The Insurance Federation of Pennsylvania, Inc.

1600 Market Street
Suite 1520
Philadelphia, PA 19103
Tel: (215) 665-0500 Fax: (215) 665-0540
E-mail: mailbox@ifpenn.org

Samuel R. Marshall
President & CEO

March 12, 2001

To: The Honorable Members of the Senate Health and Welfare Committee

From: Samuel R. Marshall

Re: Health Department managed care regulation - areas of objection

Today, we have outlined our objections to the Health Department's final form regulation implementing the managed care reforms of Act 68 and revising existing regulations of the HMO and PPO acts.

Our basic objection is that, in several key areas, the regulation goes well beyond the authority given to the Health Department under those acts, and it is either unclear, unrealistic or unreasonable. We also pointed out that our objections are with the mechanics of the regulation, not its philosophy or purpose. Our objections can be resolved without jeopardizing the consumer safeguards of Act 68; just the opposite - resolving them will help all of us who operate under Act 68, whether insurers, providers or consumers.

The following is a section-by-section analysis of our objections.

Section 9.602 - Definitions (p. 75)

"Managed care plan:" While this definition now matches that of the Insurance Department's regulation, the confusion of unexplained dual regulation remains. This regulation does not explain which agency enforces these joint provisions, and how possible differences between the two agencies are to be

resolved where they both assert regulatory authority. We accept that both the Health and Insurance Departments will regulate managed care plans - but that regulation should be joint, not separate and uncoordinated.

Section 9.606 - Penalties (p. 88)

The problem is with subsection (d): While this section concedes that the Department must operate under administrative law before penalizing a managed care plan for failure to comply with a corrective action plan, it still suggests that the Department can order the plan to draft a corrective action plan without having the chance to object. Just as Act 68 requires that managed care plans treat patients fairly, so should this regulation provide for fair treatment of those it regulates.

Section 9.633 - Location of HMO activities, staff and materials (p. 98)

Subsection (2) requires that an HMO's medical director have a Pennsylvania license. Many HMOs are multi-state entities with medical directors living and licensed elsewhere. It would make more sense to allow licensure in any jurisdiction acceptable to the Department, especially given that this section already requires that an HMO's quality assurance committee have a Pennsylvania-licensed provider.

Section 9.651 - HMO basic services (p. 102)

Subsection (c) requires that HMOs provide at least 90 days of "inpatient services for general acute care hospitalization." The preamble "clarifies" that this does not include behavioral health services. But the preamble does not define those services (I assume they include mental health and drug and alcohol abuse coverages, but who knows?) - and regulatory preambles are binding only on regulators, not third parties.

Section 9.672 - Emergency services (p. 109)

The language now matches Section 154.14 of the Insurance Department's regulation, but it still leaves unanswered the basic question of which agency enforces this area. If both agencies want to do so, fine - but the regulation should provide that they do so jointly. Otherwise, you run the needless risk of inconsistent standards and uneven enforcement.

We also recommend the regulation clarify that the testing to be covered be limited to that within the scope of any emergency evaluation (that is truly a clarification, one that can probably be addressed in the preamble).

Section 9.673 - Prescription drugs (p. 111)

Subsection (b) requires that a plan respond in writing to a question about whether a prescription is on its formulary. That makes sense if the answer is no - but what is the purpose of a written response if the answer is yes, beyond needless paper and delay?

Section 9.675 - Delegation of medical management (p. 115)

The Health Department insists on prior approval of a managed care plan's contracts with providers delegating medical management (managed care plans, correctly, cannot delegate responsibility or accountability). It wants a 60 day period in which to grant this approval - and also wants the right to take any subsequent action it wants if it does nothing in 60 days.

Nothing in Act 68 even suggests this power. The Department contends that it is a properly inferred power, as it is needed for that department to meet its duty of ensuring quality care.

A regulator must have express statutory authority before it can assert prior approval of contracts. A number of laws establish prior approval of various insurance contracts and rates, with the rules varying depending on the type of

insurance. You may want these contracts subject to a regulator's prior approval (we believe it is a needless step that benefits nobody) - but it is a legislative decision.

Further, the prior approval imposed by the Health Department here unfairly creates a bizarre contractual limbo. The regulation provides that if the Department does nothing in 60 days, the Department can come back at any time and "require the plan to correct deficiencies" it identifies. In other words, the Department benefits from doing nothing.

Section 9.676 - Enrollee rights (p. 118)

This is something of a misnomer. All of Act 68 provides rights to enrollees - as with disclosures and the complaint, grievance and utilization review provisions. Those rights are covered throughout this and the Insurance Department's regulation - so I am not sure what this section really adds.

All this section does is set forth rights that are already covered in other laws - namely, HIPAA, the Health Insurance Portability and Accountability Act - that are expressly regulated by the Insurance Department. Curiously, this section does this only for HMOs; HIPAA and the Insurance Department go broader, applying this to all managed care and group insurance plans.

This is an odd - and unlawful - usurping or bootstrapping of one regulator's power that will only produce confusion, not compliance. An agency should not be allowed regulatory oversight over an area the General Assembly has, by statute, expressly left to another agency. The Health Department has acknowledged this in making other changes to this regulation; it should also do so here.

Section 9.681 - Health care providers (p. 127)

Subsections (a) and (b) largely match Section 154.16(c)(2) of the Insurance Department's regulation in requiring managed care plans to send out provider directories to enrollees. I am not sure why both agencies have to regulate this, or why they could not at least coordinate that regulation.

The greater concern is with the minor changes the Health Department has made in its version: It requires that the directories have disclaimers on the future availability of providers, and it has added some language on affiliations of nurses. Why have different requirements from different agencies implementing the same statute?

Section 9.684 - Continuity of care (p. 131)

As with the section on emergency services, this has been changed to match the language in Section 154.15 of the Insurance Department's regulation. But again, this regulation fails to answer the basic question of which agency enforces this area. As we said before, if both agencies want to do so, fine - but the regulation should provide that they do so jointly. Otherwise, you run the needless risk of inconsistent standards and uneven enforcement.

Sections 9.702 - 9.706 - Complaints and grievances (p. 136)

The regulation imposes some impossible, or at least impractical and implausible, requisites on managed care plans that will not help achieve Act 68's purpose of timely, fair and responsive answers to complaints and grievances. The regulation's provisions related to complaints - Sections 9.702 and 9.703 - also raise the problem of separate, uncoordinated regulation with the Insurance Department's regulation.

The basic requirement of Act 68 is that a managed care plan have a two-tier internal review process that fairly answers complaints and grievances in 30 days at the first level and 45 days at the second level. The requirements of this regulation make that impossible, or at least impractical or implausible.

Sections 9.702 and 9.703 - Internal review of complaints

The first tier of review for complaints: Section 9.702(c)(2) requires that a managed care plan with a question of whether something is a complaint or grievance submit it to either the Insurance or Health Department, with that agency's (or at

least the Health Department's - the regulation is unclear) decision binding. Given that the plan must answer the complaint/grievance within 30 days and given the binding nature of the Department's resolution, this is an impossible - and based on almost three years of experience under Act 68, needless - added layer.

The regulation continues this problem in Section 9.703(c)(1)(I)(A), which requires that a managed care plan receiving a complaint notify the enrollee that it considers as such, with the enrollee having the right to question this to the Health Department. That questioning should at least include the Insurance Department, and it raises questions about the ability to do all this within 30 days.

Section 9.702(a)(4) requires that plans provide employees to assist in the preparation of a complaint or grievance against the plan; this is frequently repeated in the rest of the complaint and grievance sections. This is truly impossible, even assuming there is a uniform standard of proper assistance: The complaint or grievance has already been filed.

Section 9.703(c)(1)(III) requires that a managed care plan provide the enrollee access to all information relating to the matter being complained of, with the chance to provide written or other (oral?) supporting material. Again, with the 30 day deadline, this is impractical and, depending on when an enrollee might respond, impossible. This also raises proprietary information concerns, as does Section 9.703(c)(1)(VI)(D) on information to be given in answering a first-tier complaint; the information includes internal rules, guidelines, protocols and other criterion, which raises not only business but also patient confidentiality concerns.

The second tier of review for complaints: Many of the same concerns exist here as with the first-tier review. Again, the timing problem dominates: Section 9.703(c)(2)(I)(A) requires that a plan answer the second level complaint within 45 days, which includes 15 days notice of a hearing and flexibility on scheduling.

Other concerns are the vagueness of the requirement that second-tier reviews be "informal" to "avoid intimidating the enrollee," and that committee members must "actively" participate if doing so by phone. All hearings are, by their nature, both formal (hence, the need to transcribe a record) and at least somewhat intimidating. Who knows what "active" participation means, beyond a chance to challenge this down the road.

Subsection (a)(2) provides that a managed care plan cannot have unfair or prohibitive procedures that effectively deny access to their complaint and grievance procedures. No problem with that - but this section sets up the Health Department as the only agency that reviews any of this. While the Department says it can only speak for itself, not the Insurance Department, it does provide for joint regulation in other areas - why not here?

Section 9.704 - Appeal of a complaint decision (p. 151)

Subsection (e) actually provides for the Insurance and Health Departments to work together in determining whether an appeal is correctly a complaint or a grievance. This genuine joint regulation is a first in this regulation. We point it out not as a problem, but as a solution to the many other sections that should also expressly provide for truly joint regulation.

Section 9.705 - Internal review of grievances (p. 152)

As the language here (and in Section 9.702) largely matches that for complaints, it also raises the same problems.

There are some added ones: The answers in both the first and second tiers - subsections (c)(1)(VI)(E) and (c)(2)(VII)(F) (should be (E)) - require not just the reasons for a decision, but an explanation of the scientific or clinical judgment for a decision. This is open-ended and of doubtful value.

Subsection (c)(3)(V) has some troublesome new language on the same specialty requisite. It prohibits a primary care provider from qualifying as a "same specialty" provider

reviewing a grievance unless the service in question was provided by a primary care provider.

That directly conflicts with Act 68: It requires that any internal grievance include a licensed physician "in the same or similar specialty that typically manages or consults on the health care service." Under Act 68, it is immaterial whether the service was provided by a primary care provider; the same should hold true for this regulation.

Section 9.710 - Approval of complaint and grievance processes (p. 180)

This requires that managed care plans obtain the Health Department's prior approval of any major changes in their complaint and grievance processes. Notably, this section imposes a 60 day deadline on the Department - apparently without the open-ended portion that applies to medical management and provider contracts; that highlights the need for change in those areas.

To the extent this covers changes in a managed care plan's complaint process, it should provide for joint regulation - not just the separate, uncoordinated regulation found here.

Section 9.722 - Plan and provider contracts (p. 183)

As with contracts for delegation of medical management (Section 9.675), this section asserts the Health Department's right to require prior approval of a managed care plan's contracts with providers. Again, it wants a 60 day period in which to grant this approval - and it also wants the right to take any subsequent action it wants if it does nothing in 60 days.

As noted with respect to Section 9.6765, nothing in Act 68 even suggests this power. A regulator must have express statutory authority before it can assert prior approval of contracts. And the contractual limbo created here is as unwise and unfair as it is unlawful.

Section 9.749 - Utilization review (p. 206)

Act 68 limits its utilization review provisions to services provided pursuant to a managed care plan, not any insurance plan (i.e., not indemnity). We read this regulation as keeping that limit: It defines "utilization review" as a system of review of care "provided to an enrollee," and it defines an "enrollee" as one "entitled to receive health care services under a managed care plan."

That limit is consistent with changes made to earlier drafts of Act 68 (namely, earlier drafts of Senate Bill 100 and House Bill 977), which covered all insurance plans in their utilization review rules. The limit was one proposed by, among others, the administration itself. It was adhered to by the Health department in its October, 1998 Statement of Policy implementing its responsibilities under the act.

The Health Department apparently contends that this regulation extends its utilization review rules to indemnity health plans. This is something that merits clarification; if that is the Department's intent, the regulation goes beyond not just the plain language of Act 68, but also of the regulation itself.

These are important areas to be resolved. But more important, they can be resolved without significant delay and without jeopardizing the consumer safeguards in Act 68 and the HMO and PPO acts. Fixing these problems will better enable those acts to work - not just for those of us who provide coverage, but also those who count on that coverage, those who provide the services being covered and even those regulating all this.

We appreciate that this is a long and complicated regulation, and that the time given to you (and us) for comment is short. I hope this helps, at least in understanding some of the difficulties this regulation presents and some solutions to them. Please call with any questions or comments.

SECOND, THE MANAGED CARE PLAN HAS TO NOTIFY THE ENROLLEE THAT IS HAS GOTTEN THE MATTER AND CONSIDERS IT EITHER A COMPLAINT OR A GRIEVANCE - WITH THE ENROLLEE HAVING THE RIGHT TO QUESTION THAT DECISION TO THE HEALTH DEPARTMENT. I AM NOT SURE WHAT HAPPENED TO THE INSURANCE DEPARTMENT, BUT I ASSUME ANY REGULATORY DECISION HERE WOULD ALSO BE BINDING. THE PLAN ALSO HAS TO GIVE THE ENROLLEE ACCESS TO ALL INFORMATION RELATING TO THE MATTER, WITH THE ENROLLEE HAVING THE CHANCE TO PROVIDE HIS OWN WRITTEN OR OTHER SUPPORTING MATERIAL.

THIRD, THE PLAN HAS TO NOTIFY THE ENROLLEE THAT IT WILL ASSIST THE ENROLLEE IN PREPARING THE COMPLAINT OR GRIEVANCE. THAT'S TRULY AN IMPOSSIBLE TASK, EVEN ASSUMING YOU COULD HAVE A UNIFORM STANDARD OF PROPER ASSISTANCE: THE COMPLAINT OR GRIEVANCE HAS ALREADY BEEN FILED.

FRANKLY, I THINK THIS IS AN AWFUL LOT OF NEEDLESS PAPER AND CONFUSION FOR WHAT EXPERIENCE SHOWS ARE USUALLY PRETTY ROUTINE MATTERS. BUT WHETHER THIS PAPER IS NEEDLESS OR IMPORTANT, TWO THINGS ARE CLEAR: DOING ALL THIS WITHIN 30 DAYS WILL BE IMPOSSIBLE, AND IT WILL CREATE RATHER THAN SOLVE DISPUTES BETWEEN PLANS AND ENROLLEES.

THE SAME PROBLEMS ARISE IN THE SECOND TIER OF INTERNAL REVIEW, WHETHER FOR COMPLAINTS OR GRIEVANCES. THERE ARE SOME ADDITIONAL DRAFTING PROBLEMS WITH THIS LEVEL: THE REGULATION REQUIRES THAT THE REVIEW HEARING BE "INFORMAL" TO "AVOID INTIMIDATING THE ENROLLEE." I HAVE NEVER BEEN TO AN INFORMAL HEARING, AND IT SEEMS THAT ANY HEARING ON YOUR OWN COMPLAINT OR GRIEVANCE WILL BE AT LEAST SOMEWHAT INTIMIDATING. THE REGULATION ALSO REQUIRES THAT THOSE PARTICIPATING BY CONFERENCE CALL DO SO "ACTIVELY." I AM NOT SURE WHAT THAT MEANS.

AS I MENTIONMED, YOU ALSO HAVE THE PROBLEM OF DUAL REGULATION HERE, AT LEAST WITH RESPECT TO THE COMPLAINT PORTION. THE INSURANCE DEPARTMENT ALREADY HAS A REGULATION ON THIS. THE HEALTH DEPARTMENT IS ADDING ITS OWN REQUIREMENTS - AND IT SETS ITSELF UP AS THE SOLE REGULATOR, AT LEAST SOME OF THE TIME. WOULDN'T IT MAKE MORE SENSE FOR THE TWO AGENCIES TO WORK TOGETHER, AND FOR THAT JOINT OVERSIGHT TO BE EXPRESSLY PROVIDED FOR HERE?

SOME WILL CHARGE THAT OUR OBJECTIONS HERE UNDERMINE IMPORTANT SAFEGUARDS FOR CONSUMERS WITH COMPLAINTS OR GRIEVANCES. PLEASE UNDERSTAND THAT IS A RED HERRING. WHAT WE ARE REALLY ASKING FOR IS THAT THE RULES COVERING

INTERNAL REVIEWS OF COMPLAINTS AND GRIEVANCES NOT CREATE THE VERY PROBLEM THAT WE HAVE BEEN ACCUSED OF CREATING IN OTHER AREAS: RULES THAT ARE SO CUMBERSOME THAT THEY ULTIMATELY DON'T WORK FOR ANYBODY.

