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House of Representatives
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

COMMITTEES
HEALTH & HUMAN SERVICES,
DEMOCRATIC CHAIRMAN

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2000 FEB -8 AM 10:54
INDEPENDENT REGULATORY REVIEW COMMISSION

February 4, 2000

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

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

Dear Ms. Mitchell:

In accordance with the Regulatory Review Act, the undersigned members of the General Assembly have chosen to offer comments on the Department of Health's proposed regulations implementing Act 68 and changes to existing HMO regulations. Despite their not being required at this time, we feel compelled to offer our comments at the proposed stage of review for the following reasons:

- We are submitting the following comments because of the unprecedented affect these regulations will have on the health status of Pennsylvanians; and
- We ask the Department to keep in mind during preparation of their final-form regulations that the Regulatory Review Act gives particular weight to our comments as to whether the regulation meets statutory authority and legislative intent and take corrective action accordingly.

After a thorough review of the Department of Health's proposed regulation No. 10-160, we feel that the Pennsylvania Health Law Project's fifty-one pages of comments and recommendations, dated January 18, 2000, offer the most detailed and thoughtful analysis possible of the regulation. And, without repeating those comments and recommendations, we hereby incorporate them into our own.

Because of our special duty to protect the statutory authority and legislative intent, we must point out the following sections of the regulations that fail to include specific requirements of Act 68:

- Current HMO rules provide for specific enrollee/provider ratios. The proposed regulation only requires a medical director to maintain a license in Pennsylvania, and applies only to HMOs. Either in section 9.634, or in

another section, the final regulations should contain specific requirements for all managed care plans (plans) to maintain sufficient staff to carry out all functions required by Act 68. The Act imposes specific obligations on managed care plans and provides no justification for limiting staffing obligations to HMOs alone.

- The proposed regulation fails to provide specific guidance on standards of scope of review required by external reviews and contains no requirement that plans comply with Act 68. Section 9.676 of the proposed regulation gives sole discretion to plans to develop procedures to implement enrollee rights and responsibilities with only limited oversight by the Department. The Department of Health not only has the authority, but also has the responsibility to enumerate and elaborate upon the protections required by Act 68.

- Section 9.676(1) of the proposed regulation repeats that plans' only obligation is to "adopt policies and procedures to assure implementation of enrollee rights" including access to information. Under section 2136(a)(8)(iv) of Act 68, "all notices of decisions will include information regarding the basis for the determination." Act 68 clearly intended that enrollees receive a notice of decision whenever a service is denied, reduced or terminated, and that each such notice include "the procedure to file a complaint or grievance...(and) the right to appeal a decision." In order for the description of the right to file a grievance or complaint to be of use, it must include an explanation of the difference between the two methods of dispute resolution, and the consequences of selecting the wrong method.

- The proposed regulation, in section 9.677, removes the draft regulation's requirement that the definition of medical necessity be "consistent with national and industry standard definitions of medical necessity, is not unduly restrictive and does not rely on the sole interpretation of the plan or the plan's medical director." At a minimum, that definition should be maintained. Allowing plans to use any definition they chose so long as they are consistent in its application violates the legislative intent of Act 68. In managed care plans, access to care depends on whether a service is found to be "medically necessary." Allowing plans to determine the definition, without restriction, may lead to the denial of care. A substantive definition of medical necessity is clearly contemplated by Act 68, since the act would not propose to allow plans, by use of an unclear or ambiguous definition, to deny needed care.

- Section 9.702(c) of the proposed regulation perverts the intent of Act 68 by allowing plans to classify any appeal they receive as they please, to their possible advantage, either as a grievance or a complaint. The Department confirms in the preamble to the proposed regulations, section 9.702, that "the possibility exists that the plan could classify a matter in such a way as to

confer an advantage on itself." There is no authority in the law for assigning appeal classification responsibility to the plans.

- Act 68 is intended to promote accountability and provide protection. Enrollees should have a clear right to receive full information about the appeals process. Section 9.706, the proposed regulation's requirement that plans only mention "the basis for the decision" which an enrollee has the right to appeal fails to meet the Department's responsibility to promulgate regulations sufficient in detail to ensure the patient protections intended by Act 68.

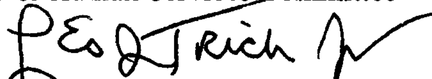
In closing, we must express concern over the Department's failure to include many of the recommendations of the Department's own managed care policy work groups. Because the work groups' recommendations reflect the consensus reached by a broad range of interests, including manage care plans, consumer groups, provider organizations and employer/purchasers, they should have been given great deference.

We are also greatly concerned by the Department of Health's violation of the Regulatory Review Act which requires that copies of all comments received by the Department be forwarded to the legislative committees. The Department of Public Welfare administers one of the largest Medicaid managed care programs in the nation. A number of commentors expressed concern over possible conflicts between existing regulations and policies governing plans contracting with the Department of Public Welfare's HealthChoices program. The Department of Public Welfare's comments on this regulation were withheld from the committees as a courtesy to the Department, but in clear violation of the Regulatory