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REVIEW COMMISSION

March 13, 2001

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

Dear Mr. Nyce:

I write on behalf of Highmark Inc., the Pennsylvania Blue Cross Blue Shield plans, and our subsidiary managed care plans, Keystone Health Plan East, Keystone Health Plan Central, Keystone Health Plan West, HealthGuard, and First Priority Health.

As you know, the Department of Health (DOH) has submitted its final-form rulemaking on the Managed Care Organization Regulations to the appropriate legislative committees and to the Independent Regulatory Review Commission (IRRC) for review and approval.

We have reviewed the proposed final-form regulations, and wish to advise you of our opposition to the regulations in their current form. Our concerns, which primarily reflect areas where the regulations go beyond the intent of Act 68 or create confusion regarding which regulatory agency has authority to make determinations affecting plan practices and operations, are reflected in the attachment "List of Concerns and Requested Changes".

We presented a brief summary of our concerns in testimony before the Senate Public Health and Welfare committee on Monday, March 12. We have provided a copy of the testimony, as well.

These issues are not insurmountable. Indeed, we look forward to working with you, the Department of Health and the legislative committees to assure that final regulations can be issued in the very near future. All of our plans have worked hard since the passage of Act 68 in 1998 to assure that we conform with the spirit and intent of Act 68, and the DOHs policy statement, websites Questions and Answers, and the Insurance Departments Final Regulations. Thus we look forward to final, definitive guidelines from the DOH with regard to Act 68.

These regulations combine other previous rule-making, policy statements and Department bulletins, and we applaud that goal. Because of the comprehensive nature of these regulations, we have reviewed them carefully. We are concerned regarding the impact on our current administrative processes, on potential costs to our customers, and their conformity to the intent of those previous rules or policy statements. Our concerns are included in the referenced attachment.

We respectfully request that you consider our concerns, and urge the IRRC to disapprove the regulations as submitted. The DOH has heard these concerns, and those of others, in the past two weeks since releasing the final-form regulations. We are hopeful that the DOH can be convinced to revise the regulation and resubmit it and the required report to the legislative committees and the IRRC for further review.

Thank you for the opportunity to provide these comments.

If you would like to discuss any of the enclosed materials, please do not hesitate to contact me at (717) 975-7426, via e-mail at Candy.Gallaher@Highmark.Com, or via facsimile at (717) 731-2337.

Sincerely,

Candy Gallaher

C.M. (Candy) Gallaher
Director,
Regulatory Affairs

Enclosures

Cc: B. Hironimus, Highmark Inc.
M. McMillen, Independence Blue Cross
K. Kockler, Blue Cross of Northeastern Pennsylvania

Sincerely,

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Highmark Inc.

Public Testimony

Prepared for the

Senate Public Health & Welfare Committee

On

Health Department Managed Care Regulations

March 12, 2001

Presented by:

C. M.(Candy) Gallaher

I am Candy Gallaher, Director of Regulatory Affairs, at Highmark and will be offering testimony on behalf of the Pennsylvania Blue Cross Blue Shield plans and our affiliated Keystone and HealthGuard managed care plans.

Highmark was closely involved in providing assistance to the General Assembly during the entire legislative development of Act 68 of 1998. We were also closely involved as a stakeholder during the development of the Pennsylvania Insurance Department regulation implementing Act 68. Many meetings involving hospitals, physicians, health plans, consumers, legislators, and regulators resulted in a balanced regulation implementing the legislative intent of Act 68.

However the regulatory development process with the Department of Health (DOH) has not followed a similar path. We have had brief periods of time to review materials, but no opportunity to participate in meetings with the DOH and the various stakeholders to discuss concerns. After a year of implementing the Act using policy statements and questions and answers – we saw proposed regulations in December 1999, and had thirty days to review and respond. Almost another year goes by, before we are provided a glimpse of what the DOH intends as final form, and the opportunity to provide comments to the DOH this January, but not for a substantive dialogue. Now we have less than two weeks to review changes and provide comments to you on this very comprehensive and significant regulation.

While not an inherent component of the regulation, we have a concern that the regulatory development process reflected by the DOH may ultimately reflect the style by which they will regulate. Given that the fundamental goal of Act 68 was to improve communication and coordination between providers, patients and health plans, the activities of the Department of Health associated with development of this regulation do not aid in promoting this goal.

In presenting this testimony to this Committee, we respectfully request your disapproval of this final regulation. We recognize improvements have been incorporated since last year's proposed regulation, yet there are still many areas troubling to our health plans. This regulation can and should be improved.

In the brief time we have to present this testimony, we will focus on several key concerns. We do not wish to abuse the committee's time with the many details of issues we've identified, so we provide a more comprehensive list as an attachment. We would be happy to discuss them at any time with you, staff, and of course, the DOH.

Camp Hill, Pennsylvania 17089
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UR Standards §9.749-9.751 - We'll start with a big one: the three new sections on Utilization Review systems standards. These regulations were *not* exposed for comment and review as proposed regulations. So they appear here for the first time. They include many items that are standard for managed care plans, but *not* for indemnity and traditional insurers. Some of the new requirements are not standard for managed care plans, either. Yet they would become effective upon the date of publication in the *Pennsylvania Bulletin.*

Our understanding of Act 68 is that licensed insurers that perform UR for a managed care plan were required to meet the UR standards of the act. Yet these regulations are drafted without that clarification. Instead, they would seem to apply the standards to any licensed insurer in the state, performing UR of any type, in any program, such as a dental plan.

This places all insurers at risk of failing to meet new standards without adequate time to prepare. The double jeopardy for us is that these new UR standards would go into effect immediately, at a time when insurers and managed care plans statewide are engaged in preparing for other necessary changes to implement the DOL ERISA claims procedures regulation. Changes, I note, that differ from some of the DOH regulations, and that will pre-empt some of this rulemaking for both managed care plans and licensed insurers. That regulation, published in November 2000, at least gives plans until January 1, 2002 to prepare the necessary system and notification changes.

What's the fuss, you ask? After all, Act 68 included licensed insurers in the standards for UR. You are right. Yet these new regulations go far beyond the Act 68 statute and intent. For example: the statute says all UR decisions must be written, and must be provided within given timeframes. Today, if a facility seeks concurrent review for a length of stay, and it is approved, the facility receives the written approval, and nothing is sent to the enrollee. This is true in both our managed care and traditional plans.

In fact, plans routinely respond to provider driven UR requests directly to the provider with approvals. The new regulations goes beyond stating written notice is required, and says that it must be sent to both the provider *and* enrollee. When approvals are received, and care has been approved, sending written notice to the enrollee of decisions that permitted their care to continue only confuses them, and sometimes angers them instead. Indeed, we are often accused of wasting precious dollars on needless forms and notices!

In the ERISA claims procedures, which we will have until January 2002 to prepare for, only adverse determinations have to be sent to the enrollee, not *all* decisions. So, we would seek changes to the DOH's regulation, to reflect that written notice of all decisions should go to the providers, unless the decision is one that results in a denial.

We urge that the UR standards be pulled from this regulation and issued separately as proposed regulation

Medical Management Contracts, Provider Contracts, and Plan-IDS Contracts §§ 9.675, 9.722 and 9.724 – These sections do not provide for a grand fathering provision of current contracts. Instead, the DOH is requiring submission and approval of contracts already entered into. This has the potential to create a vast administrative challenge to the plans, and may affect the negotiated benefits and costs of the programs. We urge recognition of a grand fathering provision that indicates contracts will be submitted for review and approval for change at renewal, if already existing contracts.

We are also concerned with the timeframes set forth for the DOH's file and use approach for these contracts. They have specified 60 days file and use. We urge consideration of a 45 day file and use period, or a 60 day deemed approved period. Even HCFA allows for contracts of its intermediaries or carriers to be deemed approved if HCFA does not respond within 60 days. We understand that the DOH has set itself a significant administrative task to review many more contracts, yet plans should not be subject to lengthy periods of uncertainty regarding the status of contracts, especially as noted above, when contracts may already be in place.

Delegation of HMO Operations §9.634 – This section should be deleted. The Insurance Department is responsible for this authority. It is not a shared one with the Department of Health. Inclusion of this section in these regulations creates confusion by implying a shared regulatory oversight exists. Here, none does. Just as the Department removed the section on HMO Boards, they should remove this section. (The second paragraph relating to medical management is already addressed in a different area of the regulation, §9.675.)

Medicare HMO's, M+C plans and federal pre-emption – The Social Security Act § 1856(b)(3)(B) provides for federal pre-emption of state standards which are superseded by the SSA for Medicare HMOs. The areas of pre-emption include (i) benefits requirements, (ii) requirements relating to inclusion or treatment of providers, and (iii) coverage determination, including related appeals and grievance processes. Accordingly, there are certain areas of these regulations that are superseded by rules applying to Medicare HMOs. We urge recognition of this in the following Sections: §§ 9.651, 9.652, 9.653, 9.654, 9.671, 9.702, and 9.721. We have included proposed language in the attachment to effect this change.

Plan Provision of Prescription Drug Benefits to Enrollees §9.673 (D)– The Prescription Drug Benefit section focuses on requests for lists of drugs on the formulary, and exceptions. Some of the section goes beyond Act 68. We understand the need for standards in prescription drug coverage, yet we are concerned that the DOH is imposing a significant cost concern in this section.

Many employer groups select multi-tier drug programs. The level of enrollee cost-sharing depends on the drug tier. For example, the generic tier may have the lowest co-pay; the brand-tier may have the highest co-pay. Employers purchase these programs based on affordability.

Yet, the DOH would require complaints regarding the level of coverage for one drug versus another be treated as a grievance. Thus, a member who has a medical need for a brand drug, versus the generic equivalent, could appeal the level of co-pay covered in their benefits, a contractual issue, as a grievance, instead of a complaint. We believe this is inconsistent with the intent of the Act, and exposes plans and employers to increased costs in their prescription drug coverage that their benefit designs were intended to address.

Complaints and Grievances § 9.703 (c)(2)(III)(H) and § 9.705 (c)(2)(III)(H) – In the sections on internal complaints and internal grievances second level reviews the DOH has added a new prohibition that "the committee may not discuss the case to be reviewed prior to the second level review". This presents an almost insurmountable challenge, as well as unreasonable recommendation. The plan must provide information related to the case to the committee in advance of the review hearing. Those reviewers frequently have questions regarding how the initial determination was made and seek to understand the terms of the members contract, etc.

In fact, each of our plans has had the experience where, once materials were provided to the committee in advance of the hearing, and committee members reviewed the material, they then proposed overturning the initial denial. Because there is not prohibition against discussing the case today, the committee members could quickly call a meeting to discuss the recommendation. This new prohibition would eliminate that possibility! Instead, the member and the plan would have to go through a formal second level review hearing, at considerable expense in time, process and costs. We cannot believe that this is the intent of Act 68, and thus urge the elimination of this "gag rule" by the DOH.

Beyond the noted issues above, we would point out a general concern that the Preamble includes inconsistent information, and thus could not be relied on in its current form as a guidance document for plans. Thus, we believe the DOH should identify those areas of the Preamble that require additional revision in follow-up to the changes they've made since November.

As you can see, we have concerns that the current regulations simply have too many open issues to be approved as final form regulation. We thus urge you to disapprove the regulation as submitted, and request the DOH to revise the final-form regulation.

We appreciate the opportunity to come before you with these comments, and respectfully provide them to you. Our attachment outlines the various areas in the which this new regulation differs from or goes beyond Act 68 and lists other concerns with the regulation.

Thank you.

List of Concerns and Requested Changes

Original: 2079

Department of Health Managed Care Organization Regulations – Proposed Final 02-28-01

Section Language	Proposed Changes	Rationale
§9.673. (d)(e) (Page 111) **Plan provision of prescription drug benefits to enrollees.** (d) The plan shall distribute its policy and process to each participating health care provider who prescribes. **A PLAN SHALL PROVIDE A DESCRIPTION OF THE PROCESS TO BE USED TO OBTAIN COVERAGE OF A DRUG THAT IS AN EXCEPTION TO THE FORMULARY TO AN ENROLLEE OR PROSPECTIVE ENROLLEE UPON REQUEST.** ~~(e) If the plan does not approve a health care provider's request for an exception, the enrollee or the health care provider with the written consent of the enrollee may file a grievance under subchapter I (relating to complaints and grievances).~~ **IF A DRUG, CLASS OF DRUGS OR DRUGS USED TO TREAT A SPECIFIC CONDITION ARE SPECIFICALLY EXCLUDED FROM COVERAGE IN THE ENROLLEE CONTRACT, APPEALS FOR COVERAGE OF SPECIFIC EXCLUSIONS SHALL BE CONSIDERED COMPLAINTS. IF NO SPECIFIC EXCLUSION EXISTS, THE APPEAL OF A DENIAL OF A PHYSICIAN'S REQUEST FOR AN EXCEPTION TO THE FORMULARY REGARDING THE COVERAGE OF OR AMOUNT OF COVERAGE FOR ONE DRUG VERSUS ANOTHER, BASED ON MEDICAL NECESSITY AND APPROPRIATENESS, SHALL BE CONSIDERED TO BE A GRIEVANCE.**	**Plan provision of prescription drug benefits to enrollees.** (d) The plan shall distribute its policy and process to each participating health care provider who prescribes. **A PLAN SHALL PROVIDE A DESCRIPTION OF THE PROCESS TO BE USED TO OBTAIN COVERAGE OF A DRUG THAT IS AN EXCEPTION TO THE FORMULARY TO AN ENROLLEE OR PROSPECTIVE ENROLLEE UPON REQUEST.** ~~(e) If the plan does not approve a health care provider's request for an exception, the enrollee or the health care provider with the written consent of the enrollee may file a grievance under subchapter I (relating to complaints and grievances).~~ **IF A DRUG, CLASS OF DRUGS OR DRUGS USED TO TREAT A SPECIFIC CONDITION ARE SPECIFICALLY EXCLUDED FROM COVERAGE IN THE ENROLLEE CONTRACT, APPEALS FOR COVERAGE OF SPECIFIC EXCLUSIONS SHALL BE CONSIDERED COMPLAINTS. IF NO SPECIFIC EXCLUSION EXISTS, THE APPEAL OF A DENIAL OF A PHYSICIAN'S REQUEST FOR AN EXCEPTION TO THE FORMULARY ~~REGARDING THE COVERAGE OF OR AMOUNT OF COVERAGE FOR ONE DRUG VERSUS ANOTHER,~~ BASED ON MEDICAL NECESSITY AND APPROPRIATENESS, SHALL BE CONSIDERED TO BE A GRIEVANCE.**	The stricken language would allow challenges to the level of co-payments, a contractual issue, to be treated as grievances rather than as complaints. This is inconsistent with the intent of Act 68. Coverage is available under the contract for the drug; only the co-pay is being challenged. This is not a grievance, and should not be deemed as such by the DOH.