A SHORTER EXAMPLE: SECTION 9.633 OF THE REGULATION REQUIRES THAT THE HMO'S MEDICAL DIRECTOR BE A PHYSICIAN LICENSED IN PENNSYLVANIA. WHAT IS THE RULE PURPOSE IN PENNSYLVANIA LICENSURE HERE? MANY HMOs ARE MULTI-STATE ENTITIES, WITH MEDICAL DIRECTORS LIVING AND LICENSED ELSEWHERE. IT WOULD MAKE MORE SENSE FOR THE DEPARTMENT TO ALLOW LICENSURE IN ANY JURISDICTION ACCEPTABLE TO IT, ESPECIALLY GIVEN THAT THIS SECTION ALREADY REQUIRES THAT THE HMO'S QUALITY ASSURANCE COMMITTEE HAVE A PENNSYLVANIA-LICENSED PROVIDER.

4. THE REGULATION IMPOSES SOME REQUISITES THAT ARE WITHOUT STATUTORY SUPPORT OR AUTHORIZATION.

SINCE I'VE BEEN TALKING ABOUT COMPLAINTS AND GRIEVANCES, I MAY AS WELL START THERE. ACT 68 REQUIRES THAT ANY INTERNAL GRIEVANCES INCLUDE A LICENSED PHYSICIAN "IN THE SAME OR SIMILAR SPECIALTY THAT TYPICALLY MANAGES OR CONSULTS ON THE HEALTH CARE SERVICE." SECTION 9.704(C)(3)(V) OVERTURNS

THAT, AT LEAST WHERE THE LICENSED PHYSICIAN ALSO SERVES AS A PRIMARY CARE PROVIDER. IT SAYS THOSE PHYSICIANS CAN ONLY MEET THE "SAME OR SIMILAR SPECIALTY" REQUISITE "IF THE SERVICE IN QUESTION WAS PROVIDED BY A PRIMARY CARE PROVIDER."

THAT RUNS CONTRARY TO ACT 68. WHETHER OR NOT A PHYSICIAN IS A PRIMARY CARE PROVIDER, HE QUALIFIES UNDER ACT 68 IF HE IS IN THE SAME OR SIMILAR SPECIALTY AS TYPICALLY MANAGES OR CONSULTS ON THE HEALTH CARE SERVICE - REGARDLESS OF WHETHER THE SERVICE WAS PROVIDED BY A PRIMARY CARE PROVIDER.

THIS REGULATION ALSO REQUIRES THAT A MANAGED CARE PLAN'S CONTRACTS FOR DELEGATING MEDICAL MANAGEMENT AND ITS CONTRACTS WITH PROVIDERS BE SUBJECT TO PRIOR APPROVAL BY THE HEALTH DEPARTMENT. THERE IS NOTHING IN ACT 68 THAT EVEN SUGGESTS THIS. THE HEALTH DEPARTMENT CONTENDS THAT IT IS A PROPERLY INFERRED POWER, AS IT IS NEEDED FOR THAT DEPARTMENT TO MEET ITS DUTY OF ENSURING QUALITY CARE.

THE SIMPLE TRUTH IS, A REGULATOR MUST HAVE EXPRESS STATUTORY AUTHORITY BEFORE IT CAN ASSERT PRIOR APPROVAL OF CONTRACTS. WE HAVE A NUMBER OF LAWS THAT ESTABLISH PRIOR APPROVAL OF VARIOUS INSURANCE CONTRACTS AND RATES, WITH THE

RULES VARYING DEPENDING ON THE TYPE OF INSURANCE. WHETHER THE CONTRACTS AT ISSUE HERE MERIT PRIOR APPROVAL IS A LEGITIMATE DEBATE. BUT THE POINT IS, THIS AUTHORITY HAS ALWAYS COME BY STATUTE, AND THE DEBATE ON THIS HAS ALWAYS BEEN A LEGISLATIVE ONE. IT SHOULD BE HERE, TOO.

EVEN IF THE HEALTH DEPARTMENT WERE ALLOWED PRIOR APPROVAL OF THESE CONTRACTS, THE RULES IN THIS REGULATION WOULD BE BOTH UNFAIR AND UNWISE. THE REGULATION SAYS, GIVE THE DEPARTMENT 60 DAYS - IF IT DOES NOTHING, THE PLAN AND THE PROVIDER CAN USE THE CONTRACT. BUT - AND THIS IS A BIG BUT - THE DEPARTMENT CAN COME IN AT ANY TIME AND "REQUIRE THE PLAN TO CORRECT ANY DEFICIENCIES IDENTIFIED BY THE DEPARTMENT." THAT PUTS MANAGED CARE PLANS AND PROVIDERS IN A BIZARRE CONTRACTUAL LIMBO, AT LEAST WHEN THE HEALTH DEPARTMENT DOES NOTHING IN THE FIRST 60 DAYS. THAT DOESN'T BENEFIT ANYBODY.

INTERESTINGLY, THE PRIOR APPROVAL FOR CONTRACTS WITH HOSPITALS AND DOCTORS IS A BROADER POWER THAN THE HEALTH DEPARTMENT ASSERTS WITH RESPECT TO ANY CHANGES IN A MANAGED CARE PLAN'S PROCEDURES FOR HANDLING COMPLAINTS AND GRIEVANCES - ARGUABLY THE MOST CONSUMER-SENSITIVE PART OF THIS REGULATION. THERE, THE REGULATION ASSERTS "ONLY" A 60

DAY PRIOR APPROVAL REQUIREMENT. IF IT DOES NOTHING, THE CHANGES ARE PRESUMABLY DEEMED APPROVED.

ANOTHER EXAMPLE: SECTION 9.651(C) PROVIDES THAT AN HMO MUST PROVIDE FOR 90 DAYS OF "INPATIENT SERVICES FOR GENERAL ACUTE CARE HOSPITALIZATION." THE PREAMBLE OFFERS A MILD CLARIFICATION THAT THIS DOES NOT APPLY TO BEHAVIORAL HEALTH SERVICES. I ASSUME THIS MEANS IT DOES NOT APPLY TO MENTAL HEALTH AND DRUG AND ALCHOHOL ABUSE COVERAGES, WHICH HAVE DIFFERENT STATUTORY MINIMUMS. BUT "BEHAVIORAL HEALTH SERVICES" IS AN UNDEFINED TERM - AND REGULATORY PREAMBLES ONLY BIND REGULATORS, NOT THIRD PARTIES.

SOMETIMES WHEN WE OBJECT TO A BILL OR A REGULATION, WE HEAR THE COMPLAINT THAT WE REALLY DON'T WANT ANYTHING DONE, THAT WE WILL FIND FAULT WITH ANY PROPOSAL. SOMETIMES THAT IS TRUE. BUT THAT IS NOT THE CASE HERE. WE RECOGNIZE THE NEED FOR A REGULATION, JUST AS WE RECOGNIZED THE NEED FOR ACT 68. THE OBJECTIONS WE HAVE SHARED WITH YOU TODAY ARE, I BELIEVE, CAPABLE OF BEING RESOLVED WITHOUT SIGNIFICANT DELAY.

MORE IMPORTANT, THESE OBJECTIONS CAN BE RESOLVED WITHOUT JEOPARDIZING THE SAFEGUARDS IN ACT 68 OR THE HMO AND PPO

ACTS. IT IS JUST THE OPPOSITE: RESOLVING THESE OBJECTIONS WILL MAKE FOR CLEARER, MORE EFFICIENT AND MORE FAIR REGULATION OF THOSE ACTS. YES, THAT WILL BENEFIT THOSE OF US WORKING TO PROVIDE COVERAGE UNDER THOSE ACTS. BUT IT WILL ALSO BENEFIT THOSE WHO COUNT ON THAT COVERAGE, THOSE WHO PROVIDE THE SERVICES BEING COVERED AND EVEN THOSE REGULATING ALL THIS.

AGAIN, THANK YOU FOR THE CHANCE TO BE HERE. I AM HAPPY TO ANSWER ANY QUESTIONS.

Original: 2079

Independence
Blue Cross

April 2, 2001

LEGISLATIVE POLICY OFFICE
500 NORTH THIRD STREET
SUITE 500
HARRISBURG, PA 17101

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

Dear Director Nyce:

Independence Blue Cross appreciates this opportunity to comment on the Department of Health's Act 68 regulations. Earlier, we corresponded with the Commission expressing our deep concern with the scope of the regulations and the burden of unnecessary administrative costs. Independence Blue Cross believes the revised regulations are improved from the regulations that were originally submitted by the Department, particularly in limiting their application in the area of utilization review to gatekeeper managed care plans as provided for in Act 68.

We also expressed concern that the Department was requiring health plans to submit existing provider contracts for review and approval. This issue was raised by both standing committees and the Secretary's tolling letter appeared to resolve the matter. Secretary Zimmerman's March 20 communication to the Commission stated, "The Department does not intend to disrupt ongoing business relationships with medical management organizations and health care providers that are based on contracts already approved by the Department." However, the revised preamble presents conflicting direction to health plans. On page 158 of the preamble the Department added new language: "The Department will not require refiling of contracts already approved." On page 407 of the preamble the Department states" "Although the Department is requiring plans to submit contracts in place prior to the effective date of the regulations for review and approval, it will permit plans to continue using those contracts." We note further that the regulations on page 185 have deleted language that would have required plans to resubmit provider contracts. We believe that the standing committees asked the Department to "grandfather" existing contracts and that they interpreted the tolling letter and revised regulations as satisfying their concern.

The Department stated in its March 20, 2001 letter to the Commission that " The Act requires written notice of all utilization review decisions to approve or deny coverage." We agree, however the Act does not require two written notices of each coverage determination. The Department has indicated that they will "waive" the new obligation that two written approval notices be sent for hospitalized patients and will advise health plans how they can satisfy this new requirement for members who are not hospitalized. Presently, health plans notify providers of all approvals and providers and members when there is an adverse determination. This additional administrative cost is unnecessary and it will only serve to confuse our members.

We appreciate the efforts of all parties--the General Assembly, the Department and the Commission--to make these regulations more workable in the legislative context of Act 68. We thank the Commission, the General Assembly and the Department for taking the views of Independence Blue Cross into consideration throughout this process.

Sincerely,

Mary Ellen McMillen
Vice President, Legislative Policy

CC: The Honorable Harold F. Mowery
The Honorable Dennis M. O'Brien

EMBARGOED MATERIAL

Original: 2079

April 2, 2001

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

Dear Mr. McGinley:

I am writing on behalf of the Pennsylvania Psychiatric Society, representing 1800 physicians specializing in psychiatry, to recommend adoption of the Department of Health's Act 68 regulations.

This recommendation does not come easily. The regulations are disappointing in a number of ways, and very worrisome in several. Nevertheless, because Act 68 in the absence of regulations has failed to provide substantive relief for either our patients or our member psychiatrists, we support the adoption of the DOH regulations as offering more hope than the alternative at this point.

We are particularly concerned by the removal of the regulations' applicability to utilization review performed by insurers for plans that do not meet the Act's definition of "managed care plan." During the debates and negotiations prior to passage of Act 68, our understanding was that the statute's procedures and standards for the performance of utilization review were meant to apply to all insurers doing utilization review [see subdivision (h), Section 2151 (e)]. This was also our understanding of the intent of the regulations as they were proposed in final form, only to be changed at the last minute when the review process was tolled. We would note that an unfair managed care process is an unfair managed care process, regardless of whether it is applied under a gatekeeper system or a fee-for-service plan. The results are the same – denial of medically necessary care, inefficient use of the health care system, and distress for all concerned.

We are also dismayed by the Department's decision, as described in the commentary attached to the regulations, to deem the denial of care through automated screening mechanisms as meeting the statutory and regulatory requirement for physician denial. We do not believe that the Department's interpretation meets the plain and common sense interpretation of the statutory and regulatory language.

Under the circumstances described by the Department of Health, the physician "involved" would have reviewed absolutely nothing pertinent to the case under review. The physician's 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 information.

Finally, we are very troubled by the regulations' failure to establish standards that would define "access" to the approval process through the required 800 number. Although plans have 800 numbers, providers must often make repeated calls, over a period of days and even weeks, in order to reach someone who says he has the authority to review the request for approval. Our members are shunted from voice mail to voice mail, leave messages that are never answered, and occasionally reach plan employees who have no idea why the caller was referred to them.

Pennsylvania Psychiatric Society

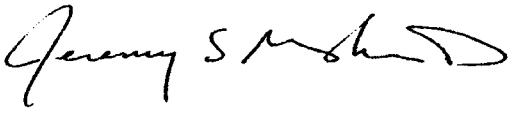
The Pennsylvania District Branch of the American Psychiatric Association

Executive Director
Gwen Yackee Lehman
777 East Park Drive
P.O. Box 8820
Harrisburg, PA
17105-8820

(800) 422-2900
(717) 558-7750
FAX (717) 558-7845
E-mail glehman@pamedsoc.org
www.papsych.org

Clearly, additional work needs to be done to ensure that Pennsylvanians have appropriate access to medically necessary healthcare in a manner that is efficient and fair to all. Nevertheless, as noted above, we view the absence of regulations at this point as less desirable than adoption of the Department of Health's currently proposed rules, and we ask that you vote to approve them.

Sincerely yours,



Jeremy S. Musher, MD, FAPA
President

Govt/IRRC

[redacted]

Original: 2079

BlueCross
of Northeastern Pennsylvania

[redacted]
70 North Main Street
Wilkes-Barre
Pennsylvania
18711

April 2, 2001

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

VIA FACSIMILE: Original to follow by mail

Dear Mr. Nyce:

The following is on behalf of Blue Cross of Northeastern Pennsylvania (BCNEPA) and our not-for-profit managed care subsidiary, First Priority Health (FPH), in regard to the Department of Health's proposed final form regulation (#10-60) on Act 68, 1998 and other managed care reforms. BCNEPA would like to first acknowledge and thank the Chairmen and members of the respective legislative standing committees and the Department of Health for working to address some of what BCNEPA viewed as serious operational concerns with the version of the final form regulation released on February 28, 2001.

Our organization is especially appreciative of language changes in regard to the following:

- Application of utilization review standards to licensed insurers;
- Classification of complaints and grievances under a tiered prescription drug structure;
- The ability of primary care physicians to serve as same or similar specialty reviewers when appropriate; and,
- Clarifications to service area access requirement notifications.

BCNEPA would ask that the IRRC consider the provisions of the regulation regarding Department review of provider and medical management contracts (Sections 9.675 and 9.722 respectively). The Preamble language does not appear to coincide with the new language contained in the regulation. Specifically, page 158 of the Preamble states, "The Department will not require re-filing of contracts already approved." The previously noted sections of the regulation, however, could be interpreted to mean that re-filing is required. The Department has stated publicly that the regulation is not intended to disrupt ongoing business relationships between plans and providers. BCNEPA asks for clarification of this issue and continues to advocate that existing, approved contracts not have to be re-submitted for Department review and/or approval.

While there remain some outstanding questions and concerns, our organization looks forward to working with the Department of Health, through technical advisories and other cooperative processes, to address future implementation issues associated with the regulation. We are gratified by the Department's publicly stated willingness to work in coordination with the industry in this manner.

Thank you for this opportunity to comment on the final form regulation.

Sincerely,

Kimberly J. Kockler
Director, Policy Management

Cc: The Honorable Hal Mowery
The Honorable Dennis O'Brien
The Honorable Vincent Hughes
The Honorable Nicholas Micozzie
The Honorable Anthony DeLuca
The Honorable Patricia Vance
The Honorable Tim Murphy

[redacted]

BlueCross
of Northeastern Pennsylvania
An Independent Licensee of the Blue Cross and Blue Shield Association
®Registered Mark of the Blue Cross and Blue Shield Association

19 North Main Street
Wilkes-Barre
Pennsylvania
18711

Fax

To: Robert E. Nyce, Executive Director, IRRC

From: Kimberly Kockler, Director, Policy Management

Date: 4/2/2001

Re: Regulation 10-60 – Department of Health – Act 68, 1998

Pages: 3

Phone: 717-783-5606

Fax: 717-783-2664

☐ **Urgent**
☐ **For Review**
☐ **Please Comment**
☐ **Please Reply**
☐ **Please Recycle**

Comments: Comment letter regarding final form regulation.

Original: 2079

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) opposes the Department of Health's regulations pursuant to the Quality and Health Care Accountability and Protection Act, known as Act 68. It is imperative that the Independent Regulatory Review Commission understands the basis of HAP's position.

