it would allow appeals regarding the level of coverage for a drug, which is a contractual issue, to be treated as grievances rather than as complaints. This is inconsistent with the intent of Act 68. For example, if an enrollee has a medical need for a brand named drug versus a generic drug, the enrollee could appeal the copayment amount under their benefit contract as a grievance, instead of a complaint.

6. § 9.674 Quality assurance standards

Language should be added to clarify that if a plan meets the quality standard of a Department-approved EQRO, then it would be deemed to have met the standards in this section of the regulations.

7. § 9.675 Delegation of Medical Management

The term "delegation" should be defined for purposes of this section and only contracts which delegate medical management functions should be required to be submitted to the Department. According to criteria used by nationally recognized accrediting entities (e.g. NCQA), delegation requires the plan to let another entity make decisions on its behalf (e.g. credentialing or UR decisions). Simply subcontracting for "work for hire" related to medical management, while retaining decision making authority does not constitute delegation. This is a critical distinction, especially in the rapidly evolving area of disease management programs.

This section should also be revised to be consistent with section 9.724(b), whereby only those medical management delegation contracts which are not based on an approved standard contract must be submitted to the Department for review and approval prior to use. Moreover, the section should be revised in accordance with IBC's recommended revisions to section 9.722 regarding a deemer provision for provider contracts. (See comments, below) A 45-day deemer provision for new contracts entered into after the effective date of the Regulations and a file and use, subject to change upon contract renewal provision for existing contracts should be included with this provision.

IBC also requests clarification of the requirements of this section with medical management contracts which are part of HMO-IDS contracts for delegated activities, under section 9.724 of the Regulations. Moreover, IBC requests clarification regarding (a) whether the Department will deem approved a delegation plan which has received approval by a national accrediting organization (e.g. NCQA). For example, NCQA accreditation review encompasses oversight of delegated activities, including quality assurance, utilization review and credentialing; (b) the latitude the Department will grant regarding such national accrediting organization's requirements for subcontractor oversight. For example, IBC suggests that a subcontractor's certification by NCQA as a CVO should relieve the plan of some oversight functions for credentialing delegation, consistent with NCQA accreditation standards; (c) the applicability of this section to ancillary service plans for any functions other than utilization review. Current NCQA standards do not require any oversight of vision or dental subcontractors.

8. § 9.678(e) Primary Care Providers

Plans do not have access to the detailed employment or affiliation arrangements of primary care providers. Hence it is inappropriate to require plans to disclose possible effects of these arrangements, which have not been entered into at the request of the plan. These requirements are more appropriate for regulations governing healthcare providers.

9. § 9.679 Access Requirements in Service Areas

§ 9.679(a) The new language is problematic and potentially limiting on plans existing customer contracts:

"A plan shall **ONLY** provide ~~services~~ **COVERAGE** to enrollees ~~only in those~~ **WHO WORK OR RESIDE IN A** service ~~area~~ **AREA** ~~in which~~ **WHEN** ~~it~~ **THE PLAN** has been approved to operate **IN THAT SERVICE AREA** by the Department."

This language creates potentially significant enrollment issues with large employers that are domiciled in our service area, and contract for benefits for all employees through a main or central office within the service area, but have multiple office locations both in and outside of the service area. The proposed regulations would appear to limit these employers' ability to provide coverage to their employees on a consolidated basis with one health plan as they do today. The reference to "work or reside in a service area" should be replaced with "**who reside in, work in or are employed by employers located within a service area...**"

§ 9.679(c) The new language added to this section requiring plans to "...**report to the Department any potential loss from the network of any general acute care hospital and any primary care provider, whether an individual or a group practice, with 2000 or more assigned enrollees**" is unduly burdensome. The reference to "potential" should be deleted. It is not uncommon for providers in managed care plans to discuss or threaten termination or non-renewal of contracts in order to renegotiate rates and other payment terms and the vast majority of these issues are resolved successfully. Requiring plans to report "potential" losses is a waste of plan time and resources and does not provide the Department with meaningful information. Additionally, IBC is concerned with the Department's authority to impose additional reporting by the plans based on such "potential" termination information. While IBC understands the Department's concern with access to providers, we believe the Regulations adequately provide assurances of access and notice of provider terminations without this additional burden.

IBC requests clarification of the reporting requirement with respect to the loss of "any primary care provider, whether an individual or a group practice..." Designating primary care providers by group practices is a managed care plan industry norm. We assume that it is not the Department's intent that plans be required to report to the Department every time an individual primary care provider in a large group practice leaves the group, even though the group practice still has the capacity to serve the threshold number of enrollees. This is unnecessary to preserve continuity of care and it would inundate the Department with notices with no practical purpose. IBC recommends that this reporting requirement be at the "group level," but that it should include reporting of solo practitioners who are not in groups.

10. § 9.681 Health Care Providers

§ 9.681(a) - The requirement to list in the provider directory any provider that a member may be referred to is unduly burdensome and costly. IBC believes this requirement should be limited to physician specialists, and not include ancillary providers or physicians whose practices are strictly hospital based or incidental to procedures or other services provided (e.g. pathologists, radiologists, anesthesiologists). Additionally, **§ 9.681(a)(3)**'s requirement to include information on the physician with whom a CRNP has a collaborative relationship is problematic and burdensome because these relationships may change frequently.

In addition, IBC requests clarification on the requirements for provision of updated directories. While IBC agrees that the information on participating providers should be updated at least annually, it is not reasonable to require plans to mail a full set of directories or updates to every member every year. Rather IBC recommends that plans be required to provide them to member upon request after enrollment and list them on web sites. The cost of mailing directories is substantial, and many members get directory information either from telephoning our plan or on our web site.

§ 9.681(d)(2) - Emergency telephone consultation. This section should be deleted. It is vague in that it does not indicate who needs to provide the consultation to members. Most primary and specialty care physicians have on-call access to their practices, but not a true consultation service. In true emergencies,

IBC encourages its members to seek care from an emergency room. If the intent of this requirement is that there is some type of "after hours" availability of participating physicians, that should be clarified. However, given the focus on access to emergency services elsewhere in the regulations, and the prudent layperson standard for emergency care mandated by Act 68, IBC recommends deleting this requirement.

11. § 9.685 Standards for Approval of Point-of-Service Options

This subsection is superfluous and should be deleted. In addition, it suggests that members utilize their out-of-network option because of access problems in the network. In fact, many point of service members sign up for POS plans knowing they want to exercise freedom of choice and select out-of-network providers. IBC believes the Regulations provide for ample quality safeguards to ensure that patient self-referrals are not a reflection of access or quality problems on the part of the PCP practice.

§9.702 Complaints and Grievances—Though not cited in every instance comments apply to both complaints and grievances wherever there are parallel regulations.

12. §9.702(c) Complaints versus Grievances.

IBC still believes that it is important that the regulations address the nature of complaints and grievances by providing guidance that goes beyond the scope of the definitions. If the regulations do not provide actual examples, they should state that the Department will periodically provide updates on its interpretation of the two classifications in its web site or through Technical Advisories. In addition, here or elsewhere the Department should indicate how it will handle the numerous appeals that present both complaint and grievance issues. How these multifaceted appeals are handled and in what sequence the issues are addressed is especially important if a case proceeds to third level review. At the third level these cases requires clear and thoughtful coordination between the Department and the external review organization to avoid confusion. (At first and second levels during internal review, the plan can address both the complaint and grievance issues.) The Department's approach to these multi-faceted cases should be relatively simple and promote appropriate decision-making that helps the parties avoid unnecessary confusion.

13. §9.702(d) Time frames.

Here or elsewhere in the regulations the Department should add a section to clarify that a plan will not be penalized for delays resulting from the request or actions of an enrollee or his/her representative. Enrollees, their representatives, and a plan need specific guidance in the regulations that describe the impact of a member's cancellations or failures to participate in a complaint or grievance meeting scheduled for level 2 review. May the plan schedule twice then proceed without member participation if the third scheduled meeting results in a no-show and the member has been given written notice of that action? How does a member's failure to participate affect the compliance time frames? Will the time begin to run on a provider grievance on behalf of a member only when a written consent form is obtained? See §9.702(a)(3).

14. §9.703(c)(1)(I)(C) Information to Be Disclosed and Copying Fees

This section grants enrollees and their representatives access to plan documentation that is inappropriate and raises issues regarding copying fees. (See also §9.702(c)(1)(III.) It is fine to permit enrollees to provide any written data or other material that they wish in support of the complaint and plans realize that they need access to basic information to prepare their appeal challenges. However, the proposed regulations' open-ended approach to plan disclosure would require the plan to disclose a variety of internal documentation, including information that is confidential and proprietary. This mandated disclosure

unnecessarily complicates the grievance and complaint appeal review process, especially for any large plan in a metropolitan area where the public is litigation-conscious. Plans have legitimate interests that prevent them from voluntarily and prematurely making available certain internal records that would normally be available only via a subpoena or litigation discovery request. Plans should be permitted to redact materials they do disclose to protect proprietary and confidential information, including the names of individual plan staff who might otherwise receive improper phone calls. Protecting plan interests is also important because the requested information can be voluminous in certain instances and the ability to charge a fee is not a cure for the problems that plan staff incur in attempting to respond. Also, problems develop as the record evolves from one level to another, since a single request might be construed as a continuing obligation.