§9.675. (a) (Page 115)		
Delegation of medical management (a) A plan may contract with an entity for the performance of medical management relating to the delivery of health care services to enrollees. The plan shall submit the medical management contract to the Department for review and approval ~~prior to implementation~~. **THE DEPARTMENT WILL REVIEW MEDICAL MANAGEMENT CONTRACTS WITHIN 60 DAYS OF RECEIPT OF THE DOCUMENT. IF THE DEPARTMENT DOES NOT ISSUE AN APPROVAL WITHIN 60 DAYS, A PLAN MAY USE THE CONTRACT WITHOUT APPROVAL. HOWEVER, THE DEPARTMENT MAY AT A LATER DATE REQUIRE THE PLAN TO CORRECT ANY DEFICIENCIES IDENTIFIED BY THE DEPARTMENT. A PLAN SHALL SUBMIT MEDICAL MANAGEMENT CONTRACTS ENTERED INTO OR RENEWED BEFORE THE EFFECTIVE DATE OF THE REGULATIONS FOR REVIEW AND APPROVAL, BUT APPROVAL BEFORE USE WILL NOT BE REQUIRED FOR THESE CONTRACTS. REIMBURSEMENT INFORMATION SUBMITTED TO THE DEPARTMENT UNDER THIS PARAGRAPH MAY NOT BE DISCLOSED OR PRODUCED FOR INSPECTION OR COPYING TO A PERSON OTHER THAN THE SECRETARY OR THE SECRETARY'S REPRESENTATIVES WITHOUT THE CONSENT OF THE PLAN WHICH PROVIDED THE INFORMATION, UNLESS OTHERWISE ORDERED BY A COURT.**	**Delegation of medical management** (a) A plan may contract with an entity for the performance of medical management relating to the delivery of health care services to enrollees. The plan shall submit the medical management contract to the Department for review and approval ~~prior to implementation~~. **THE DEPARTMENT WILL REVIEW MEDICAL MANAGEMENT CONTRACTS WITHIN ~~60~~ *45* DAYS OF RECEIPT OF THE DOCUMENT. IF THE DEPARTMENT DOES NOT ISSUE AN APPROVAL WITHIN ~~60~~ *45* DAYS, A PLAN MAY USE THE CONTRACT WITHOUT APPROVAL. HOWEVER, THE DEPARTMENT MAY AT A LATER DATE REQUIRE THE PLAN TO CORRECT ANY DEFICIENCIES IDENTIFIED BY THE DEPARTMENT. A PLAN SHALL SUBMIT MEDICAL MANAGEMENT CONTRACTS ENTERED INTO OR RENEWED BEFORE THE EFFECTIVE DATE OF THE REGULATIONS FOR REVIEW AND APPROVAL, BUT APPROVAL BEFORE USE WILL NOT BE REQUIRED FOR THESE CONTRACTS.** *ANY REQUIRED CHANGES WILL NOT AFFECT SUCH CONTRACTS UNTIL THEY RENEW.* **REIMBURSEMENT INFORMATION SUBMITTED TO THE DEPARTMENT UNDER THIS PARAGRAPH MAY NOT BE DISCLOSED OR PRODUCED FOR INSPECTION OR COPYING TO A PERSON OTHER THAN THE SECRETARY OR THE SECRETARY'S REPRESENTATIVES WITHOUT THE CONSENT OF THE PLAN WHICH PROVIDED THE INFORMATION, UNLESS OTHERWISE ORDERED BY A COURT.**	The plans request a file and use period similar to that of the Insurance Department for contracts. If the DOH seeks to maintain the 60-day period, then we request it be consider deemed approved, not file and use. The plans request that changes the DOH determines are required to contracts currently in effect will only be required when those contracts renew.

§9.679. (c) (Page 122) **Access requirements in service areas.** (c) ~~A plan shall demonstrate at all times that it has an adequate number and range of health care providers by specialty and service area to ensure that enrollees have adequate access to and availability of health care services covered by the plan.~~ ~~(d)~~ A plan shall ~~immediately~~ report to the Department any ~~serious~~ potential ~~change in the plan's ability to provide services in a particular service area through termination, cancellation or non-renewal of health care provider contracts potentially affecting 10% or more of the plan's enrollees in the service area~~ **LOSS FROM THE NETWORK OF ANY GENERAL ACUTE CARE HOSPITAL AND ANY PRIMARY CARE PROVIDER, WHETHER AN INDIVIDUAL PRACTICE OR A GROUP PRACTICE, WITH 2000 OR MORE ASSIGNED ENROLLEES.**	§9.679. (c) (Page 122) **Access requirements in service areas.** (c) ~~A plan shall demonstrate at all times that it has an adequate number and range of health care providers by specialty and service area to ensure that enrollees have adequate access to and availability of health care services covered by the plan.~~ ~~(d)~~ A plan shall ~~immediately~~ report to the Department any ~~serious~~ **~~potential~~** ~~change in the plan's ability to provide services in a particular service area through termination, cancellation or non-renewal of health care provider contracts potentially affecting 10% or more of the plan's enrollees in the service area~~ **LOSS FROM THE NETWORK OF ANY GENERAL ACUTE CARE HOSPITAL AND ANY PRIMARY CARE PROVIDER, WHETHER AN INDIVIDUAL PRACTICE OR A GROUP PRACTICE, WITH 2000 OR MORE ASSIGNED ENROLLEES.**	This change removes the word "potential" from the paragraph. The plans believe this adds an unnecessary administrative burden. Certainly plans should report significant changes in their networks, and we agree with the DOH's standard of losses affecting 2000 or more enrollees. However, the requirement to report any potential loss would mean we have to notify the Department any time we are re-contracting with facilities, or large practices. It is not uncommon for entities to use the threat of termination or non-renewal as a negotiating position. Additionally, there are situations where bankruptcy protection may or may not cause a provider to close a practice, or notice of change in ownership requires having to credential a new owner. There is no immediate threat of loss of access in either of those scenarios, but the DOH would require we report them. We urge removal of this requirement.
§9.702. (d) (Page 139) **Complaints and grievances.** (d) *Time frames.* (1) ~~A plan may not impose unreasonable time limitations on an enrollee's ability to file an appeal or grievance.~~ ~~(2) If a plan establishes a time limit for an enrollee to file the initial complaint or grievance, the plan shall allow the enrollee at least 30 calendar days to file the complaint or grievance from the date of the occurrence of the issue being complained about.~~ **IF A PLAN ESTABLISHES TIME FRAMES FOR THE FILING OF COMPLAINTS AND GRIEVANCES, IT SHALL ALLOW AN ENROLLEE AT LEAST 45 DAYS TO FILE A COMPLAINT OR GRIEVANCE FROM THE DATE OF THE OCCURRENCE OF THE ISSUE BEING COMPLAINED ABOUT, OR THE DATE OF THE ENROLLEE'S RECEIPT OF NOTICE OF	ADD NEW PARAGRAPH (e) ***(e) THE PLAN MAY NOT EXTEND THE TIMEFRAMES REQUIRED BY THIS REGULATION AND THE ACT (40 P.S.§§991.2141, 991.2142, 991.2161, AND 991.2162). HOWEVER, THE ENROLLEE MAY WAIVE OR EXTEND THE DEADLINE IF THE ENROLLEE WISHES THE PLAN TO CONSIDER ADDITIONAL INFORMATION.***	The DOH acknowledges this in the PREAMBLE, page 244. However, failure to cite it in the regulation would put plans at risk, if they chose to comply with such enrollee requests. In meetings before the legislative committees discussing the Insurance Department's regulation this right of the enrollee was discussed and acknowledged. We thus urge it be codified in the regulation.

THE PLAN'S DECISION. ~~(3) If a plan establishes a time frame for an enrollee to file a second level complaint or grievance, the plan shall allow the enrollee at least 45 days to file the second level complaint or grievance from the date of the enrollee's receipt of notice of the plan's decision.~~ ~~(4)~~**(2)** A health care provider seeking to file a grievance with enrollee consent under ~~§9.703~~ **§9.706** (relating to health care provider initiated grievances) shall have the same time frames in which to file as an enrollee.		
~~§9.704.~~ **§9.703. (c) (2) (III) (H) .(Page 148)** **Internal complaint process** (c) A plan's internal complaint process shall include the following standards: (2) *Second level review.* ~~(ii)~~ (III) ~~The plan shall notify the enrollee in writing of the right to appear before the second level review committee.~~ **The second level review ~~committee~~ shall satisfy the following:** **(H) THE COMMITTEE MAY NOT DISCUSS THE CASE TO BE REVIEWED PRIOR TO THE SECOND LEVEL REVIEW MEETING.**	**Internal complaint process** (c) A plan's internal complaint process shall include the following standards: (2) *Second level review.* ~~(ii)~~ (III) ~~The plan shall notify the enrollee in writing of the right to appear before the second level review committee.~~ **The second level review ~~committee~~ shall satisfy the following:** ~~(H) THE COMMITTEE MAY NOT DISCUSS THE CASE TO BE REVIEWED PRIOR TO THE SECOND LEVEL REVIEW MEETING~~**.**	Paragraph (H) should be removed in its entirety. The recommendation is unsound in two very significant ways – it could prevent the committee members from having necessary information and preparation for the second level review; or it could unnecessarily require the enrollee and the plan to proceed with a second level review hearing which might have otherwise been dispensed with. Reviewers frequently have questions regarding how the initial determination was made and seek to understand the terms of the enrollees contract, etc. Also, there may be times when, upon review of the materials, committee members wish to recommend overturning the initial denial. If committee members are prohibited from discussing the case, they will have to wait until the formal proceeding to do this. These second level reviews are time consuming for enrollees and the plan, costly for the plan, and sometimes represent a travel expense for the enrollee that could otherwise have been avoided.