Act 68 addresses a range of issues concerning managed care and contains two subsections, i.e., the prompt pay provisions and the utilization review operational standards, which have broader applicability, in that they apply not only to managed care plans, but also to licensed insurers. Specifically, subsection (j) imposes prompt payment requirements on *licensed insurers* and managed care plans, and subsection (h) prescribes standards and procedures for utilization review activities conducted by *licensed insurers* and managed care plans. Although Act 68 defines the term managed care plan, it does not provide a definition for the term licensed insurer. Managed care plans in the act are narrowly defined to include HMOs and other gatekeeper managed care plans. The inclusion of licensed insurers in these two sections reflects a broader applicability of these two sections.

HMOs and gatekeeper managed care plans are not the only health plans to use utilization review control to limit access to care and to deny payment for care. Non-gatekeeper managed care plans are the fastest growing managed care plans in the commonwealth and represent almost 50 percent of overall managed care enrollment in the private sector. The failure of the Department of Health regulations to recognize the broader applicability of the utilization review provisions of Act 68 means that these plans will not have to have physicians issue denials for care, will not have to provide the clinical rationale for denials, and will not have to provide patients with any opportunity to appeal the denial of care. In essence, there is little or no accountability for the decisions made by these plans to limit access or deny payment for care. Denying payments for care in these plans is tantamount to denying access given the cost of hospitalization, surgery, therapy services, mental health care, etc.

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.564.9200 Phone

HAP also is gravely concerned about the conflict between the Department of Health's interpretation of the statute and the Insurance Department's interpretation. On March 10, 2000, the Department of Insurance issued regulations implementing certain aspects of Act 68, which were within its enforcement jurisdiction, including the prompt pay provisions set forth in subsection (j). In its regulations, the Department of Insurance broadly defined licensed insurer, as follows:

> *Licensed insurer* – An individual, corporation, association, partnership, reciprocal exchange, interinsurer, Lloyds insurer and other legal entities engaged in the business of insurance, and fraternal benefit societies as defined in the Fraternal Benefit Societies Code (40 P.S. §§ 1142-101 – 1142-701), and preferred provider organizations as defined in section 630 of The Insurance Company Law of 1921 (40 P.S. § 764a) and § 152.2 (relating to definitions).

The Department of Insurance regulations implementing the prompt pay provisions track the language of Act 68 and make them applicable to *licensed insurers* and managed care plans (as defined in the statute and regulations).

On December 18, 1999 the Department of Health published proposed regulations implementing the portions of Act 68, which fall within its jurisdiction, including the utilization review provisions. In its proposed regulations, the Department of Health adopted the Department of Insurance's definition of licensed insurer. With regard to the applicability of the utilization review provisions, the Department of Health tracked the specific language of Act 68 and provided as follows: "a *licensed insurer* or a plan with a certificate of authority shall comply with section 2152 of the act [which sets forth the operational standards for utilization review entities]." In the applicability statement of the regulations (Section 9.601), the Department of Health made the specific statement that Section 9.742 (relating to the operational standards for utilization review) "applies to *licensed insurers* and managed care plans with certificates of authority."

After receiving and analyzing approximately 1400 comments to the proposed regulations, the Department of Health circulated its final Act 68 regulations. In the final regulations, the Department of Health made no substantive change to the definition of licensed insurer. With regard to utilization review, the Department of Health deleted the reference to licensed insurers in Section 9.601, but replaced it with a provision in Section 9.741 specifically referencing the utilization review provision of Act 68, and providing that pursuant to the act a Certified Review Entity, *licensed insurer* or a managed care plan with a certificate of authority shall comply with the utilization review operational standards set forth in the statute and regulations. In the preamble to the final regulations, the Department of Health explained the new provision by stating that it "*reiterates* the requirement of Act 68 that *licensed insurers* or managed care plans with certificates of authority . . . *are required to comply with the same operational standards as entities performing utilization review.*

On March 16, 2001, in a letter to the Chair of the House Health and Human Services Committee, the Department of Health stated that it would like to make certain *changes* to its final Act 68 regulations (and, pursuant to applicable statutory authority, received approval to toll the Independent Regulatory Review Commission's consideration of the regulations in order to enable it to make these changes). Specifically, the Department of Health stated that it was *deleting* Sections 9.741(c), 9.742(c) requiring licensed insurers and managed care plans to comply with the utilization review operational standards.

The purpose of the Department of Health's regulations is to set forth a comprehensive and detailed plan for implementation of the statutory objectives set forth in Act 68. In both its proposed and *initial* final Act 68 regulations, the Department of Health was consistent in including, as part of the regulations themselves, the specific statutory requirements, including the requirement that licensed insurers (and managed care plans) adhere to the utilization review operational standards. The deletion of these particular provisions creates the very problem that the Department of Health stated that it was trying to avoid, i.e., it would make the regulations unwieldy and more difficult to use.

Moreover, the elimination of the definition of licensed insurer leaves an obvious void in the regulations, which will create uncertainty as to how section 2151 of the Act should be applied. The Department of Health's failure to provide a definition will be particularly confusing given the department's public statements that it now interprets the term licensed insurer in a manner which is different from the Department of Insurance definition, and from what would ordinarily be thought to be encompassed within the plain meaning of the term itself (i.e., *all* licensed insurers).

Further, an agency regulation that is contrary to the statute under which it was promulgated is *invalid*. Agency interpretations of the statutes they are charged with enforcing are generally entitled to great deference, but only if the statute is ambiguous or unclear. On the other hand, if the intent of the legislature is clear from the statute, that is the end of the matter and the courts *as well as the agency*, must give effect to the unambiguously expressed intent of the legislature as evidenced in the statute.

This well known principle is embodied in Pennsylvania's rules of statutory construction, which expressly provide that when the words of a statute are clear and free from all ambiguity, the letter of it is not to be disregarded under the pretext of pursuing a different intent. The cardinal principle of statutory construction is that the plain words of a statute cannot be disregarded where language is free and clear from all ambiguity. The rationale for this rule is that the words utilized by the legislature are the best evidence of what the legislature intends. The Department of Health's limitation of the application of the term licensed insurers to licensed insurers who do utilization review for enrollees of managed care plans, ignores this cardinal rule. The qualification created by DOH is at variance with the express wording of the statute, which includes *all* licensed insurers without

qualification or limitation. In this case, the Department of Health is not at liberty to delete a statutory requirement from its regulations based upon its conjecture that the legislature intended something different from what it said.

By changing the regulatory definition of licensed insurer, the Department of Health violates another principle of statutory construction, which is that every statute shall be construed, if possible, *to give effect to all its provisions.* If the Department of Health now intends to apply the term "licensed insurer" as referring only to "licensed insurers who do utilization review for enrollees of a managed care plan . . ." this will essentially divest the term licensed insurer of any independent meaning. If a licensed insurer were to perform utilization review for enrollees of a managed care plan it would likely be doing so in the capacity of a managed care plan, as broadly defined in Act 68. Therefore, based upon that interpretation, the reference to licensed insurer in Section 2151(e) of the statute is, for the most part, extraneous.

Thus, the Department of Health's deletion of the references to licensed insurers based upon its conclusion that the legislature did not intend the operational utilization review standards to apply to *all* licensed insurers, is contrary to the plain wording of the statute.

Another cardinal rule of statutory construction is the avoidance of conflicts. Section 1932 of the Statutory Construction Act states that "statutes or parts of statutes are in pari materia when they relate to the same class of persons or things" and that "statutes in pari materia shall be construed together, if possible, as one statute." Moreover, statutes should be construed, if possible, so as to avoid any conflict between various agencies of the state, and the presumption is against a construction resulting in a conflict. The conflict-avoidance principle is also embodied in the review standards of the Independent Regulatory Review Commission, which is charged with reviewing and approving (or disapproving) all regulations before they take final effect.

Despite its repeated acknowledgement of the need for consistency with the Department of Insurance regulations, the Department of Health's change with regard to the definition of licensed insurer indicates that it is willing to create a direct conflict with the Department of Insurance's regulations defining and implementing the same term in the same statute. Thus, the terms licensed insurer and managed care plan in the prompt pay provision would apply to *all* licensed insurers (as defined in the Department of Insurance regulations) whereas the identical term in the utilization review provision would apply *only* to "licensed insurers who do utilization review for enrollees of a managed care plan." Such a construction violates the statutory and common law rules requiring that statutes be interpreted and implemented in a consistent manner. Its proposal to adopt an interpretation of licensed insurer, which is directly at odds with the Department of Insurance's existing interpretation of the same term in the same statute violates the rules requiring consistency in statutory construction.

HAP urges the Independent Regulatory Review Commission to reject the Department of Health's regulations pursuant to Act 68. If you have any questions about our position, feel free to contact me at (717) 561-5314 or Paula Bussard, senior vice president, policy and regulatory services, at (717) 561-5344.

Sincerely,

Carolyn F. Scanlan

CAROLYN F. SCANLAN
President and Chief Executive Officer

CFS/mg

c: The Hon. Robert S. Zimmerman, Secretary of Health
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. 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. Nicholas A. Micozzie, Chair, House Insurance Committee
The Hon. Anthony M. DeLuca, Minority Chair, House Insurance Committee
The Hon. Kathleen Eakin, Secretary for Legislative Affairs
Howard A. Burde, Esquire, Deputy General Counsel

bc: Richard Lee, Deputy Secretary, Quality Assurance, DOH
Lori McLaughlin, Chief Counsel, DOH
HAP Senior Management

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

4750 Lindle Road
PO Box 8600
Harrisburg, PA 17105-8600
Phone 717-564-9200
Fax 717-561-5334
www.haponline.org

FAX TRANSMISSION

6 *page(s), including cover sheet*

TO: Don McCoy

FAX: 717-783-2664

FROM: Paula Bussard

DATE: 3-30-01

SUBJECT: IRRC letter on Act 68

MESSAGE:

Original: #2079

recommended that language be added providing that if the Department did not take additional action in the form of specific approval within 30 days after receipt of additional information or a written request for clarification, the contract would be deemed approved.

The Department has not included "deemer" language in the regulations. The Department has the responsibility under statute to review and approve provider contracts, as well as implementing certain provisions of Act 68, including, for example, provisions prohibiting financial incentives, prohibiting gag clauses, and requiring confidentiality of medical records. For the Department to require itself to deem as acceptable a contract containing illegal language, simply because a regulatory, not statutory, time frame has run, is an abdication of the Department's responsibility under Act 68 and the HMO Act. Although the Department is requiring plans to submit contracts in place prior to the effective date of the regulations for review and approval, it will permit plans to continue using those contracts. See §9.722(a). The Department has added a provision to the regulations that states that the Department will review contracts within a ~~60~~ 45-day period, and that if the Department fails to approve or disapprove the contract within that time frame, the plan may use the contract. The contract will be presumed to meet the requirements of all applicable laws. If the Department finds at any time that the contract contains violations of law, the plan must correct those violations. The plan is, of course, responsible for ensuring that it complies with Act 68 and any other law applicable to it, for example, the HMO Act. ~~The Department has not include "deemer"~~

~~language in the regulations. The Department will, however, allow plans to use provider contracts if the Department fails to review and approve documents submitted to it pursuant to this section within the 60 day review period. Should the Department find deficiencies in these contracts, the Department will require revisions to ensure that the plan is in compliance with Act 68, the HMO and PPO Acts, and these regulations. The Department has the responsibility under statute to review and approve provider contracts, as well as implementing certain provisions of Act 68, including, for example, provisions prohibiting financial incentives, prohibiting gag clauses, and requiring confidentiality of medical records. For the Department to require itself to deem as acceptable a contract containing illegal language, simply because a regulatory, not statutory, time frame has run, is an abdication of the Department's responsibility under Act 68 and the HMO Act. Although the Department is requiring plans to submit contracts in place prior to the effective date of the regulations for review and approval, it will permit plans to continue using those contracts. See §9.722(a).~~

Another commentator commented that, although it did not support the Department's attempt to regulate IDS arrangements formally, both ID and the Department should simultaneously regulate IDSs.

The Department and ID do both regulate IDS arrangements through the licensed entity. ID has not repealed its policy statement on IDS arrangements. See 31 Pa. Code Chapter 301, Subchapter I.

Section 9.742. CREs.

Two commentators complained that pursuant to subsection (c), a licensed insurer would not be required to go through the certification process to become a CRE. One commentator raised concerns that an insurance company could pose as outside independent CRE for another insurance company, or its parent or subsidiary without having to be certified. Both commentators stated that the certification process was the only possible mechanism for sorting out potential conflicts of interest. At a minimum, these commentators recommended that licensed insurers be required to comply with sections 2151 and 2152 of Article XXI (40 P.S. §§991.2151 and 991.2152) and be required to obtain certification.

The Department has ~~not changed~~ deleted ~~this proposed~~ subsection (c). Act 68 clearly states that a licensed insurer or a managed care plan with a certificate of authority shall not be required to obtain separate certification as a utilization review entity. 40 P.S. §991.2151(e). Therefore, to require such entities to undergo certification would be a violation of Act 68. The Department has also deleted the term "licensed insurer" from §9.601 (relating to definitions) since that term no longer appears in the Department's regulations. ~~These entities, are, however, required to comply with the other requirements of sections 2151 and 2152 of Article XXI (40 P.S. §§991.2151 and 991.2152).~~ The comments concerning conflict of interest are discussed in §9.743 (relating to content of an application for certification as a CRE.

~~2152 of Article XXI. (40 P.S. §§991.2151 and 991.2152).~~ The comments concerning conflict of interest are discussed in §9.743 (relating to content of an application for certification as a CRE.

Section 9.743. Content of an application for certification as a CRE.

The Department received one comment in support of this proposed section. Several commentators requested revisions to the proposed section.

Several commentators commented concerning what they viewed as the inability of the proposed regulations to prevent conflicts of interest from arising between plans and CREs, since this proposed section would not specifically request conflict of interest information. One commentator commented that the proposed regulations do not go far enough to implement the intent of Act 68 to protect against conflicts of interest. According to the commentators, an enrollee must be able to access conflict of interest information.

The Department does not see this conflict of interest analysis as useful in the context of standard utilization review, where as discussed earlier, the CRE is compensated to perform UR functions by the plan. This can be viewed as an absolute conflict; however, since the CRE must have operating income to employ staff, and systems to conduct CRE, there is no possible way to avoid a situation in which a CRE is paid to perform UR. The Department has made no changes to the proposed section to address the comment. Service organizations are

Independence Blue Cross

FACSIMILE COVER SHEET

PLEASE DELIVER IMMEDIATELY

TO: John Jewett

FAX #: 783-2664

NUMBER OF PAGES: 5

DATE: 3/30/01

SUBJECT: A2668

FROM: Mary Ellen McMillen

PHONE #: 717-233-6464

FAX #: 717-233-6773

COMMENTS: _____

If you do not receive all of this transmission, please call 717-233-6464.

Original: 2079

PENNSYLVANIA CHAPTER,
AMERICAN COLLEGE OF
EMERGENCY PHYSICIANS

777 East Park Drive
P.O. Box 8820
Harrisburg, PA 17105-8820
http://www.paacep.org

(717) 558-7750
888-633-5784
FAX (717) 558-7841
dblunk@paacep.org

March 30, 2001

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

Ref: Department of Health Regulation No. 10-160
Managed Care Organizations

Dear Mr. McGinley:

On behalf of the Pennsylvania Chapter, American College of Emergency Physicians, I recommend approval of the final-form Department of Health Regulation No. 10-160, Managed Care Organizations (Act 68).

The chapter recommends approval, but I would like to relay a concern regarding Act 1998-68, Section 2116, Emergency Services. During the comment period, the chapter recommended that the Department of Health clarify references to federal law concerning the medical screening examination and the transfer of the emergency patient. Pennsylvania ACEP believes portions of Section 2116, Emergency Services are inconsistent with the federal Emergency Medical Transportation and Active Labor Act (EMTALA).

Sincerely,

James Holliman, MD, FACEP
President
Pennsylvania ACEP

CC: Representative Nicholas Micozzie
Senator Harold Mowery
Pennsylvania Medical Society

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

Original: 2079

Carolyn F. Scanlan
President and Chief Executive Officer

March 29, 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) opposes the Department of Health's regulations pursuant to the Quality and Health Care Accountability and Protection Act, known as Act 68. It is imperative that the Independent Regulatory Review Commission understands the basis of HAP's position.

Act 68 addresses a range of issues concerning managed care and contains two subsections, i.e., the prompt pay provisions and the utilization review operational standards, which have broader applicability, in that they apply not only to managed care plans, but also to licensed insurers. Specifically, subsection (j) imposes prompt payment requirements on *licensed insurers* and managed care plans, and subsection (h) prescribes standards and procedures for utilization review activities conducted by *licensed insurers* and managed care plans. Although Act 68 defines the term managed care plan, it does not provide a definition for the term licensed insurer. Managed care plans in the act are narrowly defined to include HMOs and other gatekeeper managed care plans. The inclusion of licensed insurers in these two sections reflects a broader applicability of these two sections.

