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

Dear Chairman Jack:

I enclose herewith a list of concerns regarding the Department of Health's proposed managed care regulations (purporting to implement Act 68). Those concerns touch upon three major shortcomings evident in the proposed regulations.

I. Ensuring access to care
II. Ensuring quality of care.
III. Ensuring the fundamental fairness of grievance & appeal processes.

In sum, unless the concerns addressed in these comments are resolved, **HMO consumers will be denied many of their rights and be denied essential remedies.**

I expect the Independent Regulatory Review Commission appreciates the urgent and necessary character of the fundamental course correction set forth in these comments and that you will be able to incorporate them into your own comments to the Department of Health. Therefore, I respectfully request you do so.

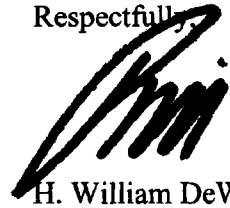
Make no mistake about it; these listed concerns go to the very heart of Act 68 and the Department's responsibilities. They must not go unresolved in the subsequent IRRC statute compliance efforts.

Please remember that IRRC has the statutory authority to question whether an unpublished document, like the Department of Health's policy statement on grievance and appeal rights, should be promulgated as a regulation. (See section 7.1 of the IRRC Act, 71 P.S. 745.7a and the IRRC regulations, 1 Pa.Code 315.2.)

I specifically request and recommend that the IRRC, in its comments, ask the Health Department: what is the status and enforceability of the Health Department's policy statement on "HMO grievance systems operational standards for fundamental fairness" (issued on 8/1/91 and reaffirmed by the Department in Questions & Answers posted on the Department's web site on or about 1/22/99)?

Thank you for your assistance in assuring the Health Department's proposed regulations bolster, not undercut, the intent and provisions of Act 68.

Respectfully,



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cc: The Honorable Frank Oliver
The Honorable Leo Trich
The Honorable Mike Veon

Concerns regarding the Department of Health's proposed managed care regulations (implementing Act 68)

1. Ensuring access to care

A. The proposed regulations (§9.651) fail to require HMOs to provide access to a provider within 24 hours for urgent care.

B. The proposed regulations (§9.654) permit networks without a single provider for a covered service as long as the service is otherwise arranged. **The effect is to deny enrollees choice.**

C. Without defining the standard: within a "reasonable travel distance," the proposed regulations (§9.654(b)(4)) permit limited networks.

D. The proposed regulations (§9.654) allow an HMO to restrict access by limiting some enrollees to a network that could potentially be inadequate. I am particularly concerned about the plight of enrollees who may be poor or regarded as being at a higher risk.

E. By prohibiting plans from requiring prior authorization for any OB/GYN services considered "routine" but allowing prior authorization for any "non-routine" procedures (§9.682) the proposed regulations limit Act 68's requirement that plans must provide "direct access to OB/GYNs by permitting an enrollee to select a health care provider participating in the plan to obtain maternity and gynecological care ... without prior authorization, ..."

F. The proposed regulations (§§9.679, 9.681) contain no standards for less frequently used specialists. Nor do they contain standards for providers who are not hospitals, PCPs or specialists [such as drug stores, home health agencies or durable medical equipment providers].

G. The proposed regulations (§9.654) allow plans to make only part of their network of providers available to enrollees, upon disclosure to potential enrollees. Nor do the proposed regulations require disclosure to current enrollees, nor do they set minimum standards for disclosure, such as inclusion of language in provider directory and/or marketing and enrollment materials.

H. The proposed regulations (§9.676) do not specify that a plan for addressing the needs of non-English-speaking enrollees is required. The proposal merely calls for: "Instructions as to how non-English speaking and visually-impaired enrollees may obtain the information in an alternative format." **Section 2136 of Act 68 requires plans to provide: "(5) a description of how the managed care plan addresses the needs of non-English-speaking enrollees."**

2. The following proposed regulations, for the reasons noted, each fail to ensure quality of care.

A. The Department of Health would be permitted to waive requirements for out-of-state HMOs. §9.636(c)

B. Health plans are required to have a quality assurance process but the regulations do not mention specific standards or outcome measures. The regulations seem to permit the Department of Health to limit its review to: whether the plans have a process and follow that process. There is no explicit responsibility placed within the Department of Health to "look behind" the plan to see if the process actually results in quality care. This regulation does not establish quality assurance STANDARDS. §9.674