~~§9.706~~. §9.705.(c) (2) (i) (h) (PAGE 161) ~~Enrollee and provider grievance system~~ **INTERNAL GRIEVANCE PROCESS.** (c) The plan's **INTERNAL** grievance process shall include the following standards: (2) *Second level review.* (i) **UPON RECEIPT OF THE REQUEST FOR A SECOND LEVEL REVIEW, THE PLAN SHALL SEND THE ENROLLEE, THE ENROLLEE'S REPRESENTATIVE, AND THE HEALTH CARE PROVIDER, IF THE HEALTH CARE PROVIDER FILED THE GRIEVANCE WITH ENROLLEE CONSENT, AN EXPLANATION OF THE PROCEDURES TO BE FOLLOWED DURING THE SECOND LEVEL REVIEW. THIS INFORMATION SHALL INCLUDE THE FOLLOWING:** (H) THE COMMITTEE MAY NOT DISCUSS THE CASE TO BE REVIEWED PRIOR TO THE SECOND LEVEL REVIEW MEETING.	~~Enrollee and provider grievance system~~ **INTERNAL GRIEVANCE PROCESS.** (c) The plan's **INTERNAL** grievance process shall include the following standards: (2) *Second level review.* (i) **UPON RECEIPT OF THE REQUEST FOR A SECOND LEVEL REVIEW, THE PLAN SHALL SEND THE ENROLLEE, THE ENROLLEE'S REPRESENTATIVE, AND THE HEALTH CARE PROVIDER, IF THE HEALTH CARE PROVIDER FILED THE GRIEVANCE WITH ENROLLEE CONSENT, AN EXPLANATION OF THE PROCEDURES TO BE FOLLOWED DURING THE SECOND LEVEL REVIEW. THIS INFORMATION SHALL INCLUDE THE FOLLOWING:** ~~(H) THE COMMITTEE MAY NOT DISCUSS THE CASE TO BE REVIEWED PRIOR TO THE SECOND LEVEL REVIEW MEETING~~.	Rationale for deletion of paragraph (H) specified above.
~~§9.706~~. §9.705. (c) (3) (v) (PAGE 166) ~~Enrollee and provider grievance system~~ **INTERNAL GRIEVANCE PROCESS.** (c) The plan's **INTERNAL** grievance process shall include the following standards: (3) *Same or similar specialty.* **(V) FOR PURPOSES OF THIS SECTION, A PRIMARY CARE PROVIDER DOES NOT QUALIFY AS A LICENSED PHYSICIAN, OR AN APPROVED LICENSED PSYCHOLOGIST, IN A SAME OR SIMILAR SPECIALTY, UNLESS THE SERVICE IN QUESTION WAS PROVIDED BY A PRIMARY CARE PROVIDER.**	~~Enrollee and provider grievance system~~ **INTERNAL GRIEVANCE PROCESS.** (c) The plan's **INTERNAL** grievance process shall include the following standards: (3) *Same or similar specialty.* ~~(V) FOR PURPOSES OF THIS SECTION, A PRIMARY CARE PROVIDER DOES NOT QUALIFY AS A LICENSED PHYSICIAN, OR AN APPROVED LICENSED PSYCHOLOGIST, IN A SAME OR SIMILAR SPECIALTY, UNLESS THE SERVICE IN QUESTION WAS PROVIDED BY A PRIMARY CARE PROVIDER.~~	This paragraph goes beyond the intent of Act 68, which provides for review by a same or similar specialist as typically manages the service or condition in question. Many internists are designated as both specialists and PCPs. Furthermore; the appropriateness of many services rendered by specialists (e.g. treatment of hypertension, etc.) can adequately be reviewed by a PCP even though reviewed by a specialist. This limitation, imposed newly here in these regulations, could have the unintended effect of increasing the cost of first level reviews. We strongly urge it be deleted.

§9.722. Plan and health care provider contracts. (a)A plan shall submit the standard form of each type of health care provider contract, INCLUDING ANY DOCUMENT INCORPORATED BY REFERENCE INTO THAT CONTRACT, to the Department for review and approval ~~prior to~~ ~~BEFORE implementation~~ THE DEPARTMENT WILL REVIEW A PROVIDER CONTRACT WITHIN 60 DAYS OF RECIEPT OF THE DOCUMENT. A PLAN SHALL SUBMIT PROVIDER CONTRACTS ENTERED INTO OR RENEWED BEFORE THE EFFECTIVE DATE OF THE REGULATIONS FOR REVIEW AND APPROVAL, BUT APPROVAL BEFORE USE WILL NOT BE REQUIRED FOR THESE CONTRACTS. IF THE DEPARTMENT DOES NOT APPROVE THE CONTRACT WITHIN 60 DAYS, THE PLAN MAY USE THE CONTRACT WITHOUT APPROVAL, HOWEVER, THE PLAN MAY AT A LATER DATE REQUIRE THE PLAN TO CORRECT ANY DEFICIENCIES IDENTIFIED BY THE DEPARTMENT	a) A plan shall submit the standard form of each type of health care provider contract, INCLUDING ANY DOCUMENT INCORPORATED BY REFERENCE INTO THAT CONTRACT, to the Department for review and approval ~~prior to~~ ~~BEFORE implementation~~ THE DEPARTMENT WILL REVIEW A PROVIDER CONTRACT WITHIN ~~60~~ *45* DAYS OF RECIEPT OF THE DOCUMENT. A PLAN SHALL SUBMIT PROVIDER CONTRACTS ENTERED INTO OR RENEWED BEFORE THE EFFECTIVE DATE OF THE REGULATIONS FOR REVIEW AND APPROVAL, BUT APPROVAL BEFORE USE WILL NOT BE REQUIRED FOR THESE CONTRACTS. *ANY REQUIRED CHANGES WILL NOT AFFECT SUCH CONTRACTS UNTIL THEY RENEW.* IF THE DEPARTMENT DOES NOT APPROVE THE CONTRACT WITHIN ~~60~~ *45* DAYS, THE PLAN MAY USE THE CONTRACT WITHOUT APPROVAL, HOWEVER, THE ~~PLAN~~ *DEPARTMENT* MAY AT A LATER DATE REQUIRE THE PLAN TO CORRECT ANY DEFICIENCIES IDENTIFIED BY THE DEPARTMENT	The plans request a file and use period similar to that of the Insurance Department for contracts. If the DOH seeks to maintain the 60-day period, then we request it be consider deemed approved, not file and use. The plans request that changes the DOH determines are required to contracts currently in effect will only be required when those contracts renew. Correction: On use of the term "Plan" should be replaced with "Department" in the last sentence.
§9.722. (e) (7) (Page 187) Plan and health care provider contracts. (e) To be approved by the Department, a STANDARD health care provider contract shall include the following consumer protection provisions: (7) Language requiring that ~~the health care provider give at least 60 days advance written notice to the plan of termination of the provider contract~~ IF THE PLAN AND THE HEALTH CARE PROVIDER AGREE TO INCLUDE A TERMINATION WITHOUT CAUSE PROVISION IN THE CONTRACT, NEITHER PARTY SHALL BE PERMITTED TO TERMINATE THE CONTRACT WITHOUT CAUSE UPON LESS THAN 60 DAYS PRIOR WRITTEN NOTICE.	Plan and health care provider contracts. (e) To be approved by the Department, a STANDARD health care provider contract shall include the following consumer protection provisions: (7) Language requiring that ~~the health care provider give at least 60 days advance written notice to the plan of termination of the provider contract~~ IF THE PLAN AND THE HEALTH CARE PROVIDER AGREE TO INCLUDE A TERMINATION WITHOUT CAUSE PROVISION IN THE CONTRACT, NEITHER PARTY SHALL BE PERMITTED TO TERMINATE THE CONTRACT WITHOUT CAUSE UPON LESS THAN 60 DAYS PRIOR WRITTEN NOTICE ***UNLESS THE PROVIDER IS A THREAT TO PUBLIC HEALTH AND SAFETY AND/OR HAS VIOLATED STATE LAW.***	The plans recommend the additional language to allow for special situations where, once notified of potential threat to enrollees' safety, plans must act to quickly terminate contracts. This includes situations where the provider no longer has a valid license, or no longer has malpractice insurance.

§9.724. (b) (Page 189) ~~HMO~~ PLAN–IDS ~~provider contract~~ CONTRACTS. (b) ~~To avoid the necessity of renegotiation under Section 8(a) of the HMO Act (40 P.S. § 1558(a)), the HMO~~ **THE PLAN** shall provide a copy of the ~~HMO~~-IDS contract **TO THE DEPARTMENT** for review and approval ~~prior to implementation.~~ **AN IDS CONTRACT NOT BASED ON AN APPROVED STANDARD CONTRACT SHALL BE SUBMITTED TO THE DEPARTMENT FOR REVIEW AND APPROVAL. AN IDS CONTRACT SHALL BE REVIEWED BY THE DEPARTMENT IN ACCORDANCE WITH § 9.722(A) (RELATING TO PLAN AND HEALTH CARE PROVIDER CONTRACTS). IF THE IDS CONTRACT IS BASED ON A STANDARD FORM CONTRACT, THE PLAN SHALL PROVIDE THE DEPARTMENT WITH NOTICE OF THE CONTRACT, INCLUDING THE NAME, ADDRESS AND DESCRIPTION OF THE IDS, BEFORE THE EFFECTIVE DATE OF THE CONTRACT.**	§9.724. (b) (Page 189) ~~HMO~~ PLAN–IDS ~~provider contract~~ CONTRACTS. (b) ~~To avoid the necessity of renegotiation under Section 8(a) of the HMO Act (40 P.S. § 1558(a)), the HMO~~ **THE PLAN** shall provide a copy of the ~~HMO~~-IDS contract **TO THE DEPARTMENT** for review and approval ~~prior to implementation.~~ *THE PLAN SHALL SUBMIT CONTRACTS ENTERED INTO OR RENEWED BEFORE THE EFFECTIVE DATE OF THE REGULATIONS FOR REVIEW AND APPROVAL, BUT APPROVAL BEFORE USE WILL NOT BE REQUIRED FOR THESE CONTRACTS. ANY REQUIRED CHANGES WILL NOT AFFECT SUCH CONTRACTS UNTIL THEY RENEW.* **AN IDS CONTRACT NOT BASED ON AN APPROVED STANDARD CONTRACT SHALL BE SUBMITTED TO THE DEPARTMENT FOR REVIEW AND APPROVAL. AN IDS CONTRACT SHALL BE REVIEWED BY THE DEPARTMENT IN ACCORDANCE WITH § 9.722(A) (RELATING TO PLAN AND HEALTH CARE PROVIDER CONTRACTS). IF THE IDS CONTRACT IS BASED ON A STANDARD FORM CONTRACT, THE PLAN SHALL PROVIDE THE DEPARTMENT WITH NOTICE OF THE CONTRACT, INCLUDING THE NAME, ADDRESS AND DESCRIPTION OF THE IDS, BEFORE THE EFFECTIVE DATE OF THE CONTRACT.**	The plans recommend this additional language be added to clarify that contracts in effect will continue until renewal. Required changes from these regulations will only be required as those contracts renew.

§9.741. (c) (Page 195) Applicability. (C) PURSUANT TO SECTION 2151(E) OF THE ACT (40 P.S. §991.2151(E)) A CRE, LICENSED INSURER OR A MANAGED CARE PLAN WITH A CERTIFICATE OF AUTHORITY SHALL COMPLY WITH §§9.749 THROUGH 9.751 OF THIS SUBCHAPTER AND THE STANDARDS AND PROCEDURES OF SECTIONS 2151 AND 2152 OF THE ACT (40 P.S. §§991.2151 AND 991.2152), BUT A LICENSED INSURER OR A MANAGED CARE PLAN WITH A CERTIFICATE OF AUTHORITY SHALL NOT BE REQUIRED TO OBTAIN SEPARATE CERTIFICATION AS A CRE.	§9.741. (c) (Page 195) Applicability. (C) ~~PURSUANT TO SECTION 2151(E) OF THE ACT (40 P.S. §991.2151(E)) A CRE, LICENSED INSURER OR A MANAGED CARE PLAN WITH A CERTIFICATE OF AUTHORITY SHALL COMPLY WITH §§9.749 THROUGH 9.751 OF THIS SUBCHAPTER AND THE STANDARDS AND PROCEDURES OF SECTIONS 2151 AND 2152 OF THE ACT (40 P.S. §§991.2151 AND 991.2152), BUT A LICENSED INSURER OR A MANAGED CARE PLAN WITH A CERTIFICATE OF AUTHORITY SHALL NOT BE REQUIRED TO OBTAIN SEPARATE CERTIFICATION AS A CRE~~.	Delete this paragraph in its entirety, as it refers to new regulation not previously exposed for public comment in the proposed regulation of December 1999. Additionally, its construction is such that it would apply the Act 68 standards of UR for managed care – gatekeeper programs to all programs. This is not the intent of Act 68
§ 9.749. UR SYSTEM DESCRIPTION. (Page 206)	DELETE THIS SECTION IN ITS ENTIRETY.	The section includes new requirements that go beyond the law, not just the intent of Act 68
§ 9.750. UR SYSTEM STANDARDS. (Page 207)	DELETE THIS SECTION IN ITS ENTIRETY.	The section includes new requirements that go beyond the law, not just the intent of Act 68
§9751. TIME FRAMES FOR UR (Page 209)	DELETE THIS SECTION IN ITS ENTIRETY.	The section includes new requirements that go beyond the law, not just the intent of Act 68
§9.761. Provider credentialing. (Page 211) (a) (7) In cases of denial or nonrenewals, notification to health care providers that includes a clear rationale for the decision.	(a) (7) In cases of denial or nonrenewals, notification to health care providers that includes a clear rationale for the decision. *IN CASES OF INITIAL DENIALS TO APPLICANTS, PLANS SHALL NOTIFY PROVIDERS IF THE DENIAL IS BASED ON NETWORK OR BUSINESS DETERMINATIONS, NOT CREDENTIALING ISSUES.*	Plans sometimes receive applications from providers at a time when the network has matured, and new providers are not being added. This was recognized in the prior statement of policy.