HMOs and gatekeeper managed care plans are not the only health plans to use utilization review control to limit access to care and to deny payment for care. Non-gatekeeper managed care plans are the fastest growing managed care plans in the commonwealth and represent almost 50 percent of overall managed care enrollment in the private sector. The failure of the Department of Health regulations to recognize the broader applicability of the utilization review provisions of Act 68 means that these plans will not have to have physicians issue denials for care, will not have to provide the clinical rationale for denials, and will not have to provide patients with any opportunity to appeal the denial of care. In essence, there is little or no accountability for the decisions made by these plans to limit access or deny payment for care. Denying payments for care in these plans is tantamount to denying access given the cost of hospitalization, surgery, therapy services, mental health care, etc.

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.564.9200 Phone
717.561.5334 Fax
http://www.hap2000.org

HAP also is gravely concerned about the conflict between the Department of Health's interpretation of the statute and the Insurance Department's interpretation. On March 10, 2000, the Department of Insurance issued regulations implementing certain aspects of Act 68, which were within its enforcement jurisdiction, including the prompt pay provisions set forth in subsection (j). In its regulations, the Department of Insurance broadly defined licensed insurer, as follows:

> *Licensed insurer* – An individual, corporation, association, partnership, reciprocal exchange, interinsurer, Lloyds insurer and other legal entities engaged in the business of insurance, and fraternal benefit societies as defined in the Fraternal Benefit Societies Code (40 P.S. §§ 1142-101 – 1142-701), and preferred provider organizations as defined in section 630 of The Insurance Company Law of 1921 (40 P.S. § 764a) and § 152.2 (relating to definitions).

The Department of Insurance regulations implementing the prompt pay provisions track the language of Act 68 and make them applicable to *licensed insurers* and managed care plans (as defined in the statute and regulations).

On December 18, 1999 the Department of Health published proposed regulations implementing the portions of Act 68, which fall within its jurisdiction, including the utilization review provisions. In its proposed regulations, the Department of Health adopted the Department of Insurance's definition of licensed insurer. With regard to the applicability of the utilization review provisions, the Department of Health tracked the specific language of Act 68 and provided as follows: "a *licensed insurer* or a plan with a certificate of authority shall comply with section 2152 of the act [which sets forth the operational standards for utilization review entities] ." In the applicability statement of the regulations (Section 9.601), the Department of Health made the specific statement that Section 9.742 (relating to the operational standards for utilization review) "applies to *licensed insurers* and managed care plans with certificates of authority."

After receiving and analyzing approximately 1400 comments to the proposed regulations, the Department of Health circulated its final Act 68 regulations. In the final regulations, the Department of Health made no substantive change to the definition of licensed insurer. With regard to utilization review, the Department of Health deleted the reference to licensed insurers in Section 9.601, but replaced it with a provision in Section 9.741 specifically referencing the utilization review provision of Act 68, and providing that pursuant to the act a Certified Review Entity, *licensed insurer* or a managed care plan with a certificate of authority shall comply with the utilization review operational standards set forth in the statute and regulations. In the preamble to the final regulations, the Department of Health explained the new provision by stating that it "*reiterates* the requirement of Act 68 that *licensed insurers* or managed care plans with certificates of authority . . . *are required to comply with the same operational standards as entities performing utilization review.*

On March 16, 2001, in a letter to the Chair of the House Health and Human Services Committee, the Department of Health stated that it would like to make certain *changes* to its final Act 68 regulations (and, pursuant to applicable statutory authority, received approval to toll the Independent Regulatory Review Commission's consideration of the regulations in order to enable it to make these changes). Specifically, the Department of Health stated that it was *deleting* Sections 9.741(c), 9.742(c) requiring licensed insurers and managed care plans to comply with the utilization review operational standards.

The purpose of the Department of Health's regulations is to set forth a comprehensive and detailed plan for implementation of the statutory objectives set forth in Act 68. In both its proposed and *initial* final Act 68 regulations, the Department of Health was consistent in including, as part of the regulations themselves, the specific statutory requirements, including the requirement that licensed insurers (and managed care plans) adhere to the utilization review operational standards. The deletion of these particular provisions creates the very problem that the Department of Health stated that it was trying to avoid, i.e., it would make the regulations unwieldy and more difficult to use.

Moreover, the elimination of the definition of licensed insurer leaves an obvious void in the regulations, which will create uncertainty as to how section 2151 of the Act should be applied. The Department of Health's failure to provide a definition will be particularly confusing given the department's public statements that it now interprets the term licensed insurer in a manner which is different from the Department of Insurance definition, and from what would ordinarily be thought to be encompassed within the plain meaning of the term itself (i.e., *all* licensed insurers).

Further, an agency regulation that is contrary to the statute under which it was promulgated is *invalid*. Agency interpretations of the statutes they are charged with enforcing are generally entitled to great deference, but only if the statute is ambiguous or unclear. On the other hand, if the intent of the legislature is clear from the statute, that is the end of the matter and the courts *as well as the agency,* must give effect to the unambiguously expressed intent of the legislature as evidenced in the statute.

This well known principle is embodied in Pennsylvania's rules of statutory construction, which expressly provide that when the words of a statute are clear and free from all ambiguity, the letter of it is not to be disregarded under the pretext of pursuing a different intent. The cardinal principle of statutory construction is that the plain words of a statute cannot be disregarded where language is free and clear from all ambiguity. The rationale for this rule is that the words utilized by the legislature are the best evidence of what the legislature intends. The Department of Health's limitation of the application of the term licensed insurers to licensed insurers who do utilization review for enrollees of managed care plans, ignores this cardinal rule. The qualification created by DOH is at variance with the express wording of the statute, which includes *all* licensed insurers without

qualification or limitation. In this case, the Department of Health is not at liberty to delete a statutory requirement from its regulations based upon its conjecture that the legislature intended something different from what it said.

By changing the regulatory definition of licensed insurer, the Department of Health violates another principle of statutory construction, which is that every statute shall be construed, if possible, *to give effect to all its provisions.* If the Department of Health now intends to apply the term "licensed insurer" as referring only to "licensed insurers who do utilization review for enrollees of a managed care plan . . ." this will essentially divest the term licensed insurer of any independent meaning. If a licensed insurer were to perform utilization review for enrollees of a managed care plan it would likely be doing so in the capacity of a managed care plan, as broadly defined in Act 68. Therefore, based upon that interpretation, the reference to licensed insurer in Section 2151(e) of the statute is, for the most part, extraneous.

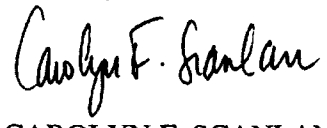
Thus, the Department of Health's deletion of the references to licensed insurers based upon its conclusion that the legislature did not intend the operational utilization review standards to apply to *all* licensed insurers, is contrary to the plain wording of the statute.

Another cardinal rule of statutory construction is the avoidance of conflicts. Section 1932 of the Statutory Construction Act states that "statutes or parts of statutes are in pari materia when they relate to the same class of persons or things" and that "statutes in pari materia shall be construed together, if possible, as one statute." Moreover, statutes should be construed, if possible, so as to avoid any conflict between various agencies of the state, and the presumption is against a construction resulting in a conflict. The conflict-avoidance principle is also embodied in the review standards of the Independent Regulatory Review Commission, which is charged with reviewing and approving (or disapproving) all regulations before they take final effect.

Despite its repeated acknowledgement of the need for consistency with the Department of Insurance regulations, the Department of Health's change with regard to the definition of licensed insurer indicates that it is willing to create a direct conflict with the Department of Insurance's regulations defining and implementing the same term in the same statute. Thus, the terms licensed insurer and managed care plan in the prompt pay provision would apply to *all* licensed insurers (as defined in the Department of Insurance regulations) whereas the identical term in the utilization review provision would apply *only* to "licensed insurers who do utilization review for enrollees of a managed care plan." Such a construction violates the statutory and common law rules requiring that statutes be interpreted and implemented in a consistent manner. Its proposal to adopt an interpretation of licensed insurer, which is directly at odds with the Department of Insurance's existing interpretation of the same term in the same statute violates the rules requiring consistency in statutory construction.

HAP urges the Independent Regulatory Review Commission to reject the Department of Health's regulations pursuant to Act 68. If you have any questions about our position, feel free to contact me at (717) 561-5314 or Paula Bussard, senior vice president, policy and regulatory services, at (717) 561-5344.

Sincerely,



CAROLYN F. SCANLAN
President and Chief Executive Officer

CFS/mg

c: The Hon. Robert S. Zimmerman, Secretary of Health
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. 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. Nicholas A. Micozzie, Chair, House Insurance Committee
The Hon. Anthony M. DeLuca, Minority Chair, House Insurance Committee
The Hon. Kathleen Eakin, Secretary for Legislative Affairs
Howard A. Burde, Esquire, Deputy General Counsel

Capital BlueCross

An Independent Licensee of the
Blue Cross and Blue Shield Association

Harrisburg, PA 17177
(717) 541-7000

March 28, 2001

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

Dear Director Nyce:

Capital Blue Cross appreciates this opportunity to comment on the Department of Health's revisions to the proposed Act 68 regulations as submitted to the Independent Regulatory Review Commission.

Capital Blue Cross believes the revised regulations are improved from the regulations as originally proposed by the Department, particularly in confining their application in the area of utilization review to gatekeeper managed care plans as provided for in Act 68.

We again, however, express our concern about the extent of the statutory authority provided to the Department of Health in any of the applicable managed care acts (i.e., the HMO Act, the PPO Act, or Act 68) to require through regulations filing of medical management and provider contracts at least 45 days prior to use for the Department's review and approval. Section 8 (a) of the HMO Act (40 P.S. Section 1558 (a)) requires contracts to be filed with the Secretary, who may require immediate renegotiation for specified reasons such as "excessive payments" or failure to include "reasonable incentives for cost control." We see no authority for review and approval prior to use, implicit or otherwise. We encourage the Commission to look very seriously at that issue.

We also would note the revised regulations now are silent on the question of whether existing medical management and provider contracts are subject to review and approval of the Department under these regulations. We note the Department, in the materials submitted to the IRRC with Secretary Zimmerman's March 20 communication, stated, "The Department does not intend to disrupt ongoing business relationships with medical management organizations and health care providers that are based on contracts already approved by the Department." We take that declaration of intent at face value on the issue of existing contracts.

Capital Blue Cross also welcomes and takes the Department at its word that it will work with plans in good faith to mutually resolve technical issues such as requiring written notice for both utilization review approvals and denials in a manner that does not add undue and unnecessary cost burdens on the plans. We are prepared to engage in good faith discussions with the department in this and other technical regards.

One issue does remain of utmost concern which we hope the Department and the Commission will take into account in the implementation and disposition of these regulations. That is the time that will be necessary for plans to come into compliance with new regulations. We estimate that plans will need a minimum of 180 days after publication in the Pennsylvania Bulletin. This time is needed for development of compliance materials and internal system changes, the review and approval process by the Health and Insurance Departments, and upon receipt of approval, final printing and distribution of the compliance amendments/riders to members and participating providers.

We appreciate the efforts of all parties--the General Assembly, the Department and the Commission--to make these regulations more workable in the legislative context of Act 68. We thank the Commission, the General Assembly and the Department for taking the views of Capital Blue Cross into consideration throughout this process.

If Capital can be of any further assistance in this or in other regulatory or legislative matters, please do not hesitate to contact me.

Sincerely,

Lee Van Valkenburgh
Vice President for Corporate Services

CC: The Honorable Dennis M. O'Brien
The Honorable Nicholas A. Micozzie
The Honorable Harold F. Mowery
The Honorable Patricia Vance
The Honorable Robert S. Zimmerman

Jefferson Health System

Douglas S. Peters
President and
Chief Executive Officer

ORIGINAL: 2079

March 27, 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 Jefferson Health System (JHS) to express our support of the Department of Health's (DOH) March 1st final form regulations. While balancing the interests of all parties affected by these regulations, we commend the DOH for ensuring consistency with the Insurance Department's regulations, establishing utilization management standards that hold health plans accountable for their decisions, and granting provider advocacy on behalf of patients.

With the majority of Pennsylvania hospitals losing money on patient care, it would be inappropriate to delay implementation of these regulations, in addition to limiting the applicability of the utilization management standards to HMOs and gatekeeper PPOs. We do not believe that the legislature's intent was to exclude the fastest growing product segment of health plans from the utilization management standards. By limiting these standards to HMOs and gatekeeper PPOs, inappropriate practices of downgrading days and denying payments will continue causing disadvantages to providers and subscribers of the excluded products.

JHS does support the DOH's utilization management standards as outlined in the March 1st final form regulations and believes it is in the best interest of providers and patients' to apply these standards to all health plans, including nongatekeeper PPOs. Please take this into consideration when making your final decision.

Thank you for the opportunity to comment.

Sincerely,

Douglas S. Peters

Jefferson Health System

Douglas S. Peters
President and
Chief Executive Officer

Original: 2079

March 27, 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 Jefferson Health System (JHS) to express our support of the Department of Health's (DOH) March 1st final form regulations. While balancing the interests of all parties affected by these regulations, we commend the DOH for ensuring consistency with the Insurance Department's regulations, establishing utilization management standards that hold health plans accountable for their decisions, and granting provider advocacy on behalf of patients.

With the majority of Pennsylvania hospitals losing money on patient care, it would be inappropriate to delay implementation of these regulations, in addition to limiting the applicability of the utilization management standards to HMOs and gatekeeper PPOs. We do not believe that the legislature's intent was to exclude the fastest growing product segment of health plans from the utilization management standards. By limiting these standards to HMOs and gatekeeper PPOs, inappropriate practices of downgrading days and denying payments will continue causing disadvantages to providers and subscribers of the excluded products.

JHS does support the DOH's utilization management standards as outlined in the March 1st final form regulations and believes it is in the best interest of providers and patients' to apply these standards to all health plans, including nongatekeeper PPOs. Please take this into consideration when making your final decision.

Thank you for the opportunity to comment.

Sincerely,

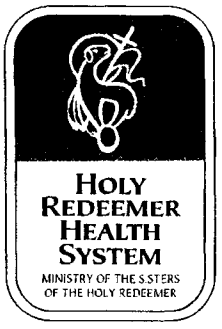
Douglas S. Peters

www.jeffersonhealth.org

259 N. Radnor-Chester Road Suite 290 • Radnor, PA 19087-5288 • 610-225-6238 • Fax: 610-225-6241

Original: 2079

March 26, 2001



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

Dear Mr. McGinley:

Please accept this letter as an indication of our support of the adoption of the final Department of Health Regulations for Act 68. We believe 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.

I would also like to take the opportunity to commend the Department of Health 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.

Again, thank you for efforts on behalf of creating accountability of Pennsylvania's health plans.

Sincerely,

Michael B. Laign
MBL/meg

667 WELSH ROAD • HUNTINGDON VALLEY, PA 19006
215-938-4650 • FAX: 215-938-4671 • www.holyredeemer.com

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

Original: 2079

Carolyn F. Scanlan
President and Chief Executive Officer

March 23, 2001

The Honorable Robert S. Zimmerman
Secretary of Health
Pennsylvania Department of Health
Room 802, Health and Welfare Building
Harrisburg, PA 17120

Dear Secretary Zimmerman:

The Hospital & Healthsystem Association of Pennsylvania (HAP) opposes the proposed March 16, 2001 changes to the Department of Health's final-form regulations pursuant to the Quality and Healthcare Accountability and Protection Act, known as Act 68. It is imperative that the Department of Health understand the basis of HAP's change in position.

The change that the Department of Health has made to the final-form regulations regarding the portions of Act 68 addressing utilization review provisions narrowly limits the applicability of utilization review standards only to HMOs and gatekeeper plans and fails to include non-gatekeeper managed care plans. These types of plans are the fastest growing in enrollment and represent almost 50 percent of overall managed care enrollment in the private sector.

Because of the change made by the Department of Health in the regulations, patient treatment and payment decisions made by these plans would not be required to have physicians issue denials, would not have to provide clinical rationales for denials, and would not have to provide any rights to patients to appeal those decisions.

We continue to urge the Department of Health to reconsider the proposed change and to modify the regulations such that all managed care plans—gatekeeper and non-gatekeeper—would have to adhere to the operational utilization review standards. The department's utilization review standards are consistent with those used by national health plan accrediting agencies and should not pose additional burdens on these plans.

If you have any questions about our position, feel free to contact me at (717) 561-5314 or Paula A. Bussard, senior vice president, policy and regulatory services, at (717) 561-5344.