It would be preferable to identify certain basic items that must always be disclosed (e.g., medical policy, member handbook materials; medical records obtained, correspondence with the attending physicians, the statement/opinion and specialty/credentials of the matched specialty reviewer without the reviewer's name or other individual identifying information.). A uniform approach statewide as to basic disclosure would be helpful and eliminate an area of contention; anything else that a plan provided would be at the plans' option.

Finally, there should also be an explicit statement on what constitutes a reasonable reproduction fee. Again, to avoid confusion, the per-page rate and applicable maximums should be stated in the regulations so that the public is on notice and another area of contention is avoided.

15. §9.703(c)(2)(i)(B) Advance Notice of Appeal Meeting

This section unrealistically states that the plan will provide the enrollee and the enrollee's representative with 15 days advance written notice of the time scheduled for the second level review. Given the 45-day review and decision-making period and the difficulties that may occur in scheduling, mandating 15 days advance notice of a level 2 appeal is excessive. (See also, §9.703(c) (2)(III)(B).) Instead, an appropriate standard would provide that the scheduling of a particular meeting date should: 1) occur as soon as possible and generally with at least seven (7) to ten (10) days' advance notice; and, 2), be determined consistent with the enrollee's schedule, appeal meeting times, and appeal time frames established by regulation.

16. §9.703(c)(2)(III)(E) Attendance at the Level 2 Appeal

This regulation on attendance at the level 2 appeal should permit a limited number of other persons to attend, but only if the permission of the enrollee/representative is obtained. For example, it is invaluable to have one or two plan staff occasionally attend as observers for training purposes. (See also §9.705(c)(2)(III)(E))

17. §9.703 (c)(2)(III)(H) Level 2 Committee Discussion of the Appeal

§9.703(c)(2)(III)(H) unreasonably precludes the plan's second level review committee from discussing the case to be reviewed prior to the second level review meeting. Committee discussions to prepare for a meeting should be allowed if conducted in good faith and in accordance with appropriate regulatory guidelines. Discussion just prior to the meeting and after their receipt of the appeal packet can help the Committee identify questions and issues so that the actual meeting proceeds effectively and efficiently. Also, the pre-presentation discussion may actually help provide education or common background for all committee members on medical, claims, technical, policy, or operations issues. Decision-making prior to the meeting should be strictly prohibited, but research, consultation and education shared by committee members solely to facilitate the committee's review should be permitted and encouraged. To ensure that

such pre-presentation contacts are appropriate, the Committee members could be 1) limited to contacts within 24-48 hours of the scheduled meeting; 2) required to share all information with all members of the decision-making panel; 3) prohibited from deliberating and deciding the case prior to the meeting; and 4) or for any committee member to contact the enrollee directly. (Also, although the plan's appeal support staff may have direct contract with the enrollee outside of the meeting for a variety of reasons, the committee members who decide the case should not.)

18. §9.705(c)(3) Same or Similar Specialty.

The requirement under §.9.705 (c)(3)(iii) regarding advance notice that a matched specialist will not be present should be changed. The expectation should be that there will be no matched specialist at the meeting. Instead, the plans should be obligated to inform the member in advance if the matched specialist is to appear and participate in–person or by telephone.

§9.705 (c)(3)(iv) requires disclosure of the credentials of the matched specialist seven (7) days in advance of the meeting. This adds another layer to the process that is likely to make the appeal more adversarial and paper-intensive. Compliance with the advance notice period can be a challenge because obtaining a written matched specialist review from independent physicians at a specified time can be just as difficult as obtaining in-person participation. More importantly, it should be sufficient to identify some basic information such as the matched specialist's specialty, board certifications, and years in practice. Although indicated in the comments, the regulations should actually state that plans may delete the matched specialist's name and office location from the copy of the matched specialty report provided to the member. This type of redaction is necessary in many cases to obtain outside reviewers who are only willing to participate if they are protected from the possibility of being contacted directly by enrollees or their representatives in order to discuss pending appeals. Such discussion, outside the defined appeals process, would be inappropriate. (See also §9.703(c)(1)(c)(C))

§9.705 (c)(3)(v) introduces new limitations that exacerbate existing difficulties in obtaining matched specialty review. It is unreasonable to limit a primary care physician to reviewing only requests for PCP services. Many internists are designated as both specialists and PCPs. Furthermore, the appropriateness of many services rendered by specialists (e.g. treatment of hypertension, administration of flu vaccines, etc.) can adequately be reviewed by a PCP even though provided by a specialist. The regulations already require review by a same or similar specialist as typically manages the service or condition in question. IBC believes this is sufficient and this additional requirement is unnecessary and inappropriately limiting.

19. §9.706(E)Automatic Rescission of Member's Consent to Provider/Enrollee Appeal

This section should clarify what it means for the consent to be "automatically rescinded upon the failure of the health care provider to file or pursue a grievance under this section." Does the rescission occur automatically upon the elapse of the time frame (if any) applicable to filing the next step in the process?

20. §9.709 Expedited Review

Expedited review as described at §9.709(D) should be reevaluated because it creates a standard that cannot be satisfied. It will be virtually impossible to obtain a three-person panel as required by the regulations within the stringent 48-hour time limit that governs expedited review. The regulations should permit a one-person decision-making panel for expedited reviews. This is reasonable since they are all virtually level 1 reviews now that the regulations eliminate the level 2 expedited reviews in favor of

directing expedited review cases straight to the external review organization

§ 9.709(H) should be adjusted to require transmission of the expedited external review request to DOH within one (1) business day rather than within 24 hours. The 24-hour requirement currently proposed would require plan and DOH to have weekend staffing available at all times for appeals. However, the Department will not act on expedited appeal cases until the next business day in any event. It would be appropriate to require plans to notify the Department by noon on the first business day after receipt of the request.

21. §9.722 Plan and Health Care Provider Contracts

§9.722(a) The Department's new language regarding review and approval of provider contracts should be revised. The Department's 60-day time period for review of new provider contracts does not include a deemer provision in the event the contract is not approved within the time period. Additionally, in the event the review and approval is not completed within the 60-day time period, the Department may require changes after that time period without a time limit for such change requests. IBC requests a 45-day deemer provision for Department approval of new plan standard provider contracts, if such must be approved prior to use. IBC is concerned that without defined time frames for Department review and approval of contracts, delays in Department review could seriously impact a plans' ability to timely implement agreed upon provider contractual arrangements. Moreover, a significant number of provider contracts with larger provider groups and health systems are negotiated by plans and providers for long terms. Requiring changes during a contract term where the Department has failed to timely review the contract unduly burdens Plans and will likely adversely impact the Plans relationships with providers.

IBC also requests that this section be revised to "grandfather" existing, Department-approved contracts. Standard contracts which have been previously approved by the Department prior to the effective date of the Regulations should not required to be submitted to the Department for review and approval as long as there are no material changes to the standard, approved contract. Under the proposed regulations, IBC would need to submit every contract, which would mean that the Department would be inundated with contracts which have already been approved. There is no useful or necessary purpose to be served by such repetitive submissions. Additionally, under the current language, the Department may require changes to previously approved contracts during an existing contract term, which again unduly burdens Plans and will likely adversely impact the Plans relationships with providers. In the alternative, IBC requests limiting the Department's ability to require changes to previously approved contracts only upon the contract's renewal date.

§9.722(e)(8)- IBC supports and agrees with the need to have a 30 day notice provision on any material contract changes or fee revisions (except as required by a regulatory agency, which would take effect immediately upon written notice from IBC to the affected providers). However, IBC requests removal of the reference to changes in "policies or procedures," which can mean any major or minor internal administrative policy or "desk procedure." There are many minor changes being made in the complex and constantly changing world of health insurance and managed care as systems are enhanced, medical treatments modified, etc., which are not covered in contract provisions and which are inherently different from the purpose of provider contracts provisions. This requirement exceeds the requirements of Act 68 and notice of the myriad of minor changes, which occur regularly in the normal course of business for managed care plans, would be unduly burdensome to the plan, both financially and administratively. Moreover, it would result in providers being inundated with trivial notices which they would disregard and which would likely result in providers overlooking substantive and important notices. This provision should be amended to limit the policies and procedures to those incorporated into the provider contract by

reference and those which materially impact provider's performance as follows:

"...NOTICE OF ANY CHANGES TO CONTRACTS, POLICIES OR PROCEDURES ~~AFFECTING HEALTH CARE PROVIDERS OR THE PROVISION OR PAYMENT OF HEALTH CARE SERVICES TO ENROLLEES~~ **INCORPORATED BY REFERENCE INTO THE PROVIDER CONTRACT OR WHICH HAVE A MATERIAL IMPACT ON THE PARTIES' PERFORMANCE UNDER THE CONTRACT."**

24. § 9.724 PLAN- IDS Provider Contracts

§9.724(b)- IBC requests clarifying language in this section stating that Plan –IDS contracts that have already received approval of the Department and Department of Insurance based on Act 68 and the previous Statements of Policy on IDS arrangements prior to the effective date of the regulations are not required to be resubmitted to the Department for review.