§9.761. **Provider credentialing.** **(Page 212)** (b) The plan shall submit its credentialing plan to the Department ~~prior to implementation~~ **FOR APPROVAL.** Changes to the credentialing plan shall also be submitted to the Department ~~prior to~~ **FOR APPROVAL BEFORE** implementation.	(b) The plan shall submit its credentialing plan to the Department ~~prior to implementation~~ **FOR APPROVAL.** Changes to the credentialing plan shall also be submitted to the Department ~~prior to~~ **FOR APPROVAL BEFORE** implementation. *THE DEPARTMENT WILL REVIEW THE CREDENTIALING PLAN WITHIN ~~60~~ 45 DAYS OF RECIEPT OF THE DOCUMENT. IF THE DEPARTMENT DOES NOT APPROVE OR DISAPPROVE THE CREDENTIALING PLAN WITHIN ~~60~~ 45 DAYS, THE PLAN MAY USE THE CREDENTIALING PLAN.*	As in the other sections, there should be a limit on the time period for review. Either a 45-day file and use period, or a 60-day deemed approve period, is suggested. We have provided proposed language that reflects the 45-day file and use approach.
NONE	**New section in Subchapter F – General** **9.607 EFFECTIVE DATE OF REGULATION-** **Plans will comply with the requirements of this regulation within 3 months of its effective date.**	The DOH notes in the PREAMBLE its intent to permit an implementation period. See Pg. 248 : "The Department will provide for a period of transition to allow plans to implement any necessary changes once the regulations are final." Failure to codify this in regulation places plans at risk of challenge or litigation.
NONE	**Add to new language to §§ 9.651, 9.652, 9.671, 9.702, and 9.721.** **The requirements of this section do not apply in the case of benefits or contracts specifically entered into for Medicare HMOs, pursuant to § 1856(b)(3) (B) (i.-iii.) of the Social Security Act.**	The cited section of the SSA specifically provides for federal preemption of state standards related to (i) benefits requirements (including cost-sharing requirements, (ii) requirements relating to the inclusion or treatment of providers, (iii) coverage determinations (including related appeals and grievance processes).

List of Suggested Revisions and Clarifications

Department of Health Managed Care Organization Regulations – Proposed Final 02-28-01

Section Language	Proposed Changes	Rationale
§9.605.(d) (Page 88) Department investigations (d) The Department will have access to medical records of ~~HMO~~ PLAN enrollees for the ~~sole~~ purpose of determining the quality of care, investigating complaints or grievances, enforcement, or other activities relating to ensuring compliance with Article XXI, this chapter or other laws of the Commonwealth.	Department investigations (d) The Department will have access to medical records of ~~HMO~~ PLAN enrollees for the ~~sole~~ purpose of determining the quality of care, investigating complaints or grievances, enforcement, or other activities relating to ensuring compliance with Article XXI, this chapter or other laws of the Commonwealth, ***TO THE EXTENT PERMITTED BY LAW.***	In view of various state and federal confidentiality laws and the expanded access of the Department to medical records under this article, this provision should recognize that certain protections and prohibitions may be envisioned by law.
~~§9.634.~~ §9.633.(1) (Page 98) Location of HMO activities, staff and materials. **(1) The HMO shall make available for review at a location within ~~in~~ this Commonwealth, by the Department or an agent of the Department, the books and records of the corporation and the essential documents as the Department may require, including signed provider contracts, credentialing files, complaint and grievance files, committee meeting (quality assurance and credentialing) minutes and hearing transcriptions. Documents need not be permanently maintained in this Commonwealth but shall be made available within this Commonwealth within ~~48 hours~~ 30 DAYS, UNLESS THE DEPARTMENT DETERMINES FOR MATTERS OF PATIENT SAFETY THE DOCUMENTS MUST BE PROVIDED WITHIN 2 BUSINESS DAYS BUSINESS DAYS.**	Location of HMO activities, staff and materials. **(1) The HMO shall make available for review at a location within ~~in~~ this Commonwealth, by the Department or an agent of the Department, the books and records of the corporation and the essential documents as the Department may require, including signed provider contracts, credentialing files, complaint and grievance files, committee meeting (quality assurance and credentialing) minutes and hearing transcriptions.** *CREDENTIALING FILIES AND CREDENTIALING COMMITTEE MINUTES SHALL BE MADE AVAILABLE FOR REVIEW IN ORDER T0 COMPLY WITH QA OR EQRO STANDARDS ONLY.* **Documents need not be permanently maintained in this Commonwealth but shall be made available within this Commonwealth within ~~48 hours~~ 30 DAYS, UNLESS THE DEPARTMENT DETERMINES FOR MATTERS OF PATIENT SAFETY THE DOCUMENTS MUST BE PROVIDED WITHIN 2 BUSINESS DAYS BUSINESS DAYS.**	Access to credentialing files fall under the PA Peer Review Protection Act as granted by Act 68. Access should be clearly limited to the need to confirm compliance with QA requirements and credentialing standards.

~~§9.635.~~ §9.634. (Page 99) **Delegation of HMO operations.**	**DELETE SECTION IN ITS ENTIRETY**	This section refers to oversight authority of the Insurance Department as reflected in the HMO Act.
~~§9.655.~~§9.654.(c) (Page 106) **HMO external quality assurance assessment.** (c) An HMO may combine the external quality assurance assessment with an accreditation review offered by an ~~external quality review organization~~ **EQRO** acceptable to the Department, if the review adequately incorporates ~~assessment factors required by the Department~~ **INFORMATION REQUIRED BY THE DEPARTMENT TO DETERMINE THE HMO'S COMPLIANCE WITH ACT 68, THE HMO ACT, AND THIS CHAPTER,** and allows for Department staff to actively participate in the external ~~review process~~ **QUALITY ASSURANCE ASSESSMENT.**	**HMO external quality assurance assessment.** (c) An HMO may combine the external quality assurance assessment with an accreditation review offered by an ~~external quality review organization~~ **EQRO** acceptable to the Department, if the ~~review adequately incorporates assessment factors required by the Department~~ **INFORMATION REQUIRED BY THE DEPARTMENT TO DETERMINE THE HMO'S COMPLIANCE WITH ACT 68, THE HMO ACT, AND THIS CHAPTER,** ~~and~~ *PLAN* allows for Department staff to actively participate in the external ~~review process~~ **QUALITY ASSURANCE ASSESSMENT.**	The deleted portion would require EQROs to develop Pennsylvania-specific accreditation reviews. Current NCQA reviews, the only EQRO approved in Pennsylvania, cost plans an average $50,000. Creation of state specific reviews increases the review costs, as well as eliminating national standards. That in turn can limit the ability of employers to properly evaluate and compare health plans based on these standards. We would even recommend that the DOH consider accepting a plan's acceptable EQRO review by a state approved EQRO to serve as a deemer for compliance of the standards.
§ 9.654 (G) (Page 107) **(G) THE DEPARTMENT WILL PUBLISH ANNUALLY IN THE *PENNSYLVANIA BULLETIN* A LIST OF EQROS ACCEPTABLE TO IT FOR THE PURPOSE OF PERFORMING EXTERNAL QUALITY ASSURANCE ASSESSMENTS**	**(G) THE DEPARTMENT WILL PUBLISH ANNUALLY IN THE *PENNSYLVANIA BULLETIN* A LIST OF EQROS ACCEPTABLE TO IT FOR THE PURPOSE OF PERFORMING EXTERNAL QUALITY ASSURANCE ASSESSMENTS** ***THE DEPARTMENT SHALL PROVIDE SUFFICIENT TRANSITION TIME OF AT LEAST SIX MONTHS FOR MANAGED CARE PLANS IF IT DETERMINES TO DELETE AN EQRO FROM ITS LIST OF ACCEPTABLE EQROS.***	Standards differ significantly between and among accreditation bodies such that plans should be given sufficient notice to transition operational processes and documentation that could impact performance reviews.
§9.674.(c) (1) (V) (Page 115) **Quality assurance standards.** (C) IN ADMINISTERING A QUALITY ASSURANCE PLAN, THE PLAN SHALL DO THE FOLLOWING: (1) INCLUDE IN ITS QUALITY ASSURANCE PLAN REGULARLY UPDATED STANDARDS FOR THE FOLLOWING: (V) ACCESS TO ROUTINE, URGENT AND EMERGENT APPOINTMENTS THAT SHALL BE APPROVED BY THE PLAN'S QUALITY ASSURANCE COMMITTEE.... **Section Language**	**Quality assurance standards.** (C) IN ADMINISTERING A QUALITY ASSURANCE PLAN, THE PLAN SHALL DO THE FOLLOWING: (1) INCLUDE IN ITS QUALITY ASSURANCE PLAN REGULARLY UPDATED STANDARDS FOR THE FOLLOWING: **(V) ACCESS TO ROUTINE, URGENT AND EMERGENT ~~APPOINTMENTS~~ *CARE* THAT SHALL BE APPROVED BY THE PLAN'S QUALITY ASSURANCE COMMITTEE....**	The provision also applies to providers that, as defined in the regulations, include medical equipment suppliers, pharmacists, etc. The term "appointments is not always applicable. The term "care" is used in this context in other sections of the regulation and would appear to be more appropriate here.

§9.679.(d) (Page 122) **Access requirements in service areas.** **(D) EXCEPT AS OTHERWISE AUTHORIZED IN THIS SECTION, A PLAN SHALL PROVIDE FOR AT LEAST 90% OF ITS ENROLLEES IN EACH COUNTY IN ITS SERVICE AREA, ACCESS TO COVERED SERVICES THAT ARE WITHIN 20 MILES OR 30 MINUTES TRAVEL FROM AN ENROLLEE'S RESIDENCE OR WORK IN A COUNTY DESIGNATED AS A METROPOLITAN STATISTICAL AREA (MSA) BY THE FEDERAL CENSUS BUREAU, AND WITHIN 45 MILES OR 60 MINUTES TRAVEL FROM AN ENROLLEE'S RESIDENCE OR WORK IN ANY OTHER COUNTY.**	No change proposed. Clarification requested.	The plans are pleased that the Department agrees to include access from work or residence. The plans propose that the NCQA standard for network access and monitoring be adopted as the DOH standard or monitoring such access.
~~§9.704.~~ §9.703.(c) (1) (III) (Page 143) **Internal complaint process.** (c) A plan's internal complaint process shall include the following standards: (1) *First level review.* ~~(ii)~~**(III)**A plan shall **PROVIDE THE ENROLLEE AND THE ENROLLEE'S REPRESENTATIVE ACCESS TO ALL INFORMATION RELATING TO THE MATTER BEING COMPLAINED OF AND SHALL** permit an enrollee to provide written data or other material in support of the complaint. ~~The enrollee may specify the remedy or corrective action being sought.~~ **THE PLAN MAY CHARGE A REASONABLE FEE FOR REPRODUCTION OF DOCUMENTS.**	**Clarification requested.**	Access to all information related to benefits, enrollment, medical policy and procedure is appropriate and available. However, information obtained during the course of investigating the complaint is protected under peer review and cannot be disclosed to the enrollee or their representative. We request the DOH recognize the protections of the Peer Review Protection Act in this regard.

§9.707.(J) (Page 175) **External grievance process.** ~~(k)~~**(J)** The plan shall authorize a health care service and pay a claim determined to be medically necessary and appropriate by the CRE whether or not the plan has appealed the CRE's decision to a court of competent jurisdiction.	**No change requested. Clarification requested, and a request for more monitoring by the DOH.**	The regulations allow for an appeal of a CRE's decision o a court of competent jurisdiction. The plans seek the DOH to review the appropriateness of CRE decisions as well. Short of costly and lengthy court proceedings, plans have no recourse to challenge CRE decisions. For example, in a case involving a request to access a non-participating provider the plan may make a decision based on location and the enrollee's access to in-network providers. The plan is not challenging the medical necessity of the procedure. However, if the CRE makes a decision that the plan must pay because the procedure is medically necessary, is that a reasonable determination? The fact that the enrollees' contract provides for in-network care is a basic component of HMOs. Must plans claims costs and then also court costs to appeal situations that the DOH should be monitoring and reviewing?
§ 9.762.(B) (Page 213) **CREDENTIALING STANDARDS** **(B) A PLAN SHALL VERIFY, AT A MINIMUM, FOR NON-PCPS AND NON-SPECIALISTS, CURRENT LICENSURE AND MALPRACTICE COVERAGE, TO THE EXTENT SUCH LICENSURE AND COVERAGE IS REQUIRED BY STATE OR FEDERAL LAW.**	**DELETE SECTION IN ITS ENTIRETY**	This would require plans to credential all non-PCPs and non-specialists, requiring proof of licensure and malpractice insurance. Current standards of national accrediting bodies do not require this of allied health professionals. This would require credentialing of every nurse, pharmacist, therapist on staff at every hospital and SNF. This would place a significant burden on plans, allied health professionals and health care facilities. Since facilities already credential their staff, this requirement would create an administrative paperwork nightmare that provides no additional benefits. This section should thus be deleted.

§ 9.763. (Page 214) **NON-PHYSICIAN PROVIDERS AT FACILITY, AGENCY OR ORGANIZATIONS.** **A PLAN IS NOT REQUIRED TO CREDENTIAL A NON-PHYSICIAN PROVIDER WHO PRACTICES AS AN EMPLOYEE OR INDEPENDENT CONTRACTOR OF A PLAN-CONTRACTED FACILITY, AGENCY OR ORGANIZATION IF THE PLAN VERIFIES THAT THE FACILITY, AGENCY OR ORGANIZATION CONDUCTS CREDENTIALING THAT MEETS THE STANDARDS OF § 9.762 (RELATING TO CREDENTIALING STANDARDS).**	**DELETE THIS SECTION IN ITS ENTIRETY.**	For reasons stated above. Although this section properly exempts certain non-physician providers from credentialing, it would require plans to audit the credentialing processes of facilities, agencies and organizations that do credential these non-physicians. Where applicable, plans generally require facilities to be accredited by JACHO, but do not perform an independent assessment. While the DOH may want to oversee the credentialing process of such entities in terms of compliance with the proposed regulations, it is beyond the scope of Act 68, and should not be imposed upon the plans in the absence of the DOHs own authority to conduct such assessments.