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.564.9200 Phone
717.561.5334 Fax
http://www.hap2000.org

Sincerely,

Carolyn F. Scanlan

CAROLYN F. SCANLAN
President and Chief Executive Officer

CFS/mg

c: 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. 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. Nicholas A. Micozzie, Chair, House Insurance Committee
The Hon. Anthony M. DeLuca, Minority Chair, House Insurance Committee
John R. McGinley, Jr., Chairperson, Independent Regulatory Review Commission
Kathleen Eakin, Esquire, Secretary for Legislative Affairs
Howard A. Burde, Esquire, Deputy General Counsel

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

4750 Lindle Road
PO Box 8600
Harrisburg, PA 17105-8600
717-564-9200, ext. 688 Phone
717-561-5334 Fax
mgammill@haponline.org

FAX TRANSMISSION

3 Pages page(s), including cover sheet

TO:	Robert Zimmerman	787-0191
	Harold Mowery	772-0576
	Vincent Hughes	772-0579
	Dennis O'Brien	787-1339
	Frank Oliver	772-2284
	Nicholas Micozzie	783-0688
	Anthony Deluca	772-9937
[redacted]	John McGinley	783-2664
	Kathleen Eakin	787-4590
	Howard Burde	772-9187
FROM:	Carolyn Scanlan	
DATE:	3/23/01	
SUBJECT:	Act 68 – Quality and Healthcare Accountability and Protection Act	

MESSAGE:

Original: 2079

CATHOLIC HEALTH INITIATIVES

St. Joseph Medical Center

March 21, 2001

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

Re: Department of Health Act 68 Regulations

Dear Mr. McGinley:

St. Joseph Medical Center, Reading, Pennsylvania, supports the 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.

We commend the Department of Health for:

- Ensuring consistency of Department of Health standards with 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.

Because of the significance of these regulations and their affect on health care delivery, I urge you to support the adoption of the Department of Health Act 68 Regulations.

Sincerely,

John R. Morahan
President/CEO

JRM:cak

MANAGED CARE ASSOCIATION OF PENNSYLVANIA

240 North Third Street
P.O. Box 12108
Harrisburg, PA 17108-2108
(717) 238-2600
Fax (717) 238-2656

Original: 2079
email: info@managedcarepa.org
website: www.managedcarepa.org

March 20, 2001

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

RE: DOH FINAL RULEMAKING - MANAGED CARE ORGANIZATIONS
REQUEST FOR TOLLING THE REVIEW PERIOD

Dear Mr. Nyce:

I am writing on behalf of the Managed Care Association of Pennsylvania (MCAP), which represents the interests of several managed care organizations across the Commonwealth. These entities provide health care coverage for more than 1.5 million people in Pennsylvania in commercial as well as Medical Assistance managed care plans.

As you know, the Pennsylvania Department of Health recently released the final regulation pertaining to managed care organizations, inclusive of provisions pertaining to Act 68 of 1998. The Department is to be congratulated on what was surely a mammoth task. Indeed, much of what the regulation contains is good for consumers. It also includes many of our previous recommendations. However, testimony given at the joint House Insurance and Health and Human Services Committees noted that there are still some sections of the regulation which must be revised in order for plans to meet legislative intent and protect the rights of enrollees without having to utilize resources that would be better spent on services.

We are requesting that the Independent Regulatory Review Commission vote to disapprove this regulation at this time due to the fact that there are still areas which are unclear and, from an operational standpoint, unreasonable. Our areas of concern are as follows:

#1 - COORDINATION BETWEEN DPW AND DOH IS ESSENTIAL IN ORDER FOR MEDICAL ASSISTANCE/HEALTHCHOICES PLANS TO OPERATE EFFICIENTLY

* Coordination between these Departments is as essential as cooperation between the Health and Insurance Departments. While we recognize the role of the Insurance and Health Departments regarding the issuance of a certificate of authority, Medical

Assistance plans are closely monitored by DPW. Although DOH views DPW as a "purchaser" of services, similar to an employer group, the fact remains that DPW is a very active regulator. One example is contained within Section 9.679(E) regarding Access Requirements in Service Areas. The regulation lists 14 specialties that enrollees must be able to access. Listed at number 12 is psychiatry and neurology. **MA managed care plans are prohibited by DPW from offering psychiatry as they are "carved out" of the program.** Where does this leave the MA plans?

* MCAP also recommends simultaneous interagency review. This "one-stop"review process would benefit enrollees as well as plans.

#2 - PERMITTING PROVIDERS TO OBTAIN AN ENROLLEE'S BLANKET CONSENT TO PURSUE A GRIEVANCE AT THE TIME OF TREATMENT IS NOT "PRO" CONSUMER, AND WILL TURN THE GRIEVANCE PROCESS INTO A VENUE FOR ADDRESSING BILLING DISPUTES (Section 9.706)

* To support this provision, it has been asserted that it is often difficult to contact MA enrollees subsequent to treatment. While we would not dispute that this happens in some cases, we question the extent and nature of this problem. Is it that the enrollee doesn't have a telephone and can be contacted only by mail? Or is it that the address is no longer valid? *We are asking that the phrase "at the time of treatment" be deleted.*

#3 - REGULATIONS PERTAINING TO TIME FRAMES FOR UTILIZATION REVIEW GO BEYOND THE SCOPE OF ACT 68

* Section 2152 of Act 68 outlines several operational standards for utilization review entities, including strict time frames for communicating prospective, concurrent and retrospective decisions. The regulations go beyond the Act to require plans to provide "written or electronic confirmation" of those decisions to providers and enrollees within the same time frames. It is not possible in many cases to provide this information electronically. As noted earlier, some MA enrollees may not be able to be reached via telephone.

*In order to provide written documentation within such short time frames, plans would need to change their systems to generate what could literally be hundreds of letters a day, just for approvals. This would be costly and time consuming and does nothing to preserve or enhance the rights of our enrollees.

** If a claim for services can serve as notice to a managed care plan that an enrollee has received emergency treatment, we believe the authorization provided for other services is*

sufficient notice of an approval. The Association recommends the regulation be revised to conform with the Act.

#4 - THE EFFECTIVE DATE OF THE REGULATION DOES NOT PERMIT PLANS TO MAKE REQUIRED CHANGES IN A TIMELY MANNER.

*Currently, this regulation becomes effective upon publication in the *Pennsylvania Bulletin*. It will entail a great deal of time and effort, not to mention money, on the part of managed care plans to come into compliance. Two major areas are enrollee materials and contracts. Each plan will have to conduct an in-depth review of all sales materials, brochures, group contracts and certificates of coverage and assess what changes will need to be made. Those materials will also have to be printed and distributed. Further, if PID determines that in view of the final regulation they should review and approve those materials, it will further delay implementation.

** We would respectfully request that the effective date of the regulation be changed to allow commercial plans to make the necessary changes as purchaser contracts come up for renewal. The Association is also requesting additional leeway for the MA plans as they renew on a calendar year basis.*

FURTHER CLARIFICATION REQUESTED

In addition to the objections listed above, MCAP is seeking clarification regarding the following sections:

#1 - Section 9.676 (Enrollee Rights) basically reflects the requirements of the National Committee on Quality Assurance (NCQA). However, the NCQA requirement lists seven elements which are not included in the DOH regulation. *Will DOH require plans to adhere to the additional NCQA elements?*

#2 - Section 9.684 (Continuity of Care) prohibits plans from requiring nonparticipating providers to undergo "full credentialing". *What is full credentialing? What is acceptable for credentialing nonparticipating providers. Clarification is requested.*

#3 - Section 9.702 (c) (Complaint vs. Grievance) outlines a process for classification of a request for internal review. The process, as written, appears contradictory. Either department's decision is final and binding. However, if an enrollee disagrees with the plan's classification, he or she may contact DOH or PID for consideration and intervention. There is great potential for contradictory decisions. *What happens if the plan contacts PID regarding a request and the enrollee contacts DOH on the same issue and the Departments make different rulings?*

#4 - Section 9.703(a) (Internal Complaint Process) and Section 9.705 (c) (Internal Grievance Process) allow an enrollee, or the enrollee's representative, to file a complaint. *MCAP requests that the enrollee be required to provide written authorization regarding the release of the enrollee's information.*

CONCLUSION

We are hopeful that these issues can be resolved quickly. We look forward to working with the Department on these as well as any other related issues.

If you have any questions, please do not hesitate to contact me at (717) 238-2600.

Sincerely,

Dolores M. Hodgkiss

Dolores M. Hodgkiss
Executive Director

Original: 2079
cc: McGinley, Mizner, Harbison, Bush

Independence
Blue Cross

March 20, 2001

LEGISLATIVE POLICY OFFICE
800 NORTH THIRD STREET
SUITE 600
HARRISBURG, PA 17101

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

Dear Commissioner McGinley:

I am writing to request that the Independent Regulatory Review Commission disapprove the Department of Health final form regulations of Act 68 of 1998. Independence Blue Cross presented testimony before the joint committee public hearing conducted by the House Health and Human Services Committee and House Insurance Committee on March 15, 2001. That testimony and an extensive appendix were sent to the Commission electronically that morning. We oppose the regulations in their current form for the following reasons:

- The regulations go far beyond the scope of Act 68 by extending the utilization review standards to "all licensed insurers."
- The regulations require prior approval of contracts between health plans and providers which is not provided for by statute.
- The regulations would permit the Department to reach back into existing contracts that have recently been approved by the Department and insist upon changes.
- The regulations restrict physician determinations during a grievance or complaint process beyond the language of the law which states that the physician must be in the same or similar specialty as typically manages the care.
- The regulations would require health plans to provide written notification of all utilization review determinations to both the member and the provider. Members should not need written notices of approvals. They add unnecessary cost and will only serve to confuse and anger our members.
- The regulations add additional regulation of provider directories which are already reviewed and approved by the Insurance Department.
- The regulations require plans to disclose, copy and provide to members all internal documents relating to an appeal. There must be some limit to the information that

must be disclosed to member, otherwise attorneys will embark on a costly fishing expedition.

I have tried to summarize the issues that Independence Blue Cross has raised with the Department of Health and the standing legislative committees. I urge you to review our testimony and the technical appendix for a fuller understanding of the serious, costly problems with these regulations. Any unnecessary administrative cost added to health insurance coverage only exacerbates the problems Pennsylvania faces with its uninsured population. The Business community is already struggling with a new round of health insurance premium increases.

Thank you for considering our concerns about the costly, overreaching nature of the Department of Health final form regulations.

Sincerely,

Mary Ellen McMillen
Vice President, Legislative Policy

Independence Blue Cross

FACSIMILE COVER SHEET

PLEASE DELIVER IMMEDIATELY

TO: IRRC

FAX #: 783-2664

NUMBER OF PAGES: 9

DATE: 3/20/01

SUBJECT: Act 68

FROM: Mary Ellen McMillen

PHONE #: 717-233-6464

FAX #: 717-233-6773

COMMENTS: _____

If you do not receive all of this transmission, please call 717-233-6464.

Capital BlueCross

An Independent Licensee of the
Blue Cross and Blue Shield Association

Orignal: 2079

Harrisburg, PA 17177
(717) 541-7000

March 19, 2001

The Honorable Dennis O'Brien
Chairman
House Health and Human Services Committee
State Capitol
Harrisburg, PA 17120

Dear Representative O'Brien:

Capital Blue Cross sincerely appreciates the opportunity to comment on the Department of Health's March 16, 2001, proposal, entitled, "Tolling Memo Changes", aimed at making the Act 68 regulations more acceptable to interested parties. While the proposed changes represent a good faith effort to address some concerns of some commenters, it is the opinion of Capital Blue Cross that these proposed changes still do not go far enough in satisfying our concerns.

We will try to summarize as briefly as possible our continuing concerns:

1. DOH's proposed amendment to 9.675, Delegation of Medical Management Contracts: while some improvement, still requires submission of medical management contracts for its review and approval, when, in our belief, it has no statutory authority in either Act 68, the PPO Act or the HMO Act to review and approve such documents.

2. The same problem arises in its proposed changes to 9.722, Plan and Health Plan Provider Contracts. Once again, the Department deletes some requirements, but continues to require that health plan contracts be submitted to it for review and approval. No such authority exists in Act 68, the PPO Act or the HMO Act. The most specific requirement relating to provider contract submission is found in Section 8(a) of the HMO Act, and this section only requires that HMOs file provider contracts with DOH. There is no granting of "review and approval" authority. The only authority the statute confers on DOH is to "require renegotiation" of filed contracts for specific reasons.

3. We concur with DOH's proposed revisions to Sections 9.741 and 9.742 (regarding utilization review applicability) and related 9.601 (regarding the definition of "licensed insurer".)

4. We concur with DOH's proposed revisions to 9.705, Initial Grievance Process. However, we must respectfully again note that statute adopted by the General Assembly simply does not confer on the Department authority to establish an expedited external grievance process, and without a statutory basis, application of and decisions arising from such a process may be subject to serious legal challenge.

5. We concur with the proposed changes to sections 9.673 (regarding prescription drug benefits), 9.679 (regarding access requirements), 9.681(a)(3) (regarding health care providers) and the addition of a coordination with the Department of Insurance (DOI) provision to the Preamble.

6. Regarding the proposed addition to section 9.705(c)(2)(III)(L) which relates to the decision of the 2nd level internal grievance review committee: We find ourselves in a difficult position regarding this proposed addition. We have already commented that we believe DOH has gone overboard throughout those portions of the regulations regarding complaint and grievance procedures. The statute provides sufficient detail for a very workable grievance review procedure. DOH's additions in general are confusing, unnecessary, unnecessarily cost-increasing, and incorporate too many specifics which should be left to the discretion of each plan. Such details are unnecessary since the results of the process—the plan's decisions regarding medical necessity—are subject to independent review by CRE's approved and assigned by DOH.

   The same position is applicable to the proposed addition to 9.705. We have no objection to the content of the addition, and have always operated our review system in such manner so as to make any medical policies, standards or opinions we utilize in determining medical necessity available to the member and the member's representative. The point is that we believe the addition is just another example of the addition of unnecessary detail to the regulations. Again, members have adequate protection because DOH has authority to review the process applied and to ensure that adequate, fundamentally fair procedures were followed. Even more importantly, as stated, decisions are subject to independent review.

   In summary, while we do not, per se, object to inclusion of the additional language, we do not believe it necessary or desirable to include it, and, in fact, strongly believe DOH should be going in the opposite direction, removing unwarranted procedural requirements from the grievance regulations, not expanding them.

7. As noted in our testimony, we continue to have significant concerns regarding the cost versus benefit ratio of the proposed regulations. If these regulations are adopted, even with DOH's proposed changes, managed care plans would still be required to file with DOH for review and approval amendments to provider contracts (to bring provider contracts into compliance with new provider contract review standards) and amendments to the member complaint and grievance systems (to bring them into compliance with the detailed additional requirements in the proposed regulations.) We have questioned the basis of DOH's authority to require the filing of such materials for its prior review and approval. In addition, two other important issues must be addressed:

   a. Time line for compliance. A minimum of 180 days would be needed to develop necessary modifications to our contracts and systems, file them with DOH for review and approval (and perhaps with DOI for review and approval also, since the complaint and grievance process description appears in member contracts and DOI has approval authority over the content of such contracts), make internal system changes, and distribute amendment modifications to our thousands of participating providers and managed care plan members.

   b. "Deemer provisions". In order to make its attempts to exercise review and approval authority over provider contracts, medical management contracts and other contracts and systems more palatable, its latest draft provides for so-called 60-day deemer provisions, whereby if DOH takes no action on a filed document, it is "deemed" approved. Any deemer provision is important, but should be changed to a more reasonable 30- or 45-day provision in order to ensure timely review of filed documents.

8. We continue to be concerned regarding what we believe to be the unnecessary cost-increasing provisions of the regulations. Added costs to the utilization process will impact on affordability while providing little or no additional value to members. The UR system standards found in 9.751, for example, continue to require "written or electronic confirmation" of all decisions. Historically and practically only negative UR decisions need be confirmed in writing or by electronic confirmation.

Thank you again for the opportunity to comment on DOH's proposed changes. In summary, while they represent some degree of improvement, the proposed changes are, in and of themselves, not comprehensive enough for Capital Blue Cross to change its recommendation to the Committee that the regulations should be disapproved. We understand the importance of having regulations to benefit and guide the Department and all affected parties, including providers, managed care plans, insurers, and consumers. We do not take this position of continued recommendation for disapproval lightly. Unfortunately, the changes proposed by the Department of Health simply do not go far enough.