Since under the new language, Plan –IDS contracts will be reviewed by the Department in accordance with §9.722(a), IBC reiterates its concerns and requested revisions to §9.722(a) regarding a 45-day deemer provision for new contracts and grandfathering of existing contracts. Additionally, the 45-day deemer provision for Department approval of such new contracts is consistent with the previous Statements of Policy on IDS arrangements.

§9.724(c)- this new provisions requires that "(i)f a Plan's Providers have executed Plan Provider contracts instead of IDS-Provider Contract, the Plan shall provide the Department with written notice of those contracts before the effective date of the Plan-IDS Contract." IBC requests clarification in the Regulation of whether the intent is that the Plan and the IDS do not need to comply with the terms of Section 9.725 or if they do, can compliance be in the form of and Addendum to the Plan-IDS Provider contract, similar to what was required under the IDS Statement of Policy? In this case does the IDS Provider contract need to be filed? If so, what happens if the IDS Provider is an employee of the IDS, does the Department want to review employment contracts if that is all that exists between the IDS and the IDS Provider?

25. § 9.744 & 9.746 CREs Participating in Internal and External Grievance Reviews

IBC questions the rationale for the extension of the additional requirements applicable for external grievances.

26. § 9.748(c) Department Review of a Certification Request This new language is overly broad and should be removed. The Regulations provide adequate access to relevant information elsewhere and this subsection is unnecessary.

27. § 9.749, 9.750, 9.751 – UR Standards

These sections are significantly troubling as they exceed the scope of Act 68 and impose entirely new utilization review requirements to licensed insurers under the new language in §9.741(c)- Applicability. Section 9.741(c) should be deleted. Sections 9.749, 9.750, 9.751- Operational Standards, are wholly new rules, exposed for the first time in a proposed final regulation and not previously issued for public comment in the proposed regulations issued in December, 1999. This is the first time many affected parties see this rulemaking intended for managed care organizations. Additionally, these rules represent significant and costly administrative requirements for indemnity and other licensed insurers which are subject to the regulations for the first time in this regulation.

The definition of a utilization review entity in the Act is: "Any entity certified pursuant to sub

article (H) **that performs utilization review on behalf of a managed care plan**." A Managed Care Plan is defined as "A health care plan that: **Uses a gatekeeper to manage the utilization of health care services...**" The utilization review section of the Act only refers to a "Utilization Review Entity." The Department Through these regulations the Department has inappropriately applied the utilization and review provisions of Act 68 to all licensed insurers, whether they are conducting utilization review on behalf of a gatekeeper managed care plan or on behalf of other products not covered by the Act, such as non-gatekeeper PPO plans. This is clearly an inappropriate expansion of authority. As such, §9.741 should be deleted.

Additionally, in the second sentence of each section 9.751(A)(B) and (C) regarding written confirmation of UR decisions regarding written confirmation of UR decisions, the reference to "the decision" should be replaced with "a denial decision." Industry norm for managed care plans is to provide written confirmation of denial decisions only. Additionally, written confirmation of a communicated UR decision to **both enrollees and providers** exceeds Act 68 requirements- and is now requiring **two** notices for every approval. Requiring plans to provide written confirmation of approval decisions which have already been communicated to providers is unnecessary, unduly burdensome to plans, both financially and administratively, and serves no benefit to enrollees who are not adversely impacted by the approval decision. Our plans issue more that 1.5 million approvals to hospitals, physicians and other providers each year, and typically provide a summary notice to providers of approvals for an entire hospitalization or course of treatment. The cost of mailing letters to every member and every provider for every approval would be almost $2 million per year. There is no benefit that justifies this cost.

Section **9.751(D)** should be removed as it introduces a category of review not included in the Act 68 UR standards, and it is superfluous as such review is an integral component of the internal and external grievance processes, addressed in cross-referenced sections 9.705 and 9.709.

28. § 9.761 and 9.762 Provider Credentialing

The definition of a health care provider set forth in Section 9.602 includes durable medical equipment providers, physical therapists, RNs and physicians assistants. The term health care provider is used in these provisions. IBC suggests that the scope of credentialing match that of nationally recognized accrediting entities such as NCQA and of federal regulators. NCQA does not require credentialing of allied health providers and HCFA does not include DME suppliers as providers of health care. Furthermore, neither NCQA nor HCFA require credentialing of physicians who provide services incidental to hospital based care (e.g. pathologists, anesthesiologists).

§9.761(a)(10) would require credentialing policies and procedures for "enrollee access to only those providers who have been properly credentialed." This seems vague and needs clarification. For example, members with an out-of-network option (e.g. POS members) can see non-credentialed providers at their will. In addition, plans are required to let members seeking emergency care do so without interference from the plan. They may seek emergency care from non-credentialed providers. Assuming the plan has properly credentialed its network, and provides members with the names of network providers, it is not clear what action the Department is requesting with this provision. IBC request clarification on the intent of this section.

§9.761(c) IBC requests clarification on how a plan may demonstrate that it meets or exceeds the standards of a nationally recognized accrediting body. Is this the same review that would be carried out by an

EQRO?

§ 9.761(F) requires the plan to submit a credentialing process every 2 years. However the cycle for external review by an accrediting body would occur every 3 years, and the credentialing cycle proposed by the regulations is every 3 years. IBC suggests the time frame for submission of the credentialing process by every 3 years to coincide with accrediting body time frames, and presumably EQRO reviews.

§ 9.762 requires plans to credential all non-PCPs and non-specialists requiring licensure and malpractice coverage. As noted above, current standards of national accrediting bodies and HCFA do not require this for allied health professionals. As drafted, this requirement goes well beyond accepted industry standards, and would expand credentialing to all allied health professionals, including every nurse, therapist, and pharmacist on staff at every hospital, skilled nursing facility, pharmacy in their network. This would be a huge burden on plans, allied health professionals, and health care facilities, and is not reasonable or necessary, since these facilities verify credentials of these allied health professionals. IBC suggests this section be deleted.

§9.763 properly exempts certain non-physician providers from credentialing, but would require the plans to audit the credentialing processes of facilities, agencies or other organizations that do credential these non-physicians. Plans have no control over who these organizations hire. Where applicable, plans frequently require facilities to be accredited by JCAHO, they do not perform an independent assessment of credentialing vis a vis the requirement of the proposed regulations. While the Commonwealth may want to oversee the credentialing process of such entities in terms of compliance with the proposed regulations, that is beyond the scope of the Act 68. Therefore, this section should be deleted.

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TESTIMONY

Capital Blue Cross

Before the

House Health and Human Services Committee,

House Insurance Committee

Proposed DoH Act 68 Regulations

March 15, 2001

Submitted by:

Lee Van Valkenburgh

VP, Corporate Services

Mr. Chairmen, Members of the House Health and Human Services and House Insurance Committees:

We appreciate the opportunity to provide the views of Capital Blue Cross regarding the Department of Health's final proposed managed care plan (Act 68) regulations.

Capital Blue Cross is a non-profit health insurer serving 1.4 million subscribers in a 21-county area of Central Pennsylvania and Lehigh Valley. We provide a broad range of consumer choice in health care benefit options, including traditional indemnity Blue Cross, comprehensive major medical, preferred provider, and Point-of-Service managed care coverages, plus administrative services to our self-funded employer groups.

Last year, we processed more than 11.5 million claims and we paid out more than $1.2 billion in benefits to our members.

Our comments are provided here today because the proposed regulations of the Department of Health directly affect our managed care point-of-service products, particularly *Health*One, and our wholly owned subsidiary, Avalon Health, which is licensed but has not begun to enroll members. Most importantly, these regulations affect our ability to provide health care coverage at a cost that our customers can afford.

Let us be absolutely clear: We support the drive for important consumer protections in the managed care area.

The critical public policy issue that the Department and other interested parties such as these committees must address, however, is a balance between the consumer benefits

of imposing wide-ranging new regulatory requirements on managed care plans, and the costs inherent in implementing them.