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

Carolyn F. Scanlan
President and Chief Executive Officer

Original: 2079

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.

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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

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

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FAX TRANSMISSION

(6 page(s), including cover sheet

TO: John McKinley

FAX: 783-2664

FROM: Carolyn J. Scanlan

DATE: 3-29-01

SUBJECT: Act 68

MESSAGE:

Original: 2079

Moses Taylor Hospital
700 Quincy Avenue, Scranton, PA 18510-1798
(570) 340-2100

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 Moses Taylor Health Care System in Scranton, Pennsylvania, I am supporting the adoption of the Department of Health Act 68 Regulations as the first step in providing health plan accountability. I believe it is critical that the Independent Regulatory Review Commission and the chairs of the standing legislative committees understand the crucial need for fair and responsible utilization review standards by our nation's health insurers.

The Moses Taylor Health Care System joins the Pennsylvania Medical Society, other provider groups and many representatives of consumer groups in endorsing the regulations. Effective implementation of these regulations can benefit patients by fostering greater coordination and cooperation between health plans and health care providers in caring for patients. This comes at a critical time for Pennsylvania hospitals and health systems, when many are losing money on patient care. It would be inappropriate to delay the implementation of regulations that establish fair and responsible oversight of managed care plans.

I acknowledge the efforts of the Department of Health to establish fair and responsible standards that hold licensed insurers and managed care plans accountable for utilization review decisions. I commend the Department for balancing the interests of patients, health care providers and health plans in developing these standards. More importantly, I appreciate that providers will have the opportunity to serve as advocates for our patients through these regulations.

Sincerely,

Harold E. Anderson
President and CEO

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 insurors 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

FAX TRANSMISSION

J.C. BLAIR MEMORIAL HOSPITAL
WARM SPRINGS AVENUE
HUNTINGDON, PENNSYLVANIA 16652
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Rec'd 3/19/01 4:26 pm

To: John R. McGinley, Jr Chairman Date: 3-19-01

Fax #: 717-783-2664 Pages: 2, including this cover sheet.

From: Richard E. D'Alberto, President/CEO

Subject:

COMMENTS:

Original: 2079

Waynesboro Hospital SM
an affiliate of Summit Health

RECEIVED
2001 MAR 19 AM 10: 12
REVIEW COMMISSION

THE PEAK OF GOOD HEALTH

March 15, 2001

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

Dear Sir:

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

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

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

Sincerely,

Rita C. Brizzee
Vice-President, Chief Operating Officer

Original: 2079

Pennsylvania Academy of
FAMILY PHYSICIANS

April 3, 2001

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

Dear Chairman McGinley:

On behalf of the over 4,800 members of the Pennsylvania Academy of Family Physicians, I am writing in support of the final proposed rulemaking to implement Act 68 of 1998, the Healthcare Accountability and Protection Act. However, the Academy has concerns related to the changes made by the Department of Health via the tolling period.

Throughout the regulatory process, the Academy and all other stakeholder organizations have been given many opportunities to express their respective opinions. However, it is very disappointing and discouraging to our physician members that the tolling process was used to make substantial changes to the regulations without any period for public input. Nevertheless, our members recognize that our patients need the protections that would be implemented through these regulations. The needs of patients outweigh our concern about the tolling process and our belief that the final draft could be improved.

The Academy believes that under at least two of the sectional revisions made through the tolling process, the regulations have changed substantially to the detriment of physicians and our patients. Specifically, we are disappointed with the omission of sections §9.741(c) and §9.742(c) on Utilization Review, which describe verbatim the language contained in Act 68 of 1998 (40 P.S.§991.2152(e)). Omission of these two sections will most likely lead to an ambiguity regarding the intent of the language contained in the Act.

Additionally, the Academy is concerned with the deletion of §9.681(a)(3) of the requirement to list the physician with whom a CRNP has a collaborative relationship. One of the primary purposes of Act 68 was to provide disclosure to Pennsylvania patients. The law requires a collaborative agreement between a physician and a CRNP who work together to provide quality patient care. Elimination of the physician listing under this section omits an important consumer protection and does not benefit patients.

Again, despite our concerns, the Academy respectfully requests that the Independent Regulatory Review Commission approve the final rulemaking on Act 68 of 1998.

Sincerely,

Kevin P. Shaffer, MD
President

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CC: Honorable Harold F. Mowery, Chair, Senate Public Health and Welfare Committee
Honorable Allyson Y. Schwartz, Minority Chair, Senate Public Health & Welfare Committee
Honorable Dennis M. O'Brien, Chair, House Health and Human Services Committee
Honorable Frank L. Oliver, Minority Chair, House Health and Human Services Committee
Honorable Nicholas A. Micozzie, Chair, House Insurance Committee
Honorable Anthony M. DeLuca, Minority Chair, House Insurance Committee
Honorable Robert S. Zimmerman, Jr., Secretary of Health, PA Department of Health

EMBARGOED MATERIAL

Original: 2079

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April 4, 2001

Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Re: Final Act 68 Regulations

Dear Sir or Madam:

I would like to take this opportunity to comment on Section 9.706 (b) of the Department of Health's Final Act 68 regulations. From the preamble, it appears that IRRC provided some comments on this particular provision to the DOH, therefore I find it appropriate to submit a comment on the provision to you in advance of the hearing on this final regulatory package.

Keystone Health Plan Central strongly advises against approving the first sentence of subsection (b) to §9.706, which permits a provider to obtain written consent from an enrollee *at the time of treatment*. Although the subsection goes on to state that a provider may not require an enrollee to authorize consent as a condition of treatment, this in no way adequately protects the member's right to file a grievance on their own behalf. Subsection (e) to §9.706 does not require that the fact that care may not be conditioned by this consent even be explained in writing on the consent form. The great majority of members will no doubt feel that this is one of a series of documents they sign when seeking care (similar to consent to treatment forms upon admission to a hospital) and required by the provider as a condition precedent to their receiving medical care.

It is inconceivable that a member should be asked to sign away their rights to file a grievance on their own behalf prior to any denial on the part of the plan. The member is basically being asked to assign a right that has not yet accrued and of which they have no information on.

Although subsection (e)(6) permits a member to revoke their assignment of rights to the provider in writing, the member will not know if the provider has filed the grievance and will not have any knowledge as to whether the provider has done a satisfactory job of

arguing its appeal until such time as the provider drops the appeal prior to CRE or a CRE has ruled. In the former situation, the member may not be billed but that is not the case in the latter situation. The provider may drop the appeal after the CRE ruling and subsequently bill the member if they lose. The member may then be forced to appeal to a court of competent jurisdiction and be stuck with the record below being that which was argued by the provider. The member could very well wind up paying for services in the end. These amounts can be substantial and the member has no idea at the time of treatment is received of the consequences of assigning the right to grieve or even the cost of care.

Providers which use up-front consents to grieve where members will not be financially responsible for denied services are using them in order to access the Act 68 external review process rather than utilize provider appeal mechanisms available through their contracts with plans.

The preamble to the final regulations at page 354 notes that DOH did indeed receive comments against blanket up-front consents but considered the fact that (1) some providers have populations that are difficult to access at the time a grievance would arise and (2) that enrollees who may not be responsible for the service will have no incentive to sign a consent for a provider to grieve. I must respectfully state that these are not legitimate reasons to permit the provider to obtain an up-front consent at the time treatment is sought. Why should all members be less than fully informed at the time of supplying consent simply because some providers may potentially find it difficult to contact a few members down the road? Further, the member may very well choose not to grant the provider the right to grieve and a legitimate reason for making such a decision could be the fact that the member is not financially responsible. This is very much a relevant consideration. Members should absolutely be aware not only of an actual denial but the cost of the care at issue and whether they are financially responsible for that care, prior to making an informed decision as to whether to waive their right to file a grievance themselves and sign over that right to the provider. Otherwise there is simply no knowing waiver or consent.

I'd like to point out that in issuing it's original questions and answers to Act 68 after the November of 1998 public meeting, the DOH specifically considered this issue and in a well-reasoned answer determined that it would not be appropriate for providers to obtain up-front consents. The question and answer is as follows:

31. **Q: Can providers get subscriber consent up front, from all patients who agree? (Will be much less cumbersome and facilitate appeals for subscriber).**

> A: ***The Departments would discourage providers from obtaining up front general consent from all managed care patients. The appropriate time to make a decision regarding complaint and grievance filing is when an incident occurs that results in consumer dissatisfaction. An enrollee may not fully understand the ramification of giving consent to a provider to file a grievance. After a claim denial is made on the basis of medical necessity, the enrollee may prefer to file the grievance himself/herself. (Emphasis added).***

The original thinking of the Department on this issue was truly in the best interests of the member. I urge IRRC to request a change to §9.706(b) and ask that DOH delete the first sentence of that subsection which permits a provider to obtain a consent to grieve from the member at the time of treatment.

Respectfully,

Laurie L. McGowan

Laurie L. McGowan
Associate Counsel

Hoffman, Stephen F.

From: Martin, Gail [Gail.Martin@khpc.com]
Sent: Wednesday, April 04, 2001 4:15 PM
To: 'irrc@irrc.state.pa.us'
Cc: McGowan, Laurie
Subject: URGENT - Comments on Act 68 Final Regs
Importance: High

Please accept the following comments on behalf of Keystone Health Plan Central.

<<IRRC Comments - Act 68 Final1.doc>>

MANAGED CARE ASSOCIATION OF PENNSYLVANIA

240 North Third Street
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(717) 238-2600
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email: info@managedcarepa.org
website: www.managedcarepa.org

Original: 2079

April 3, 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

Dear Mr. Nyce:

Thank you for the opportunity to provide an update on the comments we previously submitted to the Independent Regulatory Review Commission (IRRC) on March 20, 2001. As you know, I am writing on behalf of the Managed Care Association of Pennsylvania (MCAP), an organization representing the interest of several managed care plans across the Commonwealth. Our member plans provide health insurance coverage for more than 1.5 million people in Pennsylvania who are enrolled in commercial as well as Medical Assistance managed care plans.

We are pleased with, and most appreciative of, the efforts of the Pennsylvania Department of Health to address the issues raised by the plans as well as the standing committees of the General Assembly. However, there are still areas of concern to managed care plans which we feel must be addressed. These include:

#1 – COORDINATION WITH DOI – We were pleased to see DOH's commitment to working with DOI pursuant to the Administrative Code of 1929 as there are still areas that appear to be in conflict. Examples include the sections pertaining to Direct Access for Obstetrical and Gynecological Care as well as Enrollee Rights as they pertain to conversion policies.

#2 – COORDINATION WITH DPW – Managed care plans participating in Medical Assistance are regulated like other plans, by DOI and DOH. However, they must also adhere to federal regulations as well as regulations or requirements of DPW. While DOH has taken the position that DPW is a "purchaser of services", similar to a employer group purchasing commercial coverage, the fact of the matter is that "purchasers of services" do not have the authority to sanction plans as DPW does. NOTE: We are not asking DOH to abdicate their responsibilities regarding these plans. However, we are asking that they work with DPW in order to ensure that plans are not having to do "double" work which only takes resources that would be better spent on their enrollees.

#3 – PERMITTING PROVIDERS TO OBTAIN AN ENROLLEE'S BLANKET CONSENT TO PURSUE A GRIEVANCE AT THE TIME OF TREATMENT WILL TURN THE GRIEVANCE PROCESS INTO A VENUE FOR BILLING DISPUTES This will turn into another form for members to sign when making an office visit. Some enrollees, regardless of the disclaimer that signing the consent form is not a condition for treatment, will feel intimidated into signing it. Such a form should be employed only in the case of an adverse decision.

#4 – SECTION 9.676 ON ENROLLEE RIGHTS REFLECTS NCQA'S REQUIREMENTS. However, there are 7 elements which are not included in the DOH regulation. We are requesting clarification to be provided as to whether the additional elements are to be required.

#5 – SECTION 9.684 ON CONTINUITY OF CARE PROHIBITS PLANS FROM REQUIRING NONPARTICIPATING PROVIDERS TO UNDERGO "FULL CREDENTIALING". There is no definition or criteria included pertaining to this term. We are requesting clarification as to what will be acceptable to DOH for credentialing nonparticipating providers.

Please be advised that the issues raised by MCAP pertain to operations, not concepts. There is a great deal in the regulation which provides protection for enrollees and should be implemented.

We are looking forward to working with DOH on resolving these issues. Please contact me at 238-2600 if you have any questions.

Sincerely,

Dolores M. Hodgkiss

Dolores M. Hodgkiss
Executive Director

Pennsylvania Psychiatric Society

The Pennsylvania District Branch of the American Psychiatric Association

ORIGINAL:: 2079

Aril 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.