C. The proposed regulations would push back the deadline for the first external review for Quality Assurance. Current regulations call for that review 12 months after the HMO begins operation - (§9.93(a). The proposal would make the deadline 18 months. (§9.655) I am also concerned the external review is to be done by a firm hired and paid by the plan and that the plan will determine the scope of review and that the proposal contains no requirement of corrective action, should external review find problems. §9.655

D. The proposal contains no public access to external review. §9.655(e)

E. The proposed regulations would not require the second external review until 3 years after the first review, even if serious problems were uncovered. §9.655(a)

F. Under the proposal, the external reviews are not required to have standards for the scope of review. Nor is there a requirement that compliance with Act 68, HMO Act and the accompanying regulations are reviewed. §9.655

G. The proposal (§9.655) reduces the scope of external reviews by dropping the review of a statistically significant sample of medical records that is currently required under (§9.93(c)(5)).

H. The proposal contains no requirement that Dept. of Health regulators ever visit a plan on site. The Dept. of Health would be permitted to rely exclusively on external reviewers, who have been hired by and paid by the plan to do external reviews. §9.632(e)

I. The proposal does not require the development and use of a uniform member satisfaction survey, which would enable the **"report cards"** that, were recommended by the Dept. of Health workgroup.

J. The proposal fails to establish Quality Assurance standards that: identify special, chronic and acute needs quickly, provide a mechanism to inform providers and enrollees of updates and changes, and establish maximum appointment waiting periods. §9.674

3. The proposed regulations undermine the fundamental fairness of the grievance & appeal process.

For the past nine years, the Department of Health has required the following protections for consumers of the services available through HMOs. Those essential consumer protection provisions are set forth in the Department's policy memo of 8/1/91, entitled "HMO grievance systems operational standards for fundamental fairness." The Department's proposed regulations (proposed grievance regulations, §9.701, *et seq.*) do not include these essential consumer protection provisions.

A. The requirement that plans accept an oral grievance from an enrollee and reduce it to writing.

B. The requirement that first level complaint and grievance decisions contain:

- a description of the reviewer's understanding of the member's dispute;
- clear terms and sufficient detail for the member to respond further;
- references to the evidence and documentation used as a basis of decision;
- a statement that the decision is binding unless the person appeals.

C. The requirement that plans set forth the identity, position and credentials of individual(s) who make the plan's decisions. This exclusion from the regulations proposed is especially troubling in light of the enrollees' right to have decisions rendered by individuals who are properly credentialed.

D. The requirement that plans make available to the enrollee all documentation relating to the issue in dispute.

E. **Contrary to Act 68**, which requires notification **to both** the enrollee and provider, the proposed regulations would allow plans to send notification of decisions to **either** the enrollee or provider.

F. The requirement that members be given at least 15 days advance written notice of the second level complaint/grievance committee hearing, their right to appear, their right to prepare and be given a description of the Committee's procedures, and to be re-advised that they can be assisted by an uninvolved HMO staff person, if they need help preparing.

G. The requirement that the second level review committee (for complaints and grievances) be made up of at least 1/3 HMO members, and that the consumer attending be told who on the Committee is staff and who are members.

H. The requirement that plans make available, for questioning, those persons who made the determination in dispute, at the second level review.

I. The requirement that the entire second level review hearing be transcribed by the HMO and the guarantee of the enrollee's right to record/transcribe the proceeding.

J. The requirement that prohibits the second level review committee from basing a decision against an enrollee on a reason not specifically raised in the first level review decision.

K. The requirement that an HMO staff person knowledgeable about the grievance/complaint be present at the second level review to present the HMO's view of why the denial should be upheld, and that the staff person may be questioned by the member and by the Committee.

L. The requirement that the second level grievance/complaint committee base their decision solely on materials and testimony presented at the hearing.

M. The requirement that the second level complaint/grievance decision articulate a detailed basis, including reference to the standard used and the evidence considered.