We appreciate the massive effort made by the Department to finalize complex regulations incorporating both Act 68 compliance issues and a complete updating of its 1983 HMO regulations. The Department's submission exceeds 700 pages and is quite detailed and complex. Our statement today focuses on key issues we would like the Committees and the Department of Health to consider.

DOH Extends Level of Authority

We believe that a close reading of these proposed regulations will reveal many areas in which the Department has exceeded specific legislative intent. We believe it lacks the specific authority to reach as far as it proposes to reach. Some examples are:

- Requiring that management contracts, such as those we might enter into for disease management, be submitted for review and approval prior to use. While the Department has incorporated a 60-day "deemer" provision, we believe there is no specific statutory authority to impose this requirement in the first instance. It is also unnecessary.

  Health plans have the requisite expertise to negotiate these contracts for the benefit of their members. And, lest it be forgotten, the Department of Health, through its use and application of national standards such as those of the National Committee for Quality Assurance (NCQA) and standards set forth in existing statements of policy,

have long established health plans' obligations to monitor and oversee subcontractors in this regard.

Many of these subcontractors are directly certified and regulated by the Department under the Act's CRE certification requirements. And finally, historically DoH has reviewed a plan's medical management programs as part of its review of the plan's quality initiatives. It's the result of management that counts, not how a plan may choose to organize or contract with particular vendors.

- Requiring submission of provider contracts for prior review and approval of the Department of Health. Neither Act 68 nor the PPO Act grants the DoH the authority to review and approve provider contracts. The HMO Act (Section 8 (a)) merely requires provider contracts to be filed with the Department, and the Department may require renegotiation for a specified list of reasons. The addition of a 60-day "deemer" clause does not negate the fact that there is no authority for this proposed prior review and approval provision in the first place.

We should also note that DoH is not the statutory regulator for Capital Blue Cross and other Blue Cross plans. Under the Hospital Plan Corporation Act, the Pennsylvania Department of Insurance is the statutory license giver and regulator of non-profit hospital plans such as Capital Blue Cross. Act 68 does give The Department of Health authority to regulate "gatekeeper" managed care plans. But it supplements--it does not replace--the foundation statutes under which plans are licensed and regulated. It should also be noted that many of our provider contracts already are subject to the review of the Insurance Department. Not only does the Health Department not have the authority under Act 68 or the Hospital Plan

Corporation Act to require prior review and approval of our non-gatekeeper plan provider contracts; we also fail to see the need or benefit of duplicative oversight and regulation.

- Creating a new step in the grievance process, one not called for in Act 68, by establishing an expedited external review process. Act 68 is very specific about the various steps and procedures that must be included in the grievance process, including an expedited internal grievance process. It makes no reference, however, to an expedited external grievance process. This is not meant to split hairs. Rather, once again, the proposed regulations overstep the reach of the Act. Requiring a new step in the grievance process by regulatory rather than statutory mandate also may subject the entire process to legal challenges or questions.

  In addition, we believe the time frame for coordinating an expedited external grievance review--particularly in obtaining adequate medical records and documentation and forwarding it to an assigned external review agency for a decision--may well be impractical and unworkable in a real world environment.

Cost-increasing Provisions

As the Committees are well aware, health care costs are once again escalating for a number of reasons, and many groups and consumers are beginning to look again at the basic affordability of their health care coverage.

In attempting to provide the public with cost-effective, affordable, quality health care, one of our important duties is to minimize the administrative expense portion of the premiums

we charge. Capital Blue Cross has taken that responsibility very seriously. While administrative expenses vary among product lines, historically, we as an efficient, effective non-profit administrator of health coverage have devoted at least 90 cents of every premium dollar to health benefits, and fewer than 10 cents to administration.

We believe the regulations as promulgated by the Department of Health impose compliance costs on health plans which far exceed the marginal value they might afford consumers. Some examples of provisions that we believe need to be re-examined from a cost/benefit perspective are:

- As a result of Act 68, Capital and other managed care plans already have spent significant administrative sums to comply first with both the Insurance and Health Departments' initial statements of policy regarding Act 68 compliance, and most recently, the Insurance Department's final adopted Act 68 regulations. We have expended approximately one half-million dollars to this point to implement Act 68 provisions, and Capital already was in compliance with many of the provisions. This does not include on-going oversight, external reviews by physicians and staffing requirements to implement the complaint/grievance processes called for in the act.

  If additional regulations are now adopted adding new requirements for complaint and grievance procedures and new standards for provider contracts, terms and conditions, we will incur significant additional administrative expense in revisions to internal policies, procedures and operational guidelines. We will also be required to amend our provider contracts, member contracts, and member handbooks. Again, the critical questions are whether these newly proposed regulations provide real additional value for members to offset the costs to be incurred by Capital and other

plans in implementing them, and whether the Department of Health has any authority to promulgate them in any case.

- The Department proposes to Incorporate detailed, new UR standards found in Sections 9.749, 9.750, and 9.751. In its immediate prior draft, these sections applied to and used the phrase "A plan, CRE or insurer performing UR..." This raised concerns that some of these provisions would be inappropriately applied to indemnity insurers' utilization review programs. In its final draft, DoH has substituted a very ambiguous phrase "An entity performing UR..." The term "entity" is not defined. This ambiguity is a matter of concern to us. Additionally, this reference was not included in the DoH's original proposal. Interested and affected parties were thereby denied an opportunity to review and comment on these new sections and requirements. Once again, we point out that the Act-68 consumer protections always were directed at gatekeeper managed care plans, not indemnity insurers.

- Finally, the many new requirements found in the complaint and grievance procedure sections of the regulations, though well intended, will result in increased costs which exceed the benefits to be gained.

To cite just one specific example, prohibiting plan medical directors, who tend to be primary care physicians, from providing the medical necessity opinion at the 1st level grievance fails to take in account the potential volume of 1st level grievances versus the availability of specialists for consultation, and the cost of specialty consultation in itself. Like specialists do become involved at the 2nd level grievance, and the medical director whose denial in the first instance led to the grievance is not permitted to take part in the review. It was Capital's experience in calendar year

2000 that 136 1st-level grievances were filed. Only 26, approximately one in five, went to the 2nd-level stage. We believe this strongly indicates that the complaint and grievance process as currently constituted is working well, and is not in need of the change proposed by the Department.

- Two additional examples where the potential benefit is far less than the cost involved are the Department's proposed requirements that a plan provide a written response within 5 business days of receiving an inquiry regarding its drug formulary; and that all utilization decisions, not just negative ones, be followed-up in writing.

  We have no objection to responding to written drug formulary inquiries; but if a member calls on a toll-free number and a response is provided, we see limited if any value in following up that verbal response with a written one.

  Likewise, the customary practice in utilization review is that UR denials are confirmed in writing. What benefit there is to requiring the same treatment for UR approvals, when viewed in the context of volume and additional expense, is debatable to say the least. The point is, the procedure has been approved and both patient and provider already know that fact. What more is required?

Capital's Recommendation

While we again commend the Department for all the work and effort that went into the 700-plus-page submission, Capital believes that, for the reasons stated above, it is simply not in the public interest for these regulations to be adopted in the extensive form proposed by the Department.

We urge the Department, and these committees, to evaluate these regulations in two specific lights: The authority for the proposed regulations to reach as far and as wide as they propose to reach; and the costs versus benefits of many of its provisions.

We suggest that a two-step approach might be a better strategy. First, deal with those regulatory issues related specifically to Act 68; and when completed, then turn to the task of revising the broader HMO-related regulations. If this approach were adopted, we believe there are potential areas of agreement, particularly in the non-Act 68 arena. We commend the department, for example, for extending clear Integrated Delivery System contracting authority and standards to all gate-keeper managed care plans, not just HMOs. Such changes serve to level the playing field, promote innovation in contracting between all managed plans and provider sponsored systems, and promote competition. It's likely that other avenues of agreement will found in this two-step process.

Closing Remarks

Our final comment is that the process for adoption of final DoH Act 68 regulations must recognize the time needed by the health insurance industry to implement necessary compliance changes.

If changes in provider contract terms and conditions and member complaint and grievance procedures are required, and if the Department in fact is found to have authority to require plans to submit changes in provider contracts and complaint/grievance procedure member handbook descriptions for review and prior approval, it will take significant time for plans to achieve compliance.

Plans should be given a minimum of 180 days to comply with significant new requirements in the regulations as finally adopted.

In addition, if the Department is successful in its attempt to extend its authority beyond managed care statutes and imposes the many new requirements for filing various items for its review and approval prior to plan implementation, the Department should provide managed care plans with appropriate safeguards to ensure prompt review and action on such filings. Every filing requirement for approval prior to use should be accompanied by a so-called "deemer" provision. But we recommend a 30-day deemer rather than the 60-day timeline proposed by the department.

I thank you on behalf of Capital Blue Cross for the opportunity to present our comments to you today.