Sincerely,

Lee Van Valkenburgh
VP, Corporate Services

cc: The Honorable Nicholas Micozzie

Capital BlueCross
Agent for Pennsylvania Blue Shield
Independent Licensees of the Blue Cross and Blue Shield Association

Harrisburg, PA 17177
(717) 541-7000
www.capbluecross.com

FAX TRANSMISSION SHEET

To Be Delivered Upon Receipt

This transmission, including the cover sheet, is 4 pages.

Please deliver the following pages to:

Name	Fax Number
IRRC	717-783-2664

ATTN: MARY LOU HARRIS

Message:

FYI

From: L. VAN VALKENBURGH
Telephone Number: 717-541-6137
Date: 3/19/01

A return message, if required, should be faxed to 717.541.6696

Original: 2079

Susquehanna Health System
Divine Providence Hospital - Muncy Valley Hospital
The Williamsport Hospital & Medical Center

March 19, 2001

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

Dear Mr. McGinley:

I am writing to you as President-elect of Susquehanna Health System to ask for your support in the adoption of the final Department of Health regulations pertaining to Act 68. Effective implementation of these regulations benefit our patients by fostering greater coordination and cooperation between health plans and health care providers within the Commonwealth of Pennsylvania. With four out of five Pennsylvania hospitals and health systems losing money on patient care services, it would be inappropriate to delay implementation of regulations that establish fair and responsible oversight of Managed Care Plans (HMO's, PPO's). The Department of Health should be commended for:

- Insuring 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;
- insuring that providers may advocate for patients and may obtain written consent to do so at the time of treatment;
- and balancing the interest of patients, health care providers and health plans in the development of these regulations.

I am strongly urging that you support this initiative.

Sincerely,

Kirby O. Smith
President-elect

cc: Robert C. Wallace

Corporate Offices, 1001 Grampian Boulevard, Williamsport, PA 17701-1946
570-320-7000 Fax 570-320-7016

Regional Nursing Centers Consortium
RNCC
PA • NJ • DE

Original: 2079

March 19, 2001

Mr. Robert Nyce
Executive Director
IRRC
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Mr. Nyce:

On behalf of the Regional Nursing Centers Consortium (RNCC), an association community-based nurse-managed health centers, I would like to thank you for the opportunity to provide public comments on the implementation of Act 68. The RNCC has provided testimony and public comments on this important Act since 1999. The Consortium represents nurse-managed health centers in the Commonwealth that provide quality health care services to well over 35,000 people and encounter more than 250,000 people annually.

As you know, nurses and nurse-managed health centers in Pennsylvania have worked hard to ensure that the current definition of primary care providers in Act 68, continues to incorporate Advanced Practice Registered Nurses (APRN), which includes Nurse Practitioners. This definition ensures that APRNs can continue to provide quality health care services such as primary health care, health promotion and disease prevention services to thousands of Pennsylvanians. We have found that managed care organizations and some government departments continue to be uninformed about the inclusion of APRNs in this definition and therefore are not always responsive to credentialing issues of APRNs. Thus, we are unfortunately still experiencing some managed care organizations, public and private, that are not credentialing APRNs and Nurse Practitioners, despite their inclusion in Act 68 as primary care providers.

The consequences for excluding APRNs and Nurse Practitioners in ACT 68, would mean that over 35,000 of Pennsylvania's most vulnerable citizens would not have access to quality and cost-effective health care services. To deal with these issues, which are primarily about educating the public, we recommend that more general information be distributed about Act 68 to consumers, managed care organizations, providers and government agencies.

The RNCC Consortium members depict the future of nursing in the 21st Century. As a consultant from the Hunter Group recently said, "the nurse-managed health centers are five-years ahead of where health care is heading in the U.S." Nurse-managed health centers represent a growing movement and have emerged as a critical component in

3721 Midvale Avenue • Philadelphia, PA 19129 • Tel: (215) 951-0330 exts. 140, 141 & 147 • Fax: (215) 951-0342
E-mail: rncc@rncc.org • www.rncc.org

America's health care delivery system. Nursing, medical students and faculty rotate through nurse-managed health centers and are able to practice in health care settings outside hospitals. In a recent poll, nursing students interested in working in urban and rural underserved communities, who participated in a RNCC leadership training program, said that nurse-managed health centers made it more attractive for them to become nurses. Currently there is a national concern about the nursing shortage, and we believe that nurse-managed health centers are the place where nurses at all levels come together, have more autonomy and are valued. While nurses often start out in hospitals, nurse-managed health centers offer them a career option that encourages their development as leaders. There is no doubt that nurse-managed health centers and practice settings represent the current and future configuration of health care and nursing careers in our country.

In the current version of Act 68, we are particularly concerned that managed care organizations are now being required to list physician collaborators with the CRNP providers in their provider network booklets. To our understanding, this new requirement was added to the document following the public comment period and was not part of the final draft that was distributed by the Commonwealth. In a nurse-managed health center, CRNPs function as the primary care providers and physician collaborators are available to the CRNPs for consultation and prescription purposes. The RNCC believes it would be misleading to clients to require managed care organizations to list physician collaborators because clients receive their primary care services from qualified Nurse Practitioners and not physicians.

According to new CRNP regulations from the Department of State, a collaborative agreement between a CRNP and a physician shall "be kept at the primary practice location of the CRNP and a copy filed with the Bureau of Professional and Occupational Affairs..., be available for inspection to anyone seeking to confirm the scope of practice of the CRNP..., (and) a patient shall be informed at the time of making an appointment that the patient will be seen by a CRNP". Through these regulations, there is ample opportunity for HMO members to discern a collaborating physician's identity if they wish. Act 68 and other laws governing HMOs do not require the identification or listing of a collaborating physician.

In conclusion, the RNCC asks that you take our comments into consideration. Our member nurse-managed health centers are safety-net health care models in both rural and urban communities. Thank you for allowing the Regional Nursing Centers Consortium to provide comments on this important Act. If you have any questions or need any additional information, please feel free to call me at (215) 951-0330 ext. 147.

Sincerely,

Tine Hansen-Turton
Executive Director
Cc: Governing Council

Original: 2079

Pennsylvania MEDICAL SOCIETY®

March 19, 2001

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

Dear Commissioner McGinley:

I am writing as President of the Pennsylvania Medical Society to support approval of the Department of Health's proposed final rulemaking related to managed care organizations. These proposed regulations are to implement the Quality Health Care Accountability and Protection Act (Act 68 of 1998).

The Medical Society recognizes the need for these regulations to be promulgated without further delay despite shortcomings we and other stakeholders have pointed out during the comment process. From the physicians' perspective, one of the most serious concerns is the lack of a definition of medical necessity or inclusion of guidelines for the construction of a definition. Such a definition is essential for the determination of the appropriateness and necessity of a health care service or procedure. In recent testimony before the legislative oversight committees, a copy of which is attached, we address this concern in more detail, together with other issues.

Even though we believe the issues cited in our testimony could have been addressed in better fashion in the regulations, the Medical Society taken the position that promulgation of the regulations without further delay is necessary to fully implement provisions of the act providing patient protections. We believe that operational concerns expressed by parties which oppose the regulations can be addressed through actual practice as the regulations are implemented.

The Society has learned that efforts are being made to request a tolling of the regulations to address concerns of the insurance industry. We would ask that the Commission not grant that request. This tolling would further delay the regulations. Additionally, three of the areas being considered for changes – 9.675 Delegation of Medical Management Contracts, 9.722 Plan and Health Care Provider Contracts, and 9.741 Applicability and 9.742 CREs, would materially change the regulations and negatively impact on the health care provider community.

777 East Park Drive
P.O. Box 8820
Harrisburg, PA 17105-8820

Tel: 717-558-7750
Fax: 717-558-7840
E-Mail: stat@pamedsoc.org
www.pamedsoc.org

I would therefore ask the Independent Regulatory Review Commission not grant a tolling of the regulations and approve the Department of Health proposed final rulemaking on managed care organizations.

Sincerely,

Carol E. Rose

Carol E. Rose, MD
President

Cc: Honorable Harold F. Mowery, Chair, Senate Public Health and Welfare Committee
Honorable Dennis M. O'Brien, Chair, House Health and Human Services Committee
Honorable Nicholas A. Micozzie, Chair, House Insurance Committee
Honorable Robert S. Zimmerman Jr., Secretary of Health

DNM/doc/cor/McGinley301

Statement of the
Pennsylvania Medical Society
Before the
Senate
Public Health and Welfare Committee
Regarding
Proposed Final Rulemaking
Relating to Managed Care Organizations
March 12, 2001

Good morning. My name is Don McCoy. I am Senior Director of Policy and Regulatory Affairs for the Pennsylvania Medical Society, the largest physician organization in the Commonwealth.

The Pennsylvania Medical Society appreciates the efforts of the Department of Health to clarify the provisions of the Quality Health Care Accountability and Protection Act (Act 68 of 1998) through proposed final rulemaking. The Society is dismayed, that the proposed regulations have taken so long to get to this stage, do not address or address inadequately a number of issues important to the health care provider community, and that there has not been an open process involving all stakeholders affected by Act 68 compared to the process leading to the promulgation of the Department of Insurance Act 68 regulations. Even with these shortcomings, approval of these regulations is essential to the final implementation of Act 68. The Society would therefore ask the Senate Public Health and Welfare Committee to support these regulations as they come before the Independent Regulatory Review Commission (IRRC) for approval/disapproval.

I would like to focus the comments of the Society on just a few issues. I would be pleased to discuss any of the sections of the regulations at your convenience.

The definition of "medical necessity" or the lack thereof is a major deficiency in these regulations. The Department's response to commentators indicates that many comments were received, including from the Independent Regulatory Review Commission (IRRC), calling for the Department to "either add a definition [of medical necessity] or include in the regulations the standards for the development of a definition." The Department's comments concerning changes to the language regarding the complaint and grievance reviews, credentialing requirements, and issues pertaining to perceived limitations on access don't address the need for a consistent definition upon which to base all coverage and treatment decisions relating to the necessity of care.

Insurers have failed to justify the use of different definitions between plans and within plans between products. Why should large insurers have different definitions for each of their regions or between subscriber and provider contracts.

During the comment process, the Medical Society and several medical and surgical specialty organizations provided definitions that are recognized within the physician community. These definitions recognize the decision process undertaken at the time of diagnosis and treatment based on the patient's presenting symptoms, examination by the physician or other health care provider, and the provider's training and experience.

While the Department may be correct that it doesn't have the authority to define medical necessity, as Act 68 says that plans are to adopt their definitions, the Medical Society believes that the Department clearly has the authority and should step forward to set forth criteria that plan definitions must meet – e.g., that the definition must be consistent with accepted standards of care in the community and take into account the local infrastructure.

For the Department's information, the Society again offers a definition of medical necessity that was adopted by the American Medical Association, which is: "Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing, or treating an illness, injury, disease, or its symptoms in a manner that is (1) in accordance with generally accepted standards of medical practice; (2) clinically appropriate in terms of type, frequency, extent, site, and duration; and (3) not primarily for the convenience of the patient, physician, or other health care provider."

In a recent article, a copy of which is attached, researchers studied the variations in the process and criteria used for decisionmaking concerning the medical necessity of a treatment or service in California's health care marketplace. By surveying health plans, medical groups, and integrated health systems representing over 80% of the commercial and medical assistance enrollment, the researchers found much variation in contractual definitions of medical necessity and in the application of those definitions to practice. They also learned that each plan medical director "relies to a different extent on coverage policies, scientific evidence, expert opinion, committee consensus, personal experience, and patient characteristics and preferences when making daily decisions, while the contractual definitions remain on the shelf as a reminder of legal obligations and risks."

The article goes on to describe different outcomes among plans when presented with the same diagnosis and treatment options. Three plans had three different approaches for the same procedure. The article also described a process for "best practices" and the drawbacks to development of this approach.

Researchers looked at ways to address the problems. Better communication was identified as the best way to improve the situation. Methods including legislation, regulation, and judicial action were not considered an absolute response, but could promote more consistent behavior among the stakeholders and improve communication.

The Society therefore recommends that the Department develop a list of criteria to be included in plan definitions of "medical necessity," and that those definitions be reviewed by the Department prior to use in any plan contract or promotional materials.

The second issue is the process outlined under section 9.706 for health care provider initiated grievances. The Medical Society appreciates that the Department responded to its (the Society's) concern and permitted the obtaining of the enrollee's consent to file a grievance at the time of treatment. The process of obtaining the consent and submitting the grievance outlined in the regulations is, however, cumbersome and will prevent many physicians from using the process. The amount of information to be submitted for the consent and grievance and the formal requirement for notification and rescinding of the consent to file a grievance will serve as impediments to the health care provider in pursuing an appeal. Requiring the provider to notify the enrollee even when the provider doesn't intend to pursue an appeal also adds needlessly to the burden of the provider and his/her staff. The process will also concern the patient due to the doubt raised either about whether the provider is delivering a medically necessary service or whether the managed care plan is acting in their (the patient's) best interests by covering the services their insurance is intended to cover.

A simpler process would have been to permit the use of a basic consent statement which can be explained to the patient at the time of treatment and then notification of the patient by the provider at the time of the initial denial of service when the provider intends to pursue appeal of the denial.

The Medical Society would like to work with the Department to educate physicians and other providers on the provider initiated grievance process to minimize any administrative roadblocks to the appropriate use of this means of appeal.

A final concern deals with the definitions of "Gatekeeper" and "Primary Care Provider" (PCP), and the role of the PCP as a gatekeeper.

Section 9.602 defines a gatekeeper as a primary care provider selected by an enrollee or appointed by a managed care plan with the authority to provide health care services as well as to provide referral or approval of non-emergency care. The proposed language doesn't clarify that in the case of a non-physician health care provider serving either as a PCP or as a gatekeeper, the services that they provide are limited or that those services may require the collaboration or supervision of a physician. Further, there is no stated limitation on the non-physician PCP's decision-making authority over specialist referrals or approval of non-emergency services where those decisions involve the medical necessity of such services.

Neither the definition of gatekeeper or PCP require notice to the enrollee that the practitioner serving in either capacity may be a non-physician or permit the enrollee the option of selecting a physician instead of a non-physician. The regulations permit the plans to determine whether to include certified registered nurse practitioners (CRNPs) in their PCP network, but nowhere do the regulations indicate that the plan cannot mandate that enrollees use a CRNP as their PCP or effectively limit access to physicians by not including sufficient numbers of physician PCPs in their network. Also, there is no requirement for the plan to identify a non-physician provider's relationship to a physician. Since most non-physicians may not admit patients for inpatient care, enrollee recognition of the role of the collaborating or supervising physician is necessary.

The Medical Society would like to work with the Department and the managed care plans to ensure the adequacy of plan provider networks and the appropriate access to all levels of health care providers. We believe our concerns can be addressed through enrollee information and current complete directories of providers.

There are a number of important clarifications in the proposed regulations. The Department's intended use of technical advisories to provide guidance on interpretation of the regulations, the added coverage of treatment and stabilization prior to the transportation of an emergency patient, the standards for checking the status of plan formularies and the process for requesting exceptions, and the description of the Utilization Review (UR) process are some of the changes addressing provider concerns for which the Department is to be commended.

In conclusion, the Pennsylvania Medical Society supports the proposed final form regulations submitted by the Department of Health for the implementation of Act 68. We would urge the Senate Public Health and Welfare Committee to submit a letter of support for the proposed regulations to the IRRC.

The Act and its regulations are works in process. The Society looks forward to continued discussions with legislators, other providers and the insurance industry to improve on what we have collectively accomplished and make affordable, accessible, quality health care through managed care truly workable in the Commonwealth. We are encouraged that Representative Micozzie, Chair of the House insurance Committee, has renewed his commitment to continue to meet with interested parties to identify areas of concern as well as possible opportunities for consumers, providers, payers and regulators to come together in pursuit of these goals.

The Pennsylvania Medical Society appreciates this opportunity to present its views on these important proposed final regulations, intended to implement Act 68 and the managed care reforms.

DNM/doc/misc/Statement on Act 68 Senate PHW

Prospects For Improved Decision Making About Medical Necessity

A group-process approach to demystifying decisions of medical necessity in managed care plans.

BY SARA J. SINGER AND LINDA A. BERGTHOLD

WITH THE BACKLASH against managed care, medical necessity has become the focus of increasing controversy.[1] California's health care marketplace has provided some unique opportunities to understand the role of medical necessity in managed care decision making, as the legislature and stakeholders have discovered how little consensus there is on its meaning, ownership, and application.[2]

Nevertheless, many decisionmakers agree that medical necessity decisions generally involve authorizing treatment for an individual patient. These differ from coverage decisions, which set organizational policies regarding the coverage of treatments for populations of patients with similar conditions. Both types of decisions require medical judgment, and thus both mix considerations of payment and clinical factors.[3] Differences in coverage policies and in the application of those policies to individual decisions contribute to variation in managed care decision making.