Executive Director
Gwen Yackee Lehman
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17105-8820

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www.pepsych.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

PENNSYLVANIA PSYCHIATRIC SOCIETY

A district branch of the American Psychiatric Association

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Harrisburg, PA 17105-8820
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DATE 4/2/01

FROM Steven Lehman

PLEASE TRANSMIT THE FOLLOWING PAGES TO:

NAME Robert Nyce; John McGinley

COMPANY IRRC

TOTAL NUMBER OF PAGES 3 (including cover sheet)

FAX NUMBER 783-2664

NOTE: Comments on Act 68 regulations

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

Original: 2079

Pennsylvania MEDICAL SOCIETY®

April 2, 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 on behalf of the Pennsylvania Medical Society to support approval of the Department of Health's proposed final form regulations implementing the provisions of the Quality Health Care Accountability and Protection Act (Act 68 of 1998) Managed Care Organizations. I understand that these will be considered by the Independent Regulatory Review Commission (IRRC) on April 5.

The support for these regulations does not come easy. The Society strongly objects to the fact that during the tolling process substantial changes were made to the content and effect of the regulations in response to pressures applied by opponents of the regulations. Additionally, the Society is concerned that its comments over the issues of "medical necessity," the complaint and grievance process, and the composition and publication of provider networks were not addressed.

The implementation of Act 68 through these regulations is necessary in order to prevent further deterioration of the goals and objectives of the Act and delay of the final implementation of its provisions. It's for these reasons that the Medical Society supports approval of the regulations before IRRC.

Sincerely,

Carol E. Rose

Carol E. Rose, MD
President

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Cc: The Honorable Harold F. Mowery Jr, Chair, Senate Public Health & Welfare Committee
The Honorable Allyson Y. Schwartz, Minority Chair, Senate Public Health & Welfare Committee
The Honorable Dennis M. O'Brien, Chair, House Health & Human Services Committee
The Honorable Frank L. Oliver, Minority Chair, House Health & Human Services Committee
The Honorable Nicholas A. Micozzie, Chair, House Insurance Committee
The Honorable Anthony M. DeLuca, Minority Chair, House Insurance Committee
Robert S. Zimmerman, Secretary, Pennsylvania Department of Health

DNM/doc/cor/McGinley033001

Original: 2079

The Insurance Federation of Pennsylvania, Inc.

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

April 2, 2001

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

Re: Health Department final-form managed care regulation

Dear Chairman McGinley:

On behalf of our member companies and those of our national health insurance counterpart, the Health Insurance Association of America, this is to recommend that the Independent Regulatory Review Commission disapprove 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.

For all the changes the Health Department has made to this regulation and its preamble, it still fails to comply with the approval criteria set forth in the Regulatory Review Act. Key components are without statutory authority, are inconsistent with the intent of the General Assembly or are not in the public interest, particularly as measured by their clarity, feasibility and reasonableness.

We detailed our objections in our March 7 and March 12 testimony to the House and Senate standing committees, along with the section-by-section analysis we supplied to those committees. Copies of all that are attached and incorporated herein.

The Health Department's subsequent revisions failed, with isolated exceptions, to address those objections, or addressed them in ways that only perpetuate the underlying problems, so the testimony and analysis still stand.

The following outlines the major areas in which the regulation falls short of the criteria in the Regulatory Review Act. We offer these as illustrations of the problems with the regulation, not just as priorities among the objections listed in the attached testimony and section-by-section analysis. All of those objections are valid ones: The test under the Regulatory Review Act is whether each of a regulation's provisions satisfies the act's requirements, not whether only the most important of the provisions does.

1. Portions of the regulation lack statutory authority.

a. The regulation's provision for prior approval of certain managed care plan contracts is without statutory authority.

Sections 9.675 and 9.722 give the Health Department the power of prior approval over certain contracts between managed care plans and others providing medical management and providers generally. In the latest version of the regulation, the Department gives itself 45 days to act on these contracts. If it takes no action during that time, the contract will not be deemed approved - but the plan may use it and "it shall be presumed to meet the requirements of all applicable laws." (The Health Department should explain how that differs from a contract being deemed approved.)

To quote from Senator Harold Mowery's March 19 letter to Secretary Robert Zimmerman: "Prior approval authority for the Department of Health was not implicitly or explicitly granted in the Act. There are considerable checks on insurers if provisions are included in their respective contracts that violate the Act."

The General Assembly is clearly aware of its power to subject various insurance contracts and rates to a regulator's prior approval: The insurance laws, including the Insurance Company

Law of which Act 68 became one article, are full of statutes that do this, with the rules varying depending on the type of insurance. These laws have not become "terms of art" that are applied to areas of insurance beyond those covered within the laws. To the contrary, the prior approval laws are strictly construed on all sides, and all sides have recognized that any changes must be done through legislation rather than regulatory fiat - witness recent acts revising the statutorily-set filing requirements for health and commercial property/casualty filings.

Despite - or because of - the General Assembly's awareness of its power to subject insurance contracts to prior approval, it made no provision for this in enacting Act 68. The IRRC should follow the general rule of statutory construction: Where the General Assembly expressly covers a topic (here, regulatory prior approval) in one statute and does not do so in another, it is presumed not to extend the topic to the other statute.

Further, there are no regulations asserting this power of prior approval of insurer contracts absent express legislative authority, or at least none promulgated since the enactment of the IRRC and its own requirement of legislative review of any regulation. Allowing the Health Department to do so here would truly be an unprecedented expansion of regulatory power.

The Health Department believes it will be better able to ensure quality care if it has the power of prior approval. That argument is one to be made to the General Assembly for a statute (and we note that at least one chamber - the Senate - has expressly stated it did not intend this power here). It is also of questionable merit, or at least overkill: The contracts covered here are those with sophisticated parties, not potentially overwhelmed consumers, and the Health Department always has the power of ongoing audits and reviews to ensure compliance with the laws it enforces.

b. The regulation's enforcement of other laws already subject to the Insurance Department's enforcement is without statutory authority.

This regulation professes to implement only Act 68 and the HMO and PPO Acts. Section 9.676(b) and (c), however, gives the Health Department the power to enforce - albeit only against HMOs, not all managed care plans - certain rules that are already covered in other laws and are, under those laws, left to the Insurance Department's jurisdiction.

The laws are those of Health Insurance Portability and Accountability Act and the conversion rights in Article VI of the Insurance Company Law. Some commentators have criticized the Federation's opposition here, noting that conversion rights are not part of HIPAA; true - but conversion rights are still part of the Insurance Company Law, 40 P.S. Section 756.2(d), and their enforcement is still done solely by the Insurance Department under that law, 40 P.S. Section 763.

The rights set forth in Section 9.676(b) and (c) of this regulation do, therefore, have statutory authority - but the General Assembly has given the authority to enforce these rights to the Insurance Department, not the Health Department. An agency is not allowed regulatory enforcement over an area the General Assembly has, by statute, expressly left to another agency.

2. Portions of the regulation are inconsistent with the intent of the General Assembly.

Act 68 left to the regulatory oversight of both the Insurance and Health Departments its provisions on emergency services and continuity of care, and large portions of its provisions on complaints.

With one notable exception, this regulation does not provide for meaningful joint regulation of these shared powers with the Insurance Department. Instead, it allows for separate oversight of these sections (so, it could be argued, does the Insurance Department's regulation - but it was promulgated before the Health Department introduced this regulation).

The General Assembly intended that the shared functions in Act 68 be truly shared. As Senator Mowery stated in his March 19 letter: "The Department of Health and the Department of Insurance should work collaboratively when dealing with issues of continuity of care, complaints and grievances and emergency services... It was envisioned that the departments would work together to determine coverage and designation of complaints and grievances."

The Health Department itself acknowledges this is a general legislative requirement for all agencies and regulations. It observes in its revised preamble that this coordination is expressly required by Section 501 of the Administrative Code, 71 P.S. Section 181, which states that agencies "shall devise a practical and working basis for cooperation and coordination of work."

This regulation falls far short of the joint regulation intended by the General Assembly in Act 68 and expressly required by the Administrative Code. It offers only the vague promise in a recent revision to its preamble that "both agencies are currently, and will continue to, work together to ensure an effective and efficient application of (Act 68) and its implementing regulations."

This is insufficient. Nothing in the text of the regulation assures any cooperation. Further, the preamble itself offers no detail or stability on the "practical and working basis" called for in the Administrative Code.

The need for real and lasting detail within the regulation itself, not just vague assurances in the preamble, is particularly important with respect to emergency services, continuity of care and complaints. The Health Department is asserting separate regulatory power over areas already covered in the Insurance Department's regulation. The cooperation called for in Section 501 of the Administrative Code is, in part, intended by that section to be for "eliminating, duplicating and overlapping functions." This regulation actually creates, not eliminates, that duplication and overlap with the Insurance Department's regulation of these same areas. That is not necessarily wrong - but it heightens the

need for detailed provisions within the text of the regulation itself to assure the required cooperation and coordination.

The Health Department contends that such detail is not needed within this regulation. It contends that Section 501 of the Administrative Code and its assurances in its preamble of working together with the Insurance Department are enough, and that detailed provisions in the regulation itself would be excessive and impractical.

The short answer to this is to point to Section 9.704(e) of this regulation, where the Department expressly states that it and the Insurance Department will determine the appropriate agency for reviewing complaint appeals. That detail is appropriate, given that both agencies have the power to be involved in this area. It is equally appropriate - and necessary - in the other areas where both agencies are involved.

3. Portions of the regulation are not in the public interest, as they lack the clarity, feasibility and reasonableness necessary for compliance.

Sections 9.702 through 9.706 of the regulation, implementing the complaint and grievance provisions of Act 68, establish requisites that make compliance with the act impossible, or at least impractical - either because they conflict with the act or lack clarity, feasibility or reasonableness.

The primary illustration is with respect to the deadlines Act 68 imposes on managed care plans to answer first and second tier internal complaints and grievances. The deadlines in the act are absolute: Managed care plans have 30 days to answer at the first tier, and 45 days to answer at the second tier. Again, Senator Mowery's March 19 letter is instructive: "Nothing in the regulations should obstruct the statutory requirement that grievances and complaints be resolved in 30 and 45 days."

The regulation, however, does precisely that. First, it invites either the plan or the enrollee to question to either the Insurance or Health Departments (well, just the Health

Department if it is an enrollee) whether a matter is a complaint or a grievance, at least at the first tier of review. What happens if the question is submitted late in the passing of the 30 day clock? What happens if either department answers late in the passing of that clock (or after it has passed), or if it wants more information?

Second, the regulation requires, at both first and second tier reviews, that a managed care plan give the enrollee access to all material before it, with an opportunity to respond (and, at a second tier review, the opportunity to come to a hearing). What happens if the enrollee responds late in the passing of the 30 and 45 day clocks, or if his response is to ask for help in reviewing the information?

The Health Department's only answer is its recent revision to its preamble, stating "the Department will not impose a penalty if the plan refuses to agree to an extension of time (presumably requested by the enrollee - or maybe by a department reviewing the classification - who knows?) and completes the review within the time period permitted in the statute." The preamble also allows the plan and the enrollee to jointly agree to ignore the statutory deadlines - showing that the Department, if not the General Assembly, does not regard the deadlines as absolute.

The deadlines are, however, absolute. Statutory deadlines cannot be altered - not by regulators, or by private parties, whether they be managed care plans, enrollees or providers.

Further, the Health Department's assertion in the preamble that it will not penalize plans that insist on abiding by the statutory deadlines only creates confusion and conflict with the language in the regulation itself. The regulation allows all sorts of questions and requests to be made while the clock is running. It also prohibits plans from having "administrative requirements, time frames or tactics to directly or indirectly discourage the enrollee or health care provider from, or disadvantage the enrollee or health care provider in utilizing the procedures (Section 9.702(a)(2))."

What happens when a plan refuses to budge from a deadline? Will - can - the Health Department require it to do so, even

if it cannot penalize it? How will the Health Department respond to the enrollee who claims he was not given adequate time (or at least not more than 30 days) to question a classification to the Department, await its response, and then respond to whatever information he has been given? Some downplay these questions as fanciful hypotheticals - but complaints and grievances are, at least on occasion, adversarial, and these types of arguments will inevitably arise given the ambiguity in the regulation.

As noted at the outset, these are illustrations - key ones, but only illustrations - of this regulation's failure to comply with the criteria of the Regulatory Review Act. They and the other areas addressed in the attached testimony and analysis must be addressed before this regulation should be approved.

A final comment: Throughout the past month of legislative hearings on this regulation, many legislators and members of the public stated that it is long overdue; they also noted the considerable improvements the Health Department has made to this regulation over the past few months. We agree on both accounts.

Neither of these factors, however, is part of the criteria by which a regulation is to be judged under the Regulatory Review Act. The simple truth is, despite the wait and despite the improvements, this regulation still falls short of that criteria. That is why we recommend the IRRC disapprove it.

Sincerely,

Sam Marshall

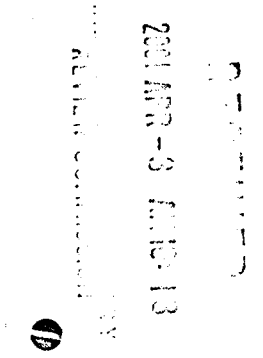
Samuel R. Marshall

C: Honorable Robert S. Zimmerman, Jr.
Secretary, Department of Health

THE INSURANCE FEDERATION OF PENNSYLVANIA, INC.