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PENNSYLVANIA PSYCHOLOGICAL ASSOCIATION

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An affiliate of the American Psychological Association

March 6, 2001

Robert E. Nyce, Executive Director
Independent Regulatory Review Commission
2 Harristown Building
333 Market Street
Harrisburg, PA 17101

RE: Proposed Regulations to Act 68

Dear Mr. Nyce:

I am writing on behalf of the Pennsylvania Psychological Association concerning the proposed regulations from the Department of Health (DOH) pursuant to Act 68. Many of our concerns with these proposed regulations will be presented in the letter on behalf of the Alliance of Health Care Providers. However, in this letter we are highlighting and supplementing those comments.

First we will review the ways in which these regulations contradict Act 68 by allowing for inadequate access to services. Then we will review other ways in which these regulations can be improved.

INADEQUATE ACCESS TO SERVICES

These proposed regulations violate the provisions of Act 68 and IRRC must reject them. Specifically, Act 68 requires that managed care plans "Assure availability and accessibility of adequate health care providers in a timely manner, which enables enrollees to have access to quality care and continuity of health care services" (Section 2111 (1)). However, the proposed regulations violate that provision of Act 68.

Section 9.679 (D) states that providers have to be within 45 miles or 60 minutes of 90% of the beneficiaries in rural areas and 20 miles or 30 minutes of 90% of the beneficiaries in urban areas. These distances are simply too far to ensure reasonable access to treatment.

The problem is best explained by giving a few examples of what would be permitted under these regulations. According to the proposed formulary, a beneficiary in Warren might be required to travel to Bradford to access their health care benefit. Beneficiaries in Meadville could be required to travel 41 miles to Erie; those in Wellsboro might have to go 43 miles to Coudersport; and those in Somerset might have to travel 42 miles to Ebensburg. These are just some examples of the potential impact of these regulations on provider panels. Each legislator in a rural district can think of similar scenarios that these regulations would permit.

The regulations fail to take into account the fact that there is already a shortage of health care professionals in rural areas. Allowing managed care companies such wide latitude in restricting those panels could only exacerbate an already bad situation.

The commentary to the proposed regulations stated that DOH did not want to "require plans to create providers when none exist" or to allow one provider to block the entry of a plan into a service area by refusing to sign a contract. We are not callous to those concerns. Indeed there may be some specialty services in which long travel may be necessary for some beneficiaries in some rural areas. Perhaps DOH could be given the discretion to make exceptions on a case-by-case basis. However, the proposed regulations allow managed care companies to provide inadequate panels in direct contradiction of the requirements of Act 68.

Furthermore, the provider access provisions apply only to 90% of the beneficiaries. The other 10% could be left without any reasonable means to access their health care benefits.

It could be argued that the free market would not allow this to happen. One might think that no health care company would be able to renew its contract if it created such barriers to health care. However, the history of managed health care in Pennsylvania reveals less long-term commitment to the health of a specific population than we would have liked. It is not unheard of for Pennsylvanians to have had four different health care plans in four consecutive years. In other words, there are short-term financial incentives for some managed care companies to deny reasonable access to services. The unregulated free market provides inadequate protection against these abuses.

In addition, the provision allowing for infrequent services is not clarified. We do not object to the list of basic services as found in 9.679 (E); however, Section 9.679 (H) appears to give managed care companies wide latitude in circumventing the requirement to have health care providers who can provide the services promised in the health care benefit package. The managed care company can simply state that the covered benefit is "infrequently used" and then fail to contract with local health care professionals who could have provided that service.

Finally, Section 9.679 (J) is a large loophole that managed care companies can use to restrict provider panels, although it is framed under benign language to "provide access to quality health care services." The net effect is that beneficiaries may have to travel long distances to get the health care services they need. Understandably, many beneficiaries cannot make these long trips and will forego health care treatment.

For example, instead of contracting with the local child psychologist, the managed care company can place another child psychologist on its panel who works 50 or 60 miles away. Understandably, fewer parents will be able to make that long trip on a regular basis, thus reducing the utilization of health care benefits under the plan. Although it is phrased in terms of "providing quality care," the net effect is that it could lead to the denial of needed care.

Worst Case Scenario

The worst case scenario is that a health care plan could advertise and offer to provide mental health services including access to psychologists. However, it could then consider these services to be "less frequently utilized," empanel only psychologists well outside of the geographic location of the majority of its beneficiaries, and be within the parameters established by these regulations.

The employers and beneficiaries will have been deceived, but there would be no legal recourse. It would not be until the contract expires that the purchasers could begin to search for another health care plan that would be more honest in its representation. In the meantime, there will be lack of reasonable access to health care services, and an increase in suicides, absenteeism at work due to depression or other mental illness, child abuse, and other social ills.

ADDITIONAL COMMENTS ON ACT 68 REGULATIONS

We have several additional concerns with Act 68 regulations, including the need for more information on the credentialing process; clarifying the plan reporting requirements; tightening up the sections dealing with time frames for utilization review decisions; and revising the section on provider contracts.

Greater Information Needed on the Credentialing Process

9.761 (F) includes data that plans have to submit to DOH regarding the credentialing process. However, we would like to review some of the problems encountered by psychologists in the credentialing process. We hope that the regulations could address these problems because they restrict access to services and impact on patient care.

A psychologist/owner has a capitated arrangement with a managed care company which states, among other things, that its beneficiaries can be treated only by persons who are credentialed by them. That company takes inordinate time in processing credentials for the employees of the psychologist (sometimes up to six months for credentials that are clear and noncontroversial). The psychologist/owner has numerous referrals and has the psychologists to service the referrals, but the managed care company will not process their credentials. The psychologist/owner goes ahead and assigns the patients to the uncredentialed psychologists (patient welfare demands nothing less). Then the managed care company wants money back because patients were being treated by psychologists who were not yet credentialed.

We have seen some managed care panels which give the appearance of an adequate supply of psychologists. However, sometimes the psychologists listed are retired or have otherwise discontinued services. This has been called the problem of "phantom panels."

We have an unusual situation in certain parts of the state where newly licensed psychologists are unable to get on a panel, whereas psychologists who are empaneled are overwhelmed with referrals. Sometimes patients have to call 10 or more psychologists before they can find one with an opening.

We have had numerous psychologists terminated from panels because they allegedly did not send in the recredentialing materials. However, often these psychologists have copies of what they sent and verification that it was sent via certified mail (or fax confirmation). Nonetheless, sometimes the credentialing organization will simply continue to deny that the materials were ever sent, refuse to answer phone calls, or otherwise delay the recredentialing process. Sometimes it takes dozens of phone calls and months to get these issues resolved.

We realize that Act 68 does not directly address these issues except as it relates to the adequacy of provider panels. Nonetheless, if DOH gathered data on the credentialing process, then it could better determine if reasonable efforts were being made to develop and maintain adequate access to services. We recommend that the data required should include data from subcontractors and the number of active providers currently within the panel. This data should help DOH monitor whether or not the managed care company has the panel needed to provide covered services.

Clarifying Plan Reporting Requirements

We support the plan reporting requirements in Section 9.604. We have found this information helpful in tracking some indices of the performance of managed care plans. For the last several years, PPA has reviewed these plan reports on a yearly basis and we have found two sources of data that were especially helpful.

First, currently DOH requires some kind of quality assurance or patient satisfaction survey. We were able to identify those plans that had generally good outcomes and patient satisfaction and those that did not. In one plan, which is now out of business, only 36% of its enrollees rated the mental health services as excellent or very good. This suggests a low quality of care. Even mediocre plans will typically get 70% of its enrollees rating the plan as excellent or very good.

Another useful source of data has been the inpatient psychiatric hospitalizations. We have found variations in the hospitalization rates that are predictable (Medicare and Medicaid HMOs tend to have higher rates of psychiatric hospitalizations) and those which cannot be readily explained by the demographics of the population served.

For example, this last year we found that most commercial managed care plans averaged between 25 and 35 inpatient psychiatric days per year per 1000 beneficiaries. One, however, had only 11.8 inpatient psychiatric days. This allowed us to ask our members about any problems that they might have encountered getting patients hospitalized.

This data alerts us to the possibility that there may be obstacles that discourage patients from seeking the care they need. Conversely, it may indicate that they provide such good outpatient treatment that they are able to circumvent the need for hospitalizations. In any event, the data signals that a closer look needs to be taken. We note that similar quality assurance activities are required under 9.674 (b) (10). Consequently, requiring them as part of the annual report should involve no additional cost to the managed care company.

In summary, we would like this Section to require managed care companies to conduct and report the results of patient satisfaction and quality assurance studies, and report on the annual rate of psychiatric hospitalizations.

Time Frames for Utilization Review

Section 9.751 deals with the time frames required for utilization review decisions. These provisions require the UR decision to be made within one business day "of the receipt of all supporting information reasonably necessary to complete the review" for concurrent UR decisions and two business days for prospective decisions.