Previous research has found considerable variation in the process and criteria used for decision making in both public and private plans.[4] The aim of our research was to understand more precisely what type of variation exists and whether more clarity and consistency in medical necessity decision making could make a difference to consumers and providers.[5] We sought to document differences in decision-making criteria and to explain the relationship between contractual definitions and the way decisions are made in practice. Given the lack of existing information on how medical necessity decisions are made in managed care organizations, we believed that describing "best practices" as well as unacceptable variations could play a powerful role, along with consumer choice and regulatory fiat, in improving the process.[6] Finally, we sought to produce, with stakeholders' involvement, a model contractual definition and decision-making process based on best-practices models.[7]

Study Methods

We conducted interviews in 1998–1999 with the medical directors of thirty-four health plans, medical groups, and integrated delivery systems in California, representing more than 88 percent of the commercial managed care enrollment and 84 percent of managed Medi-Cal enrollment. Structured interviews included four case examples to test decision-making approaches. We also requested data on plan or group characteristics and relevant documents. In addition, we interviewed other stakeholders, including consumer representatives, treating physicians, purchasers, plan legal directors, and regulators, repre-

Sara Singer is a senior research scholar at Stanford University and executive director of Stanford's Center for Health Policy. She was lead investigator for "Decreasing Variation in Medical Necessity Decision Making." Linda Bergthold was the grant project director and is a research associate at the center.

senting a total of ninety-four organizations. To understand the legal context in which medical necessity has been interpreted, we analyzed twenty-seven published California court cases. To determine the degree of variation in the interpretation and application of medical necessity by the Department of Corporations (DOC), California's managed care regulatory authority, we analyzed a sample of twenty-two consumer Requests for Assistance cases related to reconstructive surgery.[8] We then presented our preliminary findings at a three-day workshop in March 1999 involving twenty of our respondents, cosponsored by the Integrated Healthcare Association.[9]

Research Results

Our research addressed several central questions: (1) Who makes medical necessity decisions? (2) What are the variations in process and contractual definitions of medical necessity? (3) Can more information and better communication improve the process for consumers and providers? (4) What role should legislation and regulation play in promoting best practices and reducing unacceptable variation?

■ **Medical necessity decisionmakers.** Many consumers believe that nonclinical personnel make most of the decisions in managed care, including decisions to deny care. Consumers interviewed were unaware that both the National Committee for Quality Assurance (NCQA) and the Knox-Keene Act, which regulates managed care plans in California, require that only licensed physicians can make medical necessity decisions or denials, and that the NCQA audits the plans for compliance with these requirements.[10]

Although only physicians appear to be making denials based on medical necessity, in fact, nonphysician personnel do participate in initial reviews of eligibility and coverage. A clerk may have authorization to rule on a clearly excluded service. A nurse may evaluate a request against a coverage policy and recommend a denial or modification to a medical director. However, criteria and policies guiding these decisions are vague, uncertainty is present, and differences of opinion easily arise. Delays in referring such cases to medical directors leave consumers with the impression that "bean counters" are truly in charge.[11]

Although medical directors are physicians, the fact that the patient's treating physician is not the final decisionmaker in all requests continues to trouble physicians and their professional associations. Recent plan decisions to give treating physicians more autonomy may alleviate this concern, although most plans will retain authority over decisions such as coverage of transplants or experimental/investigational treatments.[12]

California's reliance on the delegated medical group for decision making has further obscured the source and process for making these decisions. California's health maintenance organizations (HMOs) generally capitate medical groups (for example, independent practice associations, multi/single-specialty medical groups, and management services organizations) for professional and often for hospital services. In doing so, they also delegate initial decision-making authority for coverage to these groups.

The medical directors of medical groups reported that they approve most treatment requests (94 percent, on average). Because plans retain final legal authority, they may overturn medical groups' decisions, often without assuming financial responsibility for the decision. Consumers generally must appeal denials first to the delegated medical group and then to the plan itself before they can seek redress from the DOC or an external review organization. This double layer of denials causes confusion and adds cost, time, and complexity to the process.

■ **Variations in process and contractual definitions.** While we found many common processes across organizations, there was much variation as well. Although variation is not necessarily negative, when consumers and employers purchase health insurance, they want to believe that Plan A will treat a given condition and patient the same way as Plan B does. We discovered variation in the contractual definitions of *medical necessity* and in the

application of those definitions to practice. We also found variation in the substance and application of coverage policies.

By asking medical directors what criteria they used to make daily medical necessity decisions, and by comparing those criteria with the ones in their own contracts, we confirmed that contractual definitions of medical necessity vary and are not the primary driving force in practice.[13] Instead, each medical director relies to a different extent on coverage policies, scientific evidence, expert opinion, committee consensus, personal experience, and patient characteristics and preferences when making daily decisions, while the contractual definition remains on the shelf as a reminder of legal obligations and risks.

The irrelevancy of contractual definitions is in part the result of the vague nature of the language, which lacks explicitly defined criteria or definitions of key terms. For example, most "evidence" criteria simply refer to "generally accepted or community standards of practice," and if cost-effectiveness is addressed at all, it may be couched as "a prudent use of plan resources" or "most appropriate level of service."

Existing definitions fail to provide guidance for decisionmakers who wish to make evidence-based decisions or explicit tradeoffs between the benefits and costs of alternative treatments. Many of our respondents reported reluctance to discuss costs or cost-effectiveness with either their contracted providers or plan members. Medical directors reported that clearer evidence and cost-effectiveness criteria could improve the utility of contractual definitions.

An additional source of variation is the proliferation of multiple, overlapping, and often inconsistent coverage policies developed by plans. Coverage policies should lead to more rational and consistent decisions for patients with a particular condition. In practice, policy development and dissemination are costly and problematic, and add to unacceptable variation in decision outcomes. Medical groups in California may contract with eight to ten health plans, each with its own set of coverage policies. Medical directors and practicing physicians are left with a bewildering array of competing policies, which are neither electronically searchable nor in formats that are easily comparable.

In addition, the substance of the policies and the evidence on which they are based differ greatly, producing the dissimilar outcomes that members and purchasers fear. A case study of autologous chondrocyte transplantation (ACT) for knee pain exemplifies this variation. In three plans' coverage policies for ACT we found only three areas of consistency and many areas of potentially clinically important inconsistency. For example, Plan B recommends coverage of treatment for a member who is age fifty-five, while Plan C only recommends coverage up to age forty-five. Plan B also recommends coverage for lesions up to 20 square centimeters in surface area, while Plan C recommends coverage for lesions up to only 10 square centimeters. Lesion thickness and length requirements also differ. The degree of specificity among the coverage policies varies, with Plans B and C outlining in detail requirements for lesion size, patient age and weight, prior therapy, and surgeon characteristics, while Plan A specifies none of these. The scientific evidence upon which plans based their policies also differed. In addition, two of the medical directors contradicted their own coverage policies when asked what decision they would make in this hypothetical case. This suggests either ignorance of the policies or their irrelevance.

The collective responses from medical directors of plans and groups to this ACT case study and three others—reconstructive surgery for cleft palate, growth hormone for short stature, and high-dose chemotherapy for ovarian cancer—suggest that coverage policies for identical patients did indeed differ and that daily decisions were not necessarily based on policies. While the sample size and brevity of the cases do not permit drawing conclusive opinions, several observations can be made. First, case responses varied across medical groups and health plans, unrelated to size, geography, or populations served. Sec-

ond, there was more agreement among medical directors in the case for which evidence was somewhat clearer (growth hormone for short stature). This consensus may reflect the considerable evidentiary literature on the effectiveness of growth hormone, medical directors' familiarity with that evidence, and the relative comfort most medical directors have with approving or denying this treatment based on patient characteristics such as those presented in the case.

Best practices in decision making. Consumers and policymakers look to regulation or legislation to reduce inconsistency. However, not all inconsistencies among organizations are negative, nor are regulation and legislation always appropriate ways of reducing them. Some variations represent more innovative ways of accomplishing an organizational goal, and many best practices are those that rely on obvious solutions: the personal touch (for example, calling physicians directly to notify them of a denied request); involving providers in suggesting ideas for improvement (for example, interdisciplinary committees); decentralizing decisions (that is, moving a decision closer to the patient and the physician); and rewarding positive behavior over punishing the "bad apples" (for example, "gold carding" providers whose utilization is circumspect and freeing them from cumbersome authorization processes).

Researchers extracted around sixty "best-practice" recommendations from the interview process and asked workshop participants to rate their potential impact on improving the decision-making process and their feasibility of implementation (Exhibit 1).

In virtually all cases, workshop participants ranked recommendations higher on impact than on feasibility, which suggests that while many of these best practices are potentially helpful, the practical barriers to their adoption are difficult to overcome. For example, a recommendation for medical directors to contact a patient's treating physician for comment before issuing a denial ranked high on impact but relatively low on feasibility. Medical directors reported that they already try to contact physicians in most cases, but

EXHIBIT 1
Sample Recommendations For Best Practices In Medical Necessity Decisions

Impact	Feasibility: High	Feasibility: Low
High	Health plans should track numbers and types of denials and their reasons and use this information for quality improvement and for comparison among organizations Plans should inform patients of requests, decisions, and reasons in a timely manner Plans should provide consumers with timely and full information about their ability to appeal, internal and external assistance, and second opinions	Medical directors should contact the patient's treating physician and the specialist to obtain a complete clinical picture prior to rendering a decision Health plans should use physician profiles as educational tools and to determine preapprovals Stakeholders should create an industrywide initiative to develop coverage policies, consistent in format and substance
Low	Legislature should require plans and provider organizations to disclose their contractual definitions Organizational policies should include references to sources	Legislature should require plans and provider organizations to develop a common definition of medical necessity for implementation in private contracts Purchasers should set up their own appeals processes accessible to employees after plan processes are exhausted Plans should conduct welcome phone calls for new members to describe the process for accessing services

SOURCE: Sample recommendations based on research project, "Decreasing Variation in Medical Necessity Decision Making" and findings from a decisionmaker workshop conducted in March 1999 at the Sierra Health Foundation, Sacramento, California.

physicians do not always return their calls.

Recommendations about streamlining authorization, enhancing communication, and providing more education were all thought to have some potential for positive impact among all stakeholder groups. Most of the recommendations that were rated highest for both impact and feasibility involved better communication. Participants, however, discriminated among communication activities, suggesting, for example, that welcome calls by health plans to new members would be neither feasible nor particularly beneficial. Recommendations expected to have the least impact entailed legislative mandates or greater purchaser involvement in the process.

■ **Better communication.** Our findings reinforced the perception that communication with consumers and their treating providers is poor. Not enough information is disclosed or requested, and the information that is disclosed is not particularly clear, helpful, or accessible. The denial letter is a case in point. Denial letters rarely explain who made the decision, the reason for the decision, what sources of evidence were considered, what coverage policies were applied, or anything else about the process of making that decision. Although a more informative denial letter will not eliminate dissatisfaction with a decision, consumers interviewed indicated that it could increase public trust in managed care.

Lack of consistent and effective communication among multiple decisionmakers is another important source of conflict. For example, medical groups that contacted physicians and plans about questionable requests claimed less conflict and fewer appeals and overturned decisions.

■ **Role of legislation and regulation.** There are many options for reducing variation, promoting consistency, and speeding dissemination of best practices in medical necessity decision making, only two of which are legislation and regulation. Judicial action, accreditation, market and performance incentives, and collective action also must play a role. Each of these approaches has strengths and weaknesses, whether pursued alone or in combination.[14]

Legislation. Despite all of the attention to legislation, there has been little discussion about whether legislation is addressing the most important problems with managed care or whether it is even the appropriate vehicle for doing so.[15] State and federal legislation have mainly addressed problems of access to providers of choice, timeliness of decision making, internal and external independent review procedures, plan accountability, and the right to sue.

Legislation can, however, promote more consistent organizational behavior. For example, California law spells out a specific process for external review of denials of experimental or investigational treatments.[16] Our research confirmed that plans were following this mandate in similar ways. Legislation also can resolve structural debates among stakeholders, such as where the authority for various decisions should reside, and it can set standard floors below which plan performance would be considered to be unacceptable. Legislation can also require information disclosure.

The danger of detailing standards and definitions in statute, however, is that clinical practice is difficult to pin down precisely, floors quickly become ceilings, and politics almost always intrudes.[17] Legislation is a weak strategy to effect deep systemic and organizational change of the type our research found necessary. Government regulation does not necessarily motivate providers to improve, and legislation does not necessarily make consumers more prudent purchasers.[18]

Regulation. Regulation is a more flexible tool than legislation to promote consistency, but it can be a barrier to innovation. Ideology and bureaucracy often prevent regulators from moving quickly or responding to emerging problems effectively.

In our review of Requests for Assistance from the DOC, we found that the department does not have a consistent process for or a standard definition of medical necessity. The consultant the DOC used for our sample cases relied largely on his own clinical judgment

with little citation of scientific literature to support his recommendations. The DOC representative who attended the project workshop acknowledged the need to improve the department's process.

Judicial action. Judicial interpretation and application of the law can cause organizations to change. However, the judicial system can also obfuscate rather than clarify the most troubling questions. Our review of court cases related to medical necessity decisions confirmed that judicial outcomes in such cases seem idiosyncratic and fact specific and do not provide useful guidance for medical necessity decision making.[19]

Accreditation. Private accrediting agencies such as the NCQA, the American Accreditation Healthcare Commission (URAC), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) serve an important standard setting and auditing role in the managed care decision-making process. Since accreditation standards are not compulsory, they can promote incremental performance improvement. We found both consistent and inconsistent implementation of NCQA standards in our interviews. All plans and groups used physicians to make medical necessity denials, but not all plans and groups demonstrated that medical evidence was documented as part of the coverage policies they use or that plans were successfully involving practitioners in the development of policies.[20]

Market and performance incentives. Accreditation promotes consistency, but market and performance incentives drive organizations to achieve optimum performance. We found considerable evidence of innovation as health plans attempted to improve their own decision-making processes in response to consumers' demands and the potential for legislation. Organizations were exceeding legislated timeline requirements and were revising the cumbersome authorization system and even eliminating it for some procedures and practitioners.

Among the most intractable problems are those that do not lend themselves to correction by any of these strategies but rather require stakeholders to work collectively. Thus, to address the problem of overlapping and conflicting coverage policies, workshop participants recommended a public/private initiative to compare, evaluate, and encourage standardization.

The problems associated with medical necessity go beyond the terminology and authority for decision making. The decision-making process itself is in need of improvement. To make the process more consistent yet provide opportunity for innovation will require multiple strategies, as outlined above. Consumers, advocacy organizations, and employers can use their buying power to effect appropriate systemic and organizational change. Only then can managed care fulfill the promise of evidence-based medical necessity decision making to improve quality of care.

The authors acknowledge researchers Carol Vorhaus, Serl Zimmerman, Suzanne Olson-Koebler, Ian Mutchnick, Ying-Ying Goh, and Alain Enthoven; consultants Wade Aubry, David Eddy, Hank Greely, Peter Lee, Mary Morgan, and Bill Sage; and funders the California HealthCare Foundation and the Sierra Health Foundation.

NOTES

1. A. Enthoven and S. Singer, "The Managed Care Backlash and the Task Force in California," *Health Affairs* (July/Aug 1998): 95–110; L.A. Bergthold, "Medical Necessity: Do We Need It?" *Health Affairs* (Winter 1995): 180–190; Linda Bergthold, "Medical Necessity: From Theory to Practice," Testimony before U.S. Senate Committee on Health, Education, Labor, and Pensions, 2 March 1999; and M. Stauffer, *Medical Necessity*, Health Policy Tracking Service Issue Brief (Washington: Health Policy Tracking Service, 1 October 1999).
2. Managed Health Care Improvement Task Force, "Public Perceptions and Experiences with Managed Care," in *Improving Managed Health Care in California, Findings and Recommendations*, vol. 2 (January 1998), 13–42; and L. Bergthold et al., "Suggestions for Addressing Medical Necessity," testimony before the Legislative Working Group on Medical Necessity (14 July 1998).
3. W. Sage, "UR Here: The Supreme Court's Guide for Managed Care," *Health Affairs* (Sep/Oct 2000):

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

Original: 2079

Carolyn F. Scanlan
President and Chief Executive Officer

March 19, 2001

The Honorable Dennis M. O'Brien
Majority Chair
House Health and Human Services Committee
100 Main Capital
Harrisburg, PA 17120

Dear Representative O'Brien:

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—requests that the House Health and Human Services Committee not request a tolling of the review period for 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. HAP sent a letter supporting these regulations on March 16 to the Independent Regulatory Review Commission (IRRC). A copy of this letter is attached for your review.