Public Testimony

Prepared for the



The House Insurance Committee

and

The House Health and Human Service Committee

on

Heath Department Managed Care Regulations

March 7, 2001

The Insurance Federation of Pennsylvania, Inc.
1600 Market Street, Suite 1520
Philadelphia, PA 19103
215-665-0500

GOOD MORNING AND THANK YOU FOR THE OPPORTUNITY TO BE HERE. I AM SAM MARSHALL, PRESIDENT OF THE INSURANCE FEDERATION OF PENNSYLVANIA. THE FEDERATION IS A NON-PROFIT TRADE ASSOCIATION REPRESENTING INSURERS OF ALL SHAPES AND SIZES DOING BUSINESS IN PENNSYLVANIA. AMONG OUR MEMBERS ARE A NUMBER OF MANAGED CARE INSURERS, RANGING FROM LARGE, MULTI-STATE ONES TO SMALLER, MORE REGIONAL AND LOCAL ONES.

I AM HERE TODAY TO RECOMMEND YOUR DISAPPROVAL OF THE HEALTH DEPARTMENT'S FINAL FORM REGULATION IMPLEMENTING ACT 68 AND REVISING EXISTING REGULATIONS OF THE HMO AND PPO ACTS. THE REGULATION FAILS TO MEET THE TWO CENTRAL CONSIDERATIONS OF A FINAL FORM REGULATION UNDER THE REGULATORY REVIEW ACT: IN SEVERAL KEY AREAS, IT GOES WELL BEYOND THE AUTHORITY GIVEN TO THE HEALTH DEPARTMENT UNDER THOSE ACTS, AND IT IS EITHER UNCLEAR OR UNREASONABLE.

THOSE ARE STRONG WORDS, SO I WANT TO PUT THEM IN CONTEXT AT THE OUTSET. FIRST, WE RECOGNIZE THE DIFFICULT TASK THE HEALTH DEPARTMENT HAS UNDERTAKEN IN THIS REGULATION. PROPERLY MANAGING MANAGED CARE IS A TOUGH TASK. IT REQUIRES THE BALANCING OF SEEMINGLY UNBALANCEABLE BUT LEGITIMATE INTERESTS - THOSE OF PATIENTS, PROVIDERS, EMPLOYERS, CONSUMERS AND INSURERS.

OF COURSE, THAT CHALLENGE HOLDS TRUE FOR THE GENERAL ASSEMBLY AS MUCH AS FOR THE REGULATOR, AS ANYONE WHO REMEMBERS THE SPIRITED DEBATES THAT LED TO ACT 68 WILL ATTEST. IT ALSO HOLDS TRUE AMONG REGULATORS, AS ANYONE WHO REMEMBERS THE SPIRITED DEBATES THAT LED TO THE INSURANCE DEPARTMENT'S REGULATION OF ACT 68 WILL ATTEST. I POINT OUT THE DIFFICULTIES THE GENERAL ASSEMBLY AND THE INSURANCE DEPARTMENT FACED NOT TO UNDERESTIMATE THE CHALLENGE THE HEALTH DEPARTMENT HAS UNDERTAKEN HERE - BUT TO CITE EVIDENCE THAT THOSE SEEMINGLY UNBALANCEABLE INTERESTS CAN BE BALANCED.

SECOND, WE APPRECIATE THE CHANGES THE HEALTH DEPARTMENT HAS MADE TO THIS REGULATION SINCE IT WAS FIRST PROPOSED A YEAR AGO, AND SINCE IT WAS FIRST UNVEILED IN FINAL FORM LAST NOVEMBER. FRANKLY, WE SUPPORTED SOME OF THE CHANGES AND OPPOSED OTHERS - BUT WE APPRECIATE THAT ALL OF THEM WERE MADE TO RESPOND TO CONCERNS THAT THE ORIGINAL REGULATION WENT WELL PAST THE UNDERLYING ACTS AND THAT IT WAS INCAPABLE OF BEING FOLLOWED AND UNDERSTOOD BY ALL AFFECTED PARTIES.

THIRD, WE ARE NOT OPPOSING THE REGULATION BECAUSE WE WANT INSURERS' INTERESTS ADDRESSED AT THE EXPENSE OF CONSUMERS.

WE OFTEN HEAR THAT - WELL, WE'RE TRYING TO BALANCE YOUR NEEDS WITH THOSE OF CONSUMERS. AS I SAID, THAT BALANCING IS A TOUGH TASK, ONE I BELIEVE WAS ACHIEVED WITH THE ENACTMENT OF ACT 68 AND WITH THE PROMULGATION OF THE INSURANCE DEPARTMENT'S REGULATION.

I ALSO THINK THE HEALTH DEPARTMENT HAS, FOR THE MOST PART, ACHIEVED THAT BALANCE HERE. OUR OBJECTIONS ARE NOT IN AREAS THAT PIT US AGAINST SOME GENERAL, UNIFIED CONSUMER INTEREST. THEY ARE IN AREAS THAT PIT US AGAINST SOME REGULATORY REQUIREMENTS THAT EITHER ARE UNSUPPORTED BY LEGISLATION OR ARE UNDULY VAGUE, BURDENSOME OR OBTUSE. I KNOW IT IS EASY TO PORTRAY ANYTHING WE DON'T LIKE AS INHERENTLY PRO-CONSUMER - EASY BUT INACCURATE AND ULTIMATLEY INEFFECTIVE AND INEFFICIENT FOR CONSUMERS AS WELL AS FOR THOSE OF US WHO INSURE THEM.

FOURTH, OUR OBJECTIONS ARE MORE MECHANICAL THAN PHILOSOPHICAL. YES, OUR OBJECTIONS ARE MAJOR ONES - A WELL-DESIGNED MACHINE DOES NOT WORK UNLESS THE MECHANICS OF IT DO, TOO. BUT THEY CAN BE ADDRESSED WITHOUT CHANGING THE DESIGN AND THE PURPOSE OF ACT 68 AND THE HMO AND PPO ACTS, OR OF THIS REGULATION - THE ESTABLISHMENT OF CLEAR AND FAIR RULES THAT ENSURE QUALITY AND EFFICIENCY IN MANAGED CARE.

THAT'S A RATHER LONG INTRODUCTION - BUT THIS IS A RATHER LONG AND IMPORTANT REGULATION. AS TO OUR OBJECTIONS: TODAY, I WANT TO ADDRESS THEM IN A GENERAL WAY; WE ARE ALSO SUBMITTING A SECTION-BY-SECTION LIST OF THEM FOR YOUR REVIEW.

1. **THE REGULATION FAILS TO COORDINATE REQUIREMENTS AND ENFORCEMENT WITH AREAS ALREADY REGULATED UNDER THE SAME TERMS BY THE INSURANCE DEPARTMENT.**

ACT 68, AS WELL AS THE HMO AND PPO ACTS, CALLS FOR REGULATION OF MANAGED CARE PLANS BY BOTH THE INSURANCE AND HEALTH DEPARTMENTS. THAT JOINT REGULATION MAKES SENSE UNDER THE CURRENT STRUCTURE OF THOSE DEPARTMENTS - ALTHOUGH I DO THINK WHETHER THAT REGULATORY STRUCTURE ITSELF MAKES SENSE WOULD BE A GOOD TOPIC FOR ANOTHER DAY.

THE PROBLEM WITH THIS REGULATION IS THAT, IN A NUMBER OF KEY AREAS, IT DOES NOT PROVIDE FOR JOINT REGULATION BETWEEN THE INSURANCE AND HEALTH DEPARTMENTS - IT PROVIDES FOR SEPARATE, UNCOORDINATED REGULATION OF DUPLICATE REQUIREMENTS BY THOSE AGENCIES.

SOME EXAMPLES:

LET'S START WITH THE MOST BASIC ONE - DETERMINING WHETHER A PARTICULAR HEALTH INSURANCE PROGRAM IS A MANAGED CARE PLAN. SECTION 9.602 OF THIS REGULATION DEFINES A MANAGED CARE PLAN. WE APPRECIATE THAT THE LANGUAGE HAS BEEN CHANGED TO MATCH ACT 68 AND THE INSURANCE DEPARTMENT'S REGULATION. BUT THE QUESTION REMAINS, WHICH AGENCY MAKES THE DETERMINATION OF WHAT IS OR IS NOT A MANAGED CARE PLAN. IF BOTH ARE TO BE INVOLVED, HOW CAN EVERYBODY BE ASSURED OF EQUAL STANDARDS AND INTERPRETATIONS?

ANOTHER EXAMPLE: SECTION 9.672 OF THIS REGULATION COVERS THE EMERGENCY SERVICE RULES OF ACT 68. THE LANGUAGE HAS BEEN CHANGED FROM EARLY VERSIONS TO MATCH BOTH THE ACT AND SECTION 154.14 OF THE INSURANCE DEPARTMENT'S REGULATION. BUT AGAIN, THE PROBLEM OF SEPARATE, UNCOORDINATED REGULATION REMAINS.

AND ANOTHER: SECTION 9.684 OF THIS REGULATION COVERS THE CONTINUITY OF CARE RULES OF ACT 68. AGAIN, THE LANGUAGE HAS BEEN CHANGED TO MATCH ACT 68 AND SECTION 154.15 OF THE INSURANCE DEPARTMENT'S REGULATION. BUT AGAIN, THE PROBLEM OF SEPARATE, UNCOORDINATED REGULATION REMAINS.

THE EASY RESPONSE TO THIS IS TO SAY, WELL, WE WANT MANAGED

CARE PLANS SUBJECTED TO MORE THAN ONE REGULATOR, AND THE TWO AGENCIES WILL NO DOUBT WORK TOGETHER, SO WHAT'S THE BIG DEAL? EASY, BUT WRONG. FIRST, WE RECOGNIZE THAT BOTH THE INSURANCE AND HEALTH DEPARTMENTS HAVE TO BE INVOLVED IN REGULATING MANAGED CARE UNDER THE VARIOUS ACTS AND THEIR CURRENT STRUCTURES, SO THAT IS NOT THE DEBATE HERE.

SECOND, WE CANNOT BE ASSURED THAT THE TWO AGENCIES WILL WORK TOGETHER TO MAKE SURE THAT THESE AREAS WILL BE JOINTLY, NOT SEPARATELY, REGULATED. THIS REGULATION DOES PROVIDE FOR JOINT REGULATION - BUT ONLY IN SECTION 9.704(E), COVERING THE NARROW AREA OF DETERMINING WHETHER A CONSUMER'S OR PROVIDER'S APPEAL OF A COMPLAINT OR A GRIEVANCE HAS BEEN PROPERLY CHARACTERIZED AS SUCH. THAT IS REALLY WHAT WE ARE ASKING FOR IN THESE OTHER AREAS WHERE THE TWO AGENCIES BOTH HAVE REGULATIONS SAYING THE SAME THING: AN EXPRESS PROVISION THAT THE AGENCIES WILL WORK TOGETHER.

2. **THE REGULATION NEEDLESSLY - AND PROBABLY UNLAWFULLY - COVERS AREAS ALREADY REGULATED BY THE INSURANCE DEPARTMENT.**

WE RECOGNIZE THE NEED FOR JOINT REGULATION OF MANAGED CARE

PLANS IN CERTAIN AREAS, WITH OUR CONCERN BEING THAT THIS REGULATION TRULY BE JOINT, NOT SEPARATE. BUT THERE IS AN ADDED CONCERN HERE: THIS REGULATION COVERS AREAS ALREADY REGULATED BY THE INSURANCE DEPARTMENT WHERE AN ADDED REGULATOR AND ADDED OR DIFFERENT REGULATORY REQUIREMENTS ARE NOT ONLY NOT NEEDED BUT PROBABLY UNLAWFUL.

ONE EXAMPLE: SECTION 9.681(A) AND (B) MATCH, FOR THE MOST PART, 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.

BUT MORE IMPORTANT ARE THE MINOR CHANGES THE HEALTH DEPARTMENT HAS MADE IN ITS VERSION: IT REQUIRES THAT THE DIRECTORIES HAVE DISCLAIMERS ON THE FUTURE AVAILABLILTY OF PROVIDERS AND IT HAS ADDED SOME LANGUAGE ON AFFILIATIONS OF NURSES. WHY HAVE DIFFERENT REQUIREMENTS FROM DIFFERENT AGENCIES IMPLEMENTING THE SAME STATUTE? I AM NOT SURE WHY THE HEALTH DEPARTMENT THOUGHT THE INSURANCE DEPARTMENT'S REGULATION WAS INADEQUATE HERE - BUT THAT SHOULD AT LEAST BE EXPLAINED, AND THE TWO AGENCIES SHOULD REGULATE ANY CHANGES TOGETHER.

A MORE TROUBLESOME EXAMPLE IS IN SECTION 9.676 COVERING ENROLLEE RIGHTS. THE HEALTH DEPARTMENT HAS SET FORTH "RIGHTS" ALREADY COVERED IN OTHER LAWS - NAMELY HIPAA - EXPRESSLY REGULATED BY THE INSURANCE DEPARTMENT. THAT IS AN ODD USURPING OR BOOTSTRAPPING OF ONE REGULATOR'S POWER.