However, our psychologists report that many times these reviews take weeks or sometimes even months. The UR decision is simply delayed because the supporting documentation is not received. However, the psychologists are not informed of what additional information is needed.

Section 9.751 needs to include a provision that requires the UR entity to inform the provider of what additional supporting information is necessary to complete the review within one business day of receiving the request. If the regulations fail to include this provision, then the intent of this section is vitiated and it becomes meaningless.

Health Care Provider Contracts

We note that under Section 9.722 (c) (4) the health care provider contracts may not contain language that prohibits providers from advocating for medically necessary services, filing grievances on behalf of an enrollee, and for other reasons. We believe that contracts should also be prohibited from disenrolling providers for filing prompt payment claims under Section 2166.

Summary

Act 68 explicitly requires managed care companies to have adequate access to services. These proposed regulations would circumvent the letter and intent of Act 68 and therefore, IRRC must reject them. In addition, we have noted other ways that these proposed regulations could be improved.

For your convenience, we are listing these comments in Table form on the next page.

Thank you for the opportunity to respond to these proposed regulations.

Sincerely,

Samuel Knapp, Ed.D.
Director of Professional Affairs

cc: House/Senate Insurance Committees
House/Senate Health Committees
Department of Health

Summary of Recommendations

Section of Draft Regulations	Nature of Problem or Proposed Change
9.604 Plan Reporting Requirements	include inpatient psychiatric hospitalizations and data on patient satisfaction or quality of care
9.679 (D) Access Requirements	Delete requirement that it applies only to 90% of its beneficiaries; 45 miles/60 minutes too far for rural areas
9.679 (H) Access Requirements	Give clear definition of infrequently used services
9.679 (J) Access Requirements	Delete this section
9.722 (c) (4) Contracts	Filing under Section 2166 ("clean claims") should not be grounds for dismissal from a contract
9.751 Utilization Reviews	Require UR to inform providers within one day for concurrent or 2 days for prospective reviews of what additional information is required to make an informed decision
9.761 Credentialing Process	Require subcontrators to report their credentialing process as well. Require information on number of active providers and efforts to develop or maintain an adequate panel

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REVIEW COMMISSION

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19 North Main Street
Wilkes-Barre
Pennsylvania
18711

Memo

[redacted]

To: All Members, Independent Regulatory Review Committee

From: Kimberly Kockler, Director, Policy Management
(717) 671-8204

Date: 03/15/2001

Re: DOH Final Form Act 68/Managed Care Regulation-#10-160

On behalf of Blue Cross of Northeastern Pennsylvania (BCNEPA) and our not-for-profit managed care subsidiary, First Priority Health (FPH), I am attaching for your review and information a copy of our March 15, 2001 public testimony and a list of concerns, questions and recommendations in regard to the Act 68, 1998/managed care final form regulation issued recently by the Department of Health (#10-160). Due to the number and scope of outstanding issues and the limited timeframe for review of this comprehensive regulation, BCNEPA is asking that the Independent Regulatory Review Commission (IRRC) **vote to disapprove the regulation.**

As you will see from the attached list, our concerns are operational or administrative in nature and not in conflict with the intent of Act 68 nor what it was designed to accomplish on behalf of the State's managed care consumers and participating providers. It is our position that enacting these regulations as written would prove costly to our health plan and ultimately our customers without a subsequent or significant improvement in health care quality or delivery. We are also concerned that, in some instances, the Department of Health has exceeded the statutory authority of the Act, particularly in regard to its application to traditional indemnity insurers.

BCNEPA asks that insurer stakeholders be granted an immediate and direct dialogue with the Health Department in an effort to resolve what we view to be significant operational questions and concerns with the final form regulation. It is critical that this dialogue take place **prior to final promulgation of the regulation**.

Once again, we respectfully request that you review our list of concerns and vote to disapprove the regulation as currently drafted.

PUBLIC TESTIMONY

Department of Health Act 68, 1998/Managed Care
Final Form Regulation

Submitted by:
Blue Cross of Northeastern Pennsylvania/First Priority Health

Submitted to:

House Health & Human Services Committee
The Honorable Dennis O'Brien, Chairman

House Insurance Committee
The Honorable Nicholas A. Micozzie, Chairman

Thursday, March 15, 2001
Harrisburg, Pennsylvania

Introduction

Thank you Chairman O'Brien, Chairman Micozzie and Committee members for the opportunity to comment on the Department of Health's final form regulation pursuant to Act 68, 1998 and other managed care reforms. My name is Kimberly Kockler and I am the Director of Policy Management at Blue Cross of Northeastern Pennsylvania/First Priority Health. I am testifying today on behalf of First Priority Health (FPH), a not-for-profit managed care subsidiary of Blue Cross of Northeastern PA.

FPH enrolls approximately 174,000 members who reside in 13 counties in northeastern and north central Pennsylvania. In our service area, we represent nearly 11,000 companies, many of them small businesses employing one to ten employees. Our comments today are reflective of the concerns we have about the effects implementation of this final form regulation will have on our ability to serve our members and employer clients in a quality-based, cost effective manner.

I would like to begin by first acknowledging the significant changes made to this regulation by the Health Department and as a result of issues and concerns raised by stakeholders in early January 2001. Those changes signify the Department's willingness to listen to the industry and to make changes that will better facilitate implementation of the regulation at the plan level.

Objectives for Moving the Process Forward

As an entity regulated by the Departments of Health and Insurance, FPH is anxious to have final guidance on the implementation of Act 68. However, we do not believe that the push to promulgate final regulations should surpass the need to achieve the following objectives:

- Address the remaining operational concerns within the proposed final form regulation and, to the extent possible, balance changes with managed care plans' commitment to effectively and efficiently serve members, comply with existing state and federal law and regulation, and meet national quality and accreditation standards.
- Develop a more direct and open dialogue between regulated entities and the Department in order to resolve current concerns and set a precedent for future communications throughout the regulatory process and implementation.
- Assure that plans will have sufficient time to implement the regulations once published.

Let us be clear at the outset: What we are NOT seeking today is to begin the regulatory process anew. What we are seeking is some additional time and a more direct dialogue with the Department in order to resolve outstanding issues and to set the stage for improved future communications.

Issues and Concerns

Attached to this testimony is a list of specific operational issues, questions and concerns with the proposed regulation. Where applicable, we have also included recommendations for change. While I will not use Committee members' time to go through the detailed list, it is important to note publicly that the concerns FPH has with this regulation are administrative in nature and not in any way contrary to the intent of Act 68 or what it was designed to accomplish on behalf of managed care consumers or providers.

We can fully appreciate the Department's task in formulating not only Act 68 regulations but also accomplishing an entire re-write of managed care oversight in the Commonwealth. Nevertheless, FPH continues to foresee a number of operational problems arising as we attempt to comply with this regulation in its current form. Overcoming these operational issues will, in our estimation, prove costly to the plan and ultimately our customers. In addition, and as outlined in our attached comments, there are numerous areas where it would be helpful to have clarification from the Department prior to final promulgation.

At first glance, our list of questions and concerns may appear minor. However, we would ask that you view them in totality and realize that each one will directly impact one or more operational areas within our managed care plan, including quality and utilization management, medical management, legal, provider relations and member services. We would also ask you to understand that this regulation must be implemented in conjunction with many other existing state and federal laws and regulations as well as national accrediting standards.

This regulation is currently under review by numerous departments and individuals within FPH – all of whom will be directly affected by its implementation. Due to the somewhat limited timeframe for review of the newly released and revised regulation, FPH is unable to provide the Committees with specific dollar impacts at this time. What we can provide are a few brief examples of operational impacts that demonstrate how the regulation will prove costly without a subsequent or significant improvement in health care quality or service delivery.

Operational Issues

Despite Act 68's strong endorsement of National Committee for Quality Assurance (NCQA) accreditation and credentialing standards, there are some inconsistencies between this regulation and NCQA requirements. Managed care plans in Pennsylvania are required to seek accreditation by an external, independent entity. Plans across the nation and in Pennsylvania most frequently chose NCQA, an organization recognized nationally as setting the standard for quality measurement and improvement in the managed care industry. FPH is among the plans that follow NCQA standards and has attained an NCQA rating of "Excellent" for the past two years.

The Department's final form regulation also appropriately seeks to address and further regulate managed care plan quality oversight as per Act 68. Unfortunately, the final form regulation at times conflicts or greatly exceeds the requirements that health plans must meet under NCQA.

One example is found in Section 9.654, subsection (c) that would allow an HMO to combine the required external quality assessment with an NCQA accreditation review IF the review adequately incorporates compliance with Act 68, the HMO Act and the regulations. FPH is concerned that this will require NCQA to tailor its current standards and create a Pennsylvania-specific accreditation review. In addition, FPH is concerned about the ability for plans to respond to issues that may not be raised during an NCQA review but may subsequently be raised by the Health Department.