Hospitals and health systems supported the enactment of Act 68 as a first step in assuring improved managed care accountability for patients. Act 68 (originally Senate Bill 91) developed from Senate Bill 100, sponsored by Senator Tim Murphy and House Bill 977, sponsored by Rep. Pat Vance. The language for Act 68 was crafted in the Senate and was sent back to the House for concurrence. Senate Bill 100 contained consumer protections that were viewed to be essential in the most rigorous managed care plans. House Bill 977 was more broadly focused on consumer disclosure, utilization review, and prompt payment and applied to all health insurers, exclusive of auto, worker's compensation, and traditional indemnity plans. The merging of these two bills into Senate Bill 91 (Act 68) reflects the intent of the legislature to have the consumer protections apply to managed care plans that use gatekeepers and the utilization review and prompt payment to all health insurers, exclusive of auto and worker's compensation.

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 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 had appropriately interpreted the act in the development of its final-form regulations by requiring licensed insurers and managed care plans to comply

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.564.9200 Phone
717.561.5334 Fax
http://www.hap2000.org

HAP

with the utilization review standards. The same language was included in Section 2166 of Act 68 regarding prompt payment and the final-form regulations promulgated by the Insurance Department requiring all licensed health insurers and managed care plans to adhere to prompt payment requirements.

In your request to toll the regulations, the Committee is asking the Department of Health to consider inappropriate changes to the regulations, specifically regarding the interpretation of legislative intent relative to the applicability of the utilization review requirements to licensed insurers and managed care plans. Should the Department of Health make your suggested changes, administration of Act 68 will be compromised because the same language in two sections will be implemented differently, one way by the Insurance Department and another way by the Department of Health.

The utilization review standards in the final-form regulations 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 utilization review 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 final-form regulations fulfilled that statutory objective. To change that objective through your suggested changes prevents consumers from benefiting from the act as was intended in its passage. The language was intended to apply to all insurers except for fee-for-service indemnity plans, therefore, PPOs with or without gatekeepers should adhere to the utilization review standards.

HAP believes that the Department of Health's final-form regulations represented 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 addressed the many concerns raised during the public comment period on behalf of the insurers, providers, and patients. Therefore, HAP opposes the tolling process and the Committee's suggested changes to the Department of Health's final-rulemaking pursuant to Act 68 and the revisions to the state's HMO regulations.

Should the Committee's recommended changes be implemented, HAP will be forced to withdraw our support for these regulations when they are considered by the Independent

HAP

Regulatory Review Commission. If you have any questions about our comments, feel free to contact me at (717) 561-5314 or Paula A. Bussard, Senior Vice President, Policy and Regulatory Services at (717) 561-5344.

Sincerely,

CAROLYN F. SCANLAN
President and Chief Executive Officer

/mg

c: The Hon. Robert S. Zimmerman, Secretary of Health
The Hon. Frank L. Oliver, Minority Chair, House Health and Human Services Committee
The Hon. Nicholas A. Micozzie, Chair House Insurance Committee
The Hon. Anthony M. DeLuca, Minority Chair, House Insurance Committee
John R. McGinley, Jr., Chairperson, Independent Regulatory Review Commission

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

4750 Lindle Road
PO Box 8600
Harrisburg, PA 17105-8600
717-564-9200 Phone
717-561-5334 Fax

FAX TRANSMISSION

Please deliver immediately

***page(s), including cover sheet*: (4) FAX: 717/561-5334**

FROM: Betsy Taylor

DATE: March 19, 2001

TO : John R. McGinley 783-2664

RE: Act 68

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

Carolyn F. Scanlan
President and Chief Executive Officer

March 19, 2001

The Honorable Harold F. Mowery
Majority Chair
Senate Public Health and Welfare Committee
169 Capital Building
Harrisburg, PA 17120

Dear Senator Mowery:

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—requests that the Senate Public Health and Welfare Committee not request a tolling of the review period for 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. HAP sent a letter supporting these regulations on March 16 to the Independent Regulatory Review Commission (IRRC). A copy of this letter is attached for your review.

Hospitals and health systems supported the enactment of Act 68 as a first step in assuring improved managed care accountability for patients. Act 68 (originally Senate Bill 91) developed from Senate Bill 100, sponsored by Senator Tim Murphy and House Bill 977, sponsored by Rep. Pat Vance. The language for Act 68 was crafted in the Senate and was sent back to the House for concurrence. Senate Bill 100 contained consumer protections that were viewed to be essential in the most rigorous managed care plans. House Bill 977 was more broadly focused on consumer disclosure, utilization review, and prompt payment and applied to all health insurers, exclusive of auto, worker's compensation, and traditional indemnity plans. The merging of these two bills into Senate Bill 91 (Act 68) reflects the intent of the legislature to have the consumer protections apply to managed care plans that use gatekeepers and the utilization review and prompt payment to all health insurers, exclusive of auto and worker's compensation.

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 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 had appropriately interpreted the act in the development of its final-form regulations by requiring licensed insurers and managed care plans to comply

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.564.9200 Phone
717.561.5334 Fax
cscanlan@hap2000.org

HAP

with the utilization review standards. The same language was included in Section 2166 of Act 68 regarding prompt payment and the final-form regulations promulgated by the Insurance Department requiring all licensed health insurers and managed care plans to adhere to prompt payment requirements.

In your request to toll the regulations, the Committee is asking the Department of Health to consider inappropriate changes to the regulations, specifically regarding the interpretation of legislative intent relative to the applicability of the utilization review requirements to licensed insurers and managed care plans. Should the Department of Health make your suggested changes, administration of Act 68 will be compromised because the same language in two sections will be implemented differently, one way by the Insurance Department and another way by the Department of Health.

The utilization review standards in the final-form regulations 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 utilization review 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 final-form regulations fulfilled that statutory objective. To change that objective through your suggested changes prevents consumers from benefiting from the act as was intended in its passage. The language was intended to apply to all insurers except for fee-for-service indemnity plans, therefore, PPOs with or without gatekeepers should adhere to the utilization review standards.

HAP believes that the Department of Health's final-form regulations represented 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 addressed the many concerns raised during the public comment period on behalf of the insurers, providers, and patients. Therefore, HAP opposes the tolling process and the Committee's suggested changes to the Department of Health's final-rulemaking pursuant to Act 68 and the revisions to the state's HMO regulations.

Should the Committee's recommended changes be implemented, HAP will be forced to withdraw our support for these regulations when they are considered by the Independent

HAP

Regulatory Review Commission. If you have any questions about our comments, feel free to contact me at (717) 561-5314 or Paula A. Bussard, Senior Vice President, Policy and Regulatory Services at (717) 561-5344.

Sincerely,

CAROLYN F. SCANLAN
President and Chief Executive Officer

/mg

c: The Hon. Robert S. Zimmerman, Secretary of Health
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
John R. McGinley, Jr., Chairperson, Independent Regulatory Review Commission

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

4750 Lindle Road
PO Box 8600
Harrisburg, PA 17105-8600
717-564-9200 Phone
717-561-5334 Fax

FAX TRANSMISSION

Please deliver immediately

***page(s), including cover sheet*:** **(4)** **FAX: 717/561-5334**

FROM: **Betsy Taylor**

DATE: **March 19, 2001**

TO : **John R. McGinley** **783-2664**

RE: **Act 68**

Original: 2079

IRRC

From: Sheila Earhart [Searhart@pahousegop.com]
Sent: Tuesday, April 03, 2001 10:29 AM
To: irrc@irrc.state.pa.us
Subject: March 19, 2001

3-28-01M.doc

Please read.
Thank you

Rep. Nicholas A. Micozzie
Room 45, East Wing
3-8808

April 2, 2001

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

Dear Mr. Nyce:

I am writing to request that the Independent Regulatory Review Commission disapprove the Department of Health final form regulation of Act 68 of 1998. As Chairman of the House Insurance Committee and the sponsor of the amendment that ultimately became the managed care reforms of Act 68, I was very involved in the development and enactment of the act. I believe that the regulation should be disapproved for the following reasons:

- The regulation requires prior approval of contracts between health plans and providers which is not provided for by statute. The Department has even indicated that they intend to require plans to submit contracts in place prior to the effective date of the regulations for review and approval (p 407 of the Preamble). This disruption of business practice should not be permitted. Prior approval of contracts is a legislative decision, not one that can be claimed by the regulator. Again, as the sponsor of the amendment, I can tell you prior approval was never something we intended.

- The regulation would require health plans to provide written notification of all utilization review determinations to both the member and the provider. Members do not need written notices of approvals. In Secretary Zimmerman's March 20, 2001 letter to you in Attachment II he states "the Act requires written notice of all utilization review decisions to approve or deny coverage." The Act states that a Utilization Review Entity shall: "Provide all decisions in writing to include the basis and clinical rationale for the decision." **It does not require two notices,** one to the member and one to the provider. Standard business practice is to notify providers of all approvals (since they are the ones who will bill the health plan for services) and to notify both the provider and the member of any adverse coverage determination. Two notices each time a plan approves coverage is costly and will only confuse the member. The Department has only agreed to "waive" the requirement for hospitalized patients and issue "technical advisories" describing acceptable written notice to enrollees. Health plans have no assurance that future administrations will "waive" existing regulations.

- The regulation adds additional regulation of provider directories which are already reviewed and approved by the Insurance Department.

- The regulation requires plans to disclose, copy and provide to members all internal documents relating to an appeal. There must be some limit to the information that must be disclosed to members.

- The regulation fails to provide for joint regulation between the Insurance and Health Departments. Act 68 provides for the two agencies to jointly work together in certain key areas. The regulation – but does not – explain how the two agencies are to do this. Saying in the preamble that they will work together is not enough. We need to know how, and it should be guaranteed.

- The regulation should clear up the confusion on the 30 and 45 day deadlines we imposed on managed care plans for complaints and grievances. In Act 68, we meant these to be binding – not something that anybody could open up. The regulation allows that, and it should be corrected.

Thank you for considering my concerns about the overreaching of the Department of Health final form regulation.

Sincerely,

Nicholas A. Micozzie

Original: 2079

Pennsylvania Psychiatric Society

The Pennsylvania District Branch of the American Psychiatric Association

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

Executive Director
Gwen Yackee Lehman
777 East Park Drive
P.O. Box 8820
Harrisburg, PA
17105-8820

(800) 422-2900
(717) 558-7750
FAX (717) 558-7845
E-mail glehman@pamedsoc.org
www.papsych.org

(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

Gwen Yackee Lehman
Executive Director

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

PENNSYLVANIA PSYCHIATRIC SOCIETY

A district branch of the American Psychiatric Association

777 East Park Drive
P.O. Box 8820
Harrisburg, PA 17105-8820
FAX (717) 558-7841

DATE 3/16/01

FROM Gwen Lehman

PLEASE TRANSMIT THE FOLLOWING PAGES TO:

NAME Robert Nyce

COMPANY IRRC

TOTAL NUMBER OF PAGES 3 (including cover sheet)

FAX NUMBER 783-2664

NOTE:

If all pages are not received, please contact the Pennsylvania Psychiatric Society at (717) 558-7750 or (800) 422-2900 (within state).

Original: 2079

WAYNE MEMORIAL
HEALTH SYSTEM, INC.

March 16, 2001

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

Re: Act 68 Final Regulations

Dear Mr. McGinley,

Representing Wayne Memorial Health Systems, a rural health care system in Honesdale, PA and the Upper Delaware Area Physician Hospital Association, I am requesting your support of the final regulations of Act 68 as proposed by the Department of Health. The need for fair and responsible utilization review standards is necessary.

The following proposed changes are very important to our organization:

- Delivery and payment for emergency medical services by managed care plans include evaluation, testing and stabilization of emergencies consistent with "prudent layperson definition,
- Managed care plans allow providers to initiate grievances and obtain patient's written consent at the time of treatment,
- Managed care plans notify providers in advance of contract changes,
- Managed care plans' provider contracts can address informal dispute resolution between the plan and providers without requiring patient consent and allows alternative dispute resolution of external review process,
- **Requires insurers and managed care plans to provide the clinical rationale for a denial, disclose utilization review criteria upon written request, and have a physician issue on utilization review decisions.**

If I can offer you any additional information from a provider's perspective, please do not hesitate to contact me directly at 570-253-8424. Your assistance is greatly appreciated.

Sincerely,

Patricia Petlock
Director - Physician Practice Management
Coordinator- Upper Delaware Area Physician Hospital Organization

WAYNE MEMORIAL HOSPITAL

FAX TRANSMITTAL MEMO

TOTAL NUMBER OF PAGES (INCLUDING TRANSMITTAL MEMO): 2

DELIVERY: _____ ROUTINE _____ PLEASE PROTECT "Confidential Document!"

_____ PRIORITY

CONFIDENTIALITY NOTE: *The documents accompanying this telecopy transmission contain information from Wayne Memorial Hospital which is confidential and/or legally privileged. The information is intended only for the use of the individual or entity named on this transmission sheet. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of this telecopied information is strictly prohibited, and that the documents should be returned to this facility immediately. In this regard, if you have received this telecopy in error, please notify us by telephone immediately so that we can arrange for the return of the original documents to us at no cost to you.*

TO: John McGinley FAX # 717-783-2664

COMPANY: _____

DEPARTMENT: _____

FROM: Patricia Petlock TELEPHONE # 570-253-8424

(Name of Person Sending Fax) FAX # (570) 253-8425

DATE SENT: 3/16/01 TIME SENT: 1:20 p

COMMENTS: _____

Telephone (570) 253-8100 • 601 Park Street Honesdale Pennsylvania 18431-1498 • FAX (570) 253-8425

Original: 2079

March 19, 2001

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

Dear Mr. McGinley,

On behalf of the Board of Directors, Medical Staff, and Employees of J.C. Blair Memorial Hospital, I support the adoption of the final Department of Health Act 68 Regulations as an important first step in providing health plan accountability. Effective implementation of the regulations can benefit patients by fostering greater coordination and cooperation between health plans and health care providers in caring for patients. We are one of the more than two-thirds of Pennsylvania's hospitals and health systems losing money on patient care and 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:

- Ensuring consistency of Department of Health standards with 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.

Sincerely,

Richard E. D'Alberto
President/CEO

Original: 2079

Phoenixville Hospital

University of Pennsylvania Health System

March 16, 2001

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

Re: PA Department of Health Regulations for Act 68

Dear Mr. McGinley:

The Phoenixville Hospital supports the adoption of the final Department of Health regulation for Act 68 as an important first step in providing health plan accountability in the Commonwealth. 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. Last year, more than two-thirds of the Commonwealth's hospitals and health systems lost money on patient care. It is therefore inappropriate, in my opinion, to delay implementation of the regulations that establish fair and responsible oversight of the managed care plans.

I would also like to commend the Department of Health for 1) insuring the consistency of standards with the insurance department's regulations, 2) establishing fair and responsible utilization of review standards, 3) insuring that providers may advocate for patients and obtain written consent to do so with a plan of treatment, and 4) for balancing the interests of patients, health care providers and health plans in the development of these regulations.

I hope you will support the final implementation of the Department of Health regulations for Act 68.

Thank you.

Very truly yours,

Kevin B. Mahoney
Executive Director

cc: R. Molloy, J.D.

140 Nutt Road • P.O. Box 809 • Phoenixville, PA 19460-0809 • Tel. (610) 983-1000 • Fax (610) 983-1488

Original: 2079

Meyersdale Medical Center
Member Concmaugh Health System

March 16, 2001

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

Re: Support of Department of Health Act 68 Regulations

Dear Mr. McGinley:

As President of Meyersdale Medical Center, I support adoption of the final Department of Health Act 68 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.

Sincerely,

Mary L. Libengood
President

MLL:skl

200 Hospital Drive
Meyersdale, PA 15552
814-634-5911
www.meyersdalemedicalcenter.com

Original: 2079

IRRC

From: Lehman, Gwen [GLehman@pamedsoc.org]
Sent: Friday, March 16, 2001 4:47 PM
To: 'irrc@irrc.state.pa.us'
Subject: Act 68 regulations

Please see the attached letter from the Pennsylvania Psychiatric Society to the Department of Health, regarding DOH's proposed regulations for Act 68.

Gwen Lehman, Executive Director
Pennsylvania Psychiatric Society
P. O. Box 8820
Harrisburg, PA 17105-8820
glehman@pamedsoc.org