I KNOW THE REACTION: WHAT IS WRONG WITH HAVING MORE THAN ONE REGULATOR MONITOR AND ENFORCE THE LAW? I GO TO THE OLD ADDAGES OF TOO MANY COOKS, TOO MANY CHIEFS AND RIGHT AND LEFT HANDS NOT ACTING IN CONCERT. I ALSO THINK THE GENERAL ASSEMBLY SHOULD BE CONCERNED WHEN ANY AGENCY SEEKS TO GET INVOLVED IN AREAS THAT YOU HAVE, BY STATUTE, EXPRESSLY LEFT TO ANOTHER AGENCY.

THE HEALTH DEPARTMENT ITSELF ACKNOWLEDGED THIS IN ANOTHER AREA: IN EARLIER DRAFTS, IT WANTED TO BE INVOLVED IN THE REGULATION OF HMO MARKETING MATERIALS. IT DELETED THAT HERE, CORRECLY RECOGNIZING THAT THIS IS AN AREA ALREADY REGULATED BY THE INSURANCE DEPARTMENT UNDER THE UNFAIR INSURANCE PRACTICES ACT. THAT SAME THINKING SHOULD APPLY WITH RESPECT TO ENFORCING PENNSYLVANIA'S HIPAA REQUIREMENTS.

3. **THE REGULATION IMPOSES SOME IMPOSSIBLE, OR AT LEAST IMPRACTICAL AND IMPLAUSIBLE, REQUISITES.**

THE PRIMARY EXAMPLE HERE IS WITH RESPECT TO THE REGULATION'S PROVISIONS IMPLEMENTING ACT 68'S RULES ON COMPLAINTS AND GRIEVANCES, BEGINNING AT SECTION 9.701 OF THE REGULATION. THESE AREAS - OR AT LEAST THE COMPLAINT PORTION OF THEM - ALSO RAISE THE PROBLEM OF DUAL REGULATION BETWEEN THE INSURANCE AND HEALTH DEPARTMENTS, SO I WILL RAISE SOME CONCERNS ALONG THOSE LINES, TOO.

THE BASIC REQUIREMENT OF ACT 68 IN THIS AREA 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. NOW TAKE A LOOK AT WHAT THE HEALTH DEPARTMENT EXPECTS TO HAPPEN DURING THAT TIME.

FIRST, IF A MANAGED CARE PLAN "HAS A QUESTION" AS TO WHETHER A PARTICULAR MATTER IS A COMPLAINT OR A GRIEVANCE, IT MUST GO TO EITHER THE INSURANCE OR THE HEALTH DEPARTMENT FOR GUIDANCE - WITH THAT AGENCY MAKING A DECISION THAT IS BINDING.

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Samuel R. Marshall
President & CEO

March 8, 2001

To: The Honorable Members of the House Health and Welfare and Insurance Committees

From: Samuel R. Marshall

Re: Health Department managed care regulation - areas of objection

Yesterday, we 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

<u>The first tier of review for complaints:</u> 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.

THE INSURANCE FEDERATION OF PENNSYLVANIA, INC.

Public Testimony

prepared for the

SENATE HEALTH AND HUMAN SERVICES COMMITTEE

on

HEALTH DEPARTMENT MANAGED CARE REGULATIONS

March 12, 2001

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215-665-0500

GOOD MORNING AND THANK YOU FOR THE OPPORTUNITY TO BE HERE. I AM SAM MARSHALL, PRESIDENT OF THE INSURANCE FEDERATION OF PENNSYLVANIA. THE FEDERATION IS A NON-PROFIT TRADE ASSOCIATION REPRESENTING INSURERS OF ALL SHAPES AND SIZES DOING BUSINESS IN PENNSYLVANIA. AMONG OUR MEMBERS ARE A NUMBER OF MANAGED CARE INSURERS, RANGING FROM LARGE, MULTI-STATE ONES TO SMALLER, MORE REGIONAL AND LOCAL ONES.

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THOSE ARE STRONG WORDS, SO I WANT TO PUT THEM IN CONTEXT AT THE OUTSET. FIRST, WE RECOGNIZE THE DIFFICULT TASK THE HEALTH DEPARTMENT HAS UNDERTAKEN IN THIS REGULATION. PROPERLY MANAGING MANAGED CARE IS A TOUGH TASK. YOU FACED IT IN YOUR OWN DELIBERATIONS LEADING UP TO THE ENACTMENT OF ACT 68. THE INSURANCE DEPARTMENT FACED IT WITH THE PROMULGATION OF ITS REGUATION. IT CAN BE DONE.

SECOND, WE ARE NOT OPPOSING THE REGULATION BECAUSE WE WANT INSURERS' INTERESTS ADDRESSED AT THE EXPENSE OF CONSUMERS. THIS REGULATION SHOULD NOT INVOLVE A BALANCING TEST - FRANKLY, THAT IS WHAT OCCURS AT THE LEGISLATIVE LEVEL, NOT THE REGULATORY LEVEL. OUR OBJECTIONS ARE NOT IN AREAS THAT PIT US AGAINST SOME GENERAL, UNIFIED CONSUMER INTEREST. THEY ARE IN AREAS THAT PIT US AGAINST SOME REGULATORY REQUIREMENTS THAT EITHER ARE UNSUPPORTED BY LEGISLATION OR ARE UNDULY VAGUE, BURDENSOME OR OBTUSE.

THIRD, OUR OBJECTIONS ARE MORE MECHANICAL THAN PHILOSOPHICAL. YES, OUR OBJECTIONS ARE MAJOR ONES - A WELL-DESIGNED MACHINE DOES NOT WORK UNLESS THE MECHANICS OF IT DO, TOO. BUT THEY CAN BE ADDRESSED WITHOUT CHANGING THE DESIGN AND THE PURPOSE OF ACT 68 AND THE HMO AND PPO ACTS, OR OF THIS REGULATION - THE ESTABLISHMENT OF CLEAR AND FAIR RULES THAT ENSURE QUALITY AND EFFICIENCY IN MANAGED CARE.

AS TO OUR OBJECTIONS: WE HAVE ATTACHED TO OUR TESTIMONY A SECTION-BY-SECTION ANALYSIS OF THEM. THEY FALL INTO FOUR GENERAL CATEGORIES, AND I'LL GIVE THE MAJOR EXAMPLES OF EACH AS I OUTLINE THEM.

1. **THE REGULATION FAILS TO COORDINATE REQUIREMENTS AND ENFORCEMENT WITH AREAS ALREADY REGULATED UNDER THE SAME TERMS BY THE INSURANCE DEPARTMENT.**

ACT 68, AS WELL AS THE HMO AND PPO ACTS, CALLS FOR REGULATION OF MANAGED CARE PLANS BY BOTH THE INSURANCE AND HEALTH DEPARTMENTS. WE ACCEPT THAT. THE PROBLEM WITH THIS REGULATION IS THAT, IN A NUMBER OF KEY AREAS, IT DOES NOT PROVIDE FOR JOINT REGULATION BETWEEN THE INSURANCE AND HEALTH DEPARTMENTS - IT PROVIDES FOR SEPARATE, UNCOORDINATED REGULATION OF DUPLICATE REQUIREMENTS. THAT WILL LEAD TO CONFLICTING ANSWERS AND INTERPRETATIONS FROM THOSE AGENCIES THAT BENEFIT NOBODY.

LET'S START WITH THE MOST BASIC EXAMPLE - DETERMINING WHETHER A PARTICULAR HEALTH INSURANCE PROGRAM IS A MANAGED CARE PLAN. SECTION 9.602 OF THIS REGULATION DEFINES A MANAGED CARE PLAN AND MATCHES ACT 68 AND THE INSURANCE DEPARTMENT'S REGULATION. BUT THE QUESTION REMAINS, WHICH AGENCY MAKES THE DETERMINATION OF WHAT IS OR IS NOT A MANAGED CARE PLAN. IF BOTH ARE TO BE SEPARATELY INVOLVED, HOW CAN EVERYBODY BE ASSURED OF EQUAL STANDARDS AND INTERPRETATIONS?

TWO OTHER EXAMPLES: SECTION 9.672 OF THIS REGULATION COVERS THE EMERGENCY SERVICE RULES OF ACT 68, AND SECTION 9.684 COVERS THE ACT'S CONTNUITY OF CARE RULES. THE LANGUAGE IN BOTH SECTIONS NOW MATCHES BOTH THE ACT AND THE INSURANCE DEPARTMENT'S REGULATION. BUT AGAIN, THE PROBLEM OF SEPARATE, UNCOORDINATED REGULATION REMAINS.

THIS REGULATION DOES PROVIDE FOR JOINT REGULATION - BUT ONLY IN SECTION 9.704(E), COVERING THE NARROW AREA OF DETERMINING WHETHER A CONSUMER'S OR PROVIDER'S APPEAL OF A COMPLAINT OR A GRIEVANCE HAS BEEN PROPERLY CHARACTERIZED AS SUCH. THAT IS WHAT WE ARE ASKING FOR IN THE OTHER AREAS WHERE THE TWO AGENCIES HAVE REGULATIONS SAYING THE SAME THING: AN EXPRESS PROVISION THAT THEY WILL WORK TOGETHER.

2. THE REGULATION NEEDLESSLY - AND PROBABLY UNLAWFULLY - COVERS AREAS ALREADY REGULATED BY THE INSURANCE DEPARTMENT.

THE MOST TROUBLESOME EXAMPLE IS IN SECTION 9.676 COVERING ENROLLEE RIGHTS. THE REGULATION SETS FORTH "RIGHTS" ALREADY COVERED IN OTHER LAWS - NAMELY HIPAA - EXPRESSLY REGULATED BY THE INSURANCE DEPARTMENT.

THAT IS AN ODD - AND UNLAWFUL - USURPING OR BOOTSTRAPPING OF ONE REGULATOR'S POWER BY ANOTHER. IT WON'T ADD ANYTHING FOR CONSUMERS - IF THE HEALTH DEPARTMENT WERE CONCERNED A VIOLATION OF HIPAA HAD OCCURRED, IT COULD REFER IT TO THE INSURANCE DEPARTMENT JUST AS EASILY AS TAKE ACTION ITSELF. I ALSO THINK THE GENERAL ASSEMBLY SHOULD BE CONCERNED WHEN AN AGENCY SEEKS TO GET INVOLVED IN AREAS THAT YOU HAVE, BY STATUTE, EXPRESSLY LEFT TO ANOTHER AGENCY.

THE HEALTH DEPARTMENT ITSELF ACKNOWLEDGED THIS IN ANOTHER AREA: IT NO LONGER SEEKS TO BE INVOLVED IN THE REGULATION OF HMO MARKETING MATERIALS, RECOGNIZING THIS IS ALREADY REGULATED BY THE INSURANCE DEPARTMENT UNDER THE UNFAIR INSURANCE PRACTICES ACT. THAT SAME THINKING SHOULD APPLY WITH RESPECT TO ENFORCING THE HIPAA REQUIREMENTS.

3. THE REGULATION IMPOSES SOME IMPOSSIBLE, OR AT LEAST IMPRACTICAL AND IMPLAUSIBLE, REQUISITES.

THE PRIMARY EXAMPLE HERE IS WITH THE REGULATION'S PROVISIONS IMPLEMENTING ACT 68'S RULES ON COMPLAINTS AND GRIEVANCES, BEGINNING AT SECTION 9.701.

ACT 68 REQUIRES 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. NOW TAKE A LOOK AT WHAT THE HEALTH DEPARTMENT EXPECTS TO HAPPEN DURING THAT TIME.

FIRST, IF A MANAGED CARE PLAN "HAS A QUESTION" AS TO WHETHER A MATTER IS A COMPLAINT OR A GRIEVANCE, IT MUST GO TO EITHER THE INSURANCE OR THE HEALTH DEPARTMENT FOR GUIDANCE - WITH THAT AGENCY'S DECISION BEING BINDING.

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). 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 HIM 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, NOT 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 HERE: THE REGULATION REQUIRES THAT THE REVIEW HEARING BE "INFORMAL" TO "AVOID INTIMIDATING THE ENROLLEE," AND THAT THOSE PARTICIPATING BY CONFERENCE CALL DO SO "ACTIVELY." I AM NOT SURE WHAT ANY OF THIS MEANS BEYOND A FIELD DAY FOR LATER LITIGATION.

YOU ALSO HAVE THE PROBLEM OF DUAL REGULATION WITH RESPECT TO THE COMPLAINT PORTION OF THIS REGULATION. 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 - JUST AS IT IS FOR THE THIRD LEVEL OF REVIEW, WHEN THE COMPLAINT GOES TO THE DEPARTMENTS?

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

ACT 68 REQUIRES THAT 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) OF THIS REGULATION OVERTURNS THAT, AT LEAST WHERE THE LICENSED PHYSICIAN IS ALSO 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 CONTRADICTS 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. NOTHING IN ACT 68 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 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.

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 THAT MEANS MENTAL HEALTH AND DRUG AND ALCHOHOL ABUSE SERVICES, WHICH HAVE DIFFERENT STATUTORY MINIMUMS. BUT "BEHAVIORAL HEALTH SERVICES" IS AN UNDEFINED TERM - AND REGULATORY PREAMBLES ONLY BIND REGULATORS, NOT THIRD PARTIES.

WE RECOGNIZE THIS REGULATION IS LONG OVERDUE. OUR OBJECTIONS 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.