Creating a Pennsylvania-specific review or having to undergo quality reviews in addition to NCQA will add to costs. The current cost of an NCQA review stands at $45-50,000 and does not include: the countless personnel hours and support systems necessary to collect, prepare and report data; time spent preparing for and undergoing the review itself; and, the personnel and resources necessary to follow-up and address quality issues raised during the review.

FPH is also concerned about the application of provider credentialing requirements found in the regulation. Specifically, in section 9.762, subsection (B), plans are required to verify credentials for all health care providers. Provider credentialing is also a major NCQA requirement. However, as defined by Act 68, health care providers extend well beyond Primary Care Physicians (PCPs) to non-physicians such as nurse midwives, physician assistants, pharmacists, etc. We interpret this regulation as requiring plans to verify the credentials of this extensive list of individuals, all of which would be extremely time consuming and costly, potentially doubling or tripling the need for credentialing staff. If this is not the case, then we are seeking the Department's clarification. If it is the case, we are recommending that the regulation be scaled back to require that managed care plans verify credentials only for all non-physician providers "under direct contract" with the plan.

Some of the other differences between the regulation and NCQA involve timeliness standards for determining starting dates and deadlines. These may seem to be minor concerns, however, when you are a health plan trying to adhere to State law and regulation while maintaining your accreditation status, small differences can become costly, time-consuming operational nightmares.

For managed care plans such as FPH, NCQA compliance and accreditation represent a major expenditure of human and financial resources. For the Commonwealth to add to this expense through regulation that is, at times, in conflict with national accrediting standards does not seem to be an efficient use of plan resources.

While we can certainly appreciate the fact that the Department, through this regulation or otherwise, would not relinquish its quality oversight authority to an external accrediting body, it would be beneficial to the industry if the proposed regulation recognized those standards and, to the extent possible, conflicts were resolved. Such conflicts place managed care plan personnel in the position of having to decide how to rectify differences between State regulation and national accrediting standards and needlessly consume plan resources that would be better dedicated to the needs of customers.

Conclusion

In conclusion, Chairman Micozzie and Chairman O'Brien, FPH is asking for the Committee to not approve this regulation at this time. However, in an effort to move the process forward, FPH suggests that we engage in an immediate interactive process much like the one undertaken prior to finalization of the Insurance Department's Act 68 regulations. At that time, Chairman Micozzie took the lead in convening stakeholders and the Department for an open, face-to-face dialogue that led to an expeditious resolution of outstanding concerns between and among interested parties.

FPH recognizes that the Health Department's regulation is much more voluminous and far-reaching than the DOI regulation. Nonetheless, a face-to-face dialogue could facilitate alternative solutions that would achieve the Department's objectives without placing an undue regulatory burden on the State's managed care plans. FPH stands ready to participate in such a process on this final form regulation. Once again, First Priority Health appreciates the opportunity to testify before you today.

ATTACHMENT
Issues/Questions/Recommendations
DOH Act 68, 1998/Managed Care Final Form Regulations

Section 9.633 – Location of HMO activities, staff materials

Subsection (1) requires that HMOs make available for Department review at a location within the Commonwealth, the books and records of the corporation and the essential documents as the Department may require, including signed provider contracts, credentialing files, complaint and grievance files, meeting (quality assurance and credentialing) minutes and hearing transcriptions. Access to credentialing files fall under the PA Peer Review Protection Act as granted by Act 68. Meeting minutes and specific elements of credentialing files should not be given general access to the Department. **FPH suggests the following language: "Credentialing files and credentialing committee minutes shall be made available for review in order to comply with EQRO standards only."**

Section 9.654 – HMO External Quality Assessment

Subsection (c) would allow an HMO to combine the external quality assurance assessment with an accreditation review IF the review adequately incorporates compliance with Act 68, the HMO Act and the regulations. FPH is concerned that this will require NCQA to tailor current standards to a Pennsylvania-specific accreditation review. In addition to adding to the cost of an NCQA accreditation review (which currently stands at approximately $45-50,000), the requirement will defeat the purpose of national standards and the ability to rate and compare health plans based on those standards. **FPH advocates that an accreditation review by a DOH-designated entity satisfy the external quality assessment requirement.**

In addition, FPH is concerned about the prospects of the DOH identifying any issues not raised during an NCQA review/audit and the plan subsequently having no avenue to appeal the finding. **FPH recommends that there be a stated process within the regulation whereby plans may appeal an external quality assessment issue not identified during the independent review.**

In subsection (F), it is noted that the Department's documents resulting from the external quality assessment regarding deficiencies requiring an HMO response, and the HMO's ensuing responses, including plans of correction and follow-up documentation, will be made available to the public under the Right to Know Act. The section further states that assessment information containing proprietary information will not be made available. These two provisions are inconsistent, in that, information contained in quality assurance corrective action plans is proprietary. FPH advocates that it should be sufficient to notify the public that deficiencies were found and that a corrective action plan is underway. The specific plan and comments should remain proprietary. **FPH suggests: "The Department's documents resulting from the external quality assurance assessment concerning deficiencies found requiring a response will be made available to the public upon request as required under the Right to Know Act. The managed care plan's ensuing responses, including plans of correction and follow-up documentation and the remainder of the assessment containing proprietary information, may not be disclosed."**

Subsection (G) indicates that the Department will publish annually in the *Pennsylvania Bulletin* a list of acceptable EQROs. Standards differ significantly between and among accreditation bodies and sufficient notice of changes should be given in order to enable plans to transition operational processes and documentation that could impact performance reviews. **FPH asks that the Department provide at least six months notice in the event EQROs are added to or deleted from the existing list.**

Section 9.672 – Emergency Services

Continuity of care in regard to provision of emergency services is a concern and a recurring problem for FPH. Emergency providers often fail to provide necessary notification and information to the managed care plan or primary care physician when a member has received emergency services. Subsection (F) contains no enforcement mechanism in the event emergency service providers do not notify the enrollee's managed care plan that emergency services have been provided. **FPH advocates that an enforcement provision be added and also that continuity of care issues be expanded to include a requirement that the member's primary care physician be provided a copy of the discharge summary of emergency services.**

Section 9.673 – Plan provision of prescription drug benefit to enrollees

Most managed care plans have gone beyond a "closed formulary" structure to a tiered structure where drugs are available with varying co-pays. Tiered structures ensure drug availability for the consumer with the understanding that different co-pays will apply to different types and classes of drugs. Therefore, the actual language of this provision may no longer be relevant to the current administration of the majority of managed care pharmacy benefits. **FPH recommends that this entire section be limited to a "closed formulary" structure.**

The same reasoning should apply in subsection (c) that requires plans utilizing a formulary to have a written policy that includes an exceptions process. Again, the movement toward tiered formularies makes the exceptions process different than it would be under a "closed formulary." **FPH recommends that this provision be limited to plans utilizing "closed" formularies.**

There is additional concern regarding classification of consumer prescription drug coverage disputes. As proposed, and keeping in mind the tiered systems previously discussed, the regulation would allow consumer complaints regarding level of tiered drug coverage to be classified as grievances. Grievances as defined by the Act, however, are based upon medical necessity - which would not be at issue in these cases. It is the level of coverage that is in dispute under the tiered system. Therefore, **FPH advocates that such disputes be classified and treated as complaints and not grievances as per the intent of Act 68.**

Section 9.674 – Quality Assurance Standards

Subsection (C)(1)(III) requires that quality improvement plans include standards for access to "routine, urgent and emergent" appointments. This provision applies to providers that, as defined in the regulations and the Act, include medical equipment suppliers, physician assistants, pharmacists, etc. The term appointments, therefore, is not always applicable. **FPH advocates that this be clarified and that the term "routine care" be used as in other sections of the regulation.**

Subsection (C)(3) requires that enrollees be involved in updating the quality assurance plan. This should be a data driven process based upon utilization, customer service and consumer satisfaction information – all of which includes direct consumer experience and feedback. To include enrollees in the formal planning process would be no more than a check on the existing quality assurance process. In addition, timeliness is an issue due to the fact that work plans are required annually. Increased complexity in the process will impact timeliness. This requirement exists in the Medicare program where FPH experience has been that: 1) it was difficult and costly to expand the current physician-driven quality assurance committee to include consumers; and, 2) consumer involvement ultimately resulted in no significant impact upon quality improvement or assurance standards. **FPH recommends removal of this requirement.**

Section 9.678 – Primary Care Providers

Subsection (e) regarding specific disclosure about the possibility of a limited subnetwork is too broad and may mislead consumers. While PCPs, in general, do have referral patterns, the plan's responsibility lies not with making members aware of this fact, but reinforcing that members are free to choose any specialist in the network. **FPH supports removal of this specific provider directory notice requirement.**

Section 6.679 – Access requirements in service areas

Subsection (c) requires managed care plans to report "potential losses" of a network provider or providers. In addition to our concern that this would be detrimental to the negotiating process and physician and health plan members, FPH would ask the following: **What is a "potential loss?" How is a plan to definitively identify and report a "potential loss?" Finally, how will this provision be monitored by the Department?**

Subsection (D) outlines specific service area access requirements that conflict with NCQA standards. NCQA monitors plans for network adequacy relevant to specific membership needs. In particular, FPH is concerned about the requirement that 90% of enrollees have access to services "from work or residence." It is unclear how plans are to determine enrollee access from work since this information is not part of the current geo-access database (which is based upon residence). It is also unclear how the Department intends to determine if a plan is in compliance with such access requirements. Managed care plans can reasonably assure geographic access, however, if an enrollee is provided with the necessary network information and makes the decision to enroll in the plan, should it not be assumed that they have had the opportunity to make an informed choice? **FPH recommends that the NCQA standard for network access and monitoring be adopted.**

Subsection (F) may discourage plans from entering rural markets. For plans in rural markets – like FPH – this provision represents nothing more than a major, costly and time-consuming paper chase of documentation for rationale. **FPH recommends that this provision apply only to counties or areas designated as MSAs where multiple health care delivery sites should be available.**

Subsection (I) would require that ancillary service plans and prescription drug and other riders be held to the same standards of coverage as those for basic health services coverage. These standards include network adequacy, etc. as defined in subsections (D)(F)(G). This exceeds any accreditation or traditional insurance requirement. In addition to questions as to how this would be monitored for compliance, FPH would point out that coverage choices made by enrollees are typically based upon whether or not the enrollee finds the health care provider of his/her choice. Such a prescriptive standard will increase the administrative burden on the plan without directly or positively influencing consumer choice. **FPH advocates for elimination of this requirement.**

Subsection (J) regarding a "therapeutic reason" to arrange for services at a distance would seem to relate only to rare circumstances and does not use definitive language. It would not appear to result in quality of care improvement and would be subject to significant interpretation if audited. **FPH advocates for removal.**

Section 9.681 – Health Care Providers

Subsection (d)(5) regarding routine appointments applies to health care providers – not just PCPs. As pointed out previously, the regulations and Act define health care providers broadly and exceed PCPs and specialists – those to whom the term typically applies. It is therefore difficult to determine how to apply the term. **The Department has made it clear in**

other sections of the regulation that "routine care" must be provided and FPH is seeking clarification of the term "appointment" as it applies to non-physician providers.

Section 9.682 – Direct Access for Ob/Gyn Care

Subsections (A) and (B) should be combined for clarity. For example, taken alone, subsection (A) could mean that ob/gyn services and follow-up care are covered under direct access. However, subsection (B) includes exceptions for prior authorizations. **FPH recommends that the sections be combined and that exceptions for prior authorized services be specifically noted within subsection (A).**

Section 9.684 – Continuity of Care

Subsection (c) refers to new enrollees seeking to continue care. This provision has broad implications and should be clearly defined for the member and plan. The transition period for an enrollee (for reasons other than pregnancy) is not defined. FPH has experienced members requesting to see an out-of-network provider for a routine check-up a year after enrolling in the plan and citing continuity of care and ongoing course of treatment as the rationale. **In order to help plans better assure continuity of care, FPH recommends that members be required to notify plans at the time of enrollment of any continuity of care concerns and the desire to continue a course of treatment for a defined period of time.**

Subsection (f) would allow plans to require non-participating providers to meet the same terms and conditions as participating providers but would not allow plans to require non-participating providers undergo full credentialing. In order to ensure that enrollee care will not be disrupted but that providers who will be treating FPH members are licensed and have appropriate credentials, we recommend the following change to the language: **"A plan may require non-participating health care providers to meet the same terms and conditions as participating providers and may require non-participating health care providers to undergo full credentialing to the extent that the plan may verify licensure, hospital privileges, Drug Enforcement Agency education and training, Medicare and Medicaid sanctions and malpractice insurance coverage."**

Section 9.703 – Internal Complaint Process

Subsection (C)(1)(III) entitles enrollees or their representative to all information related to the complaint. Access to all information related to benefits, enrollment, medical policy and procedure is appropriate and available. However, some information obtained during the course of investigating a quality of care complaint is protected under peer review and cannot be disclosed to the enrollee or the representative. **FPH recommends that plans be required to provide the enrollee or their representative with access to all information that IS NOT protected under peer review.**

Section 9.705 – Internal Grievance Process

Subsection (c)(3)(V) would prohibit a primary care provider from qualifying as a "same or similar specialty reviewer" during the plan's first level internal grievance process, except in cases where the service in question was requested by a primary care provider. The Act contains no such specific prohibition for primary care providers. This prohibition is problematic, most especially in the case of internists who are designated as both specialists and primary care providers. **FPH advocates for removal of this subsection.**

Subsection (V) establishes that plans must resolve first level internal grievances within 30 days of receipt. **FPH advocates that the requirement be changed to 30 working days in order to be consistent with NCQA.**

Section 9.707 – External Grievance Process

The regulations allow for an appeal of the CRE's decision to a court of competent jurisdiction. Is there any appeal process short of court that would address whether the CRE made a decision on the correct issue? For example, in a case involving a request to access a non-participating provider, the plan may not be questioning the medical necessity of the service, but rather the location where the service is to be delivered. **If the CRE made the decision based upon medical necessity and not service location, can the plan appeal to DOH and not the court?**

Section 9.722 – Plans and Health Care Provider Contracts

There is great concern about existing provider contracts and whether or not the Department will allow current contracts to stand or be "grand fathered in" until the next renewal. Lack of such accommodation will prove costly for plans that may, in fact, be forced to renegotiate contracts as a result. **FPH advocates that existing provider contracts be permitted to stand as written and not have to be submitted to the Department until the time of the next renewal.**

Subsection (e)(7) requires that health care providers and plans give 60 days advance written notice in the event of a contractual termination. This does not allow for an immediate termination of a provider for violation of state law (no longer has a valid license, no longer has malpractice insurance, etc.). **FPH recommends that such notice be required unless the practitioner is a threat to public health and safety and/or has violated State laws to include, but not be limited to, those noted previously.**

Subsection (e)(8) requires plans to give at least 30 days advance written notice of changes to contracts, policies or procedures that affect health care providers or provision of payment of health care services to enrollees. **FPH is seeking clarification that this provision does not apply to information to enrollees that is, in this sense, proprietary.**

Sections 7.49, 7.50, 7.51 – Utilization Review Operations and Standards

There is great concern that these new sections of the regulation apply to licensed insurers. Expanding these provisions of the Act to include licensed insurers is outside the scope, intent and language of the Act. The Act clearly states that such standards would apply only if a licensed insurer were performing utilization review on behalf of a managed care plan. As drafted, the regulation clearly exceeds the intent of the Act. **FPH strongly advocates for clarification that the standards DO NOT apply to all licensed insurers or for removal of the sections.**

Section 9.761 – Provider Credentialing

Subsection (a) requires plans to "evaluate and enroll" qualified health care providers. **FPH is seeking a clarification to eliminate the term "enroll" in order to make it clearer as to which practitioners the plan is obligated to review as part of the credentialing process. FPH recommends that plans "shall establish, maintain and adhere to a health care provider credentialing system to evaluate and contract with qualified health care providers for the purpose of creating an adequate health care network."**

Subsection (F) requires plans to submit a report to the Department every two years regarding the plan's credentialing process. **For purposes of efficiency, FPH recommends that such reports be due at the same time that the plan's annual reports are due to the Department.**

Section 9.762 – Credentialing Standards

Subsection (B) includes verification requirements. Such requirements should only extend to those non-PCPs and non-physician specialists who are contracted with the plan. If such specificity is not included in the regulation, it would be interpreted to mean that the plan must credential all nurses or other medical professionals who are employed by physicians. This would be extremely burdensome and costly, entailing significant new staff and resources. **FPH recommends: "A plan shall verify, at a minimum, for <u>all contracted</u> PCPs and non-specialists . . ."**

9.763 – Non-physician providers at facility, agency or organizations

This section indicates that plans are not required to credential non-physician providers who are employed by or contracted with a plan contracted facility, agency or organization if the plan verifies that the facility, agency or organization conducts credentialing that meets the standards established in 9.762. The Department does not specify what a "facility, agency or organization" is and it is unclear whether this would then exceed NCQA standards. For example, if a plan contracts with a pharmacy benefits manager (PBM), is the plan required to verify the PBM's credentialing process or individual pharmacies? **FPH recommends that credentialing requirements not exceed current NCQA standards, that the Department clarify the types of facilities, etc. being referenced and, if the intent is to exceed NCQA, to provide a response to the specific inquiry regarding credentialing and PBMs.**

3/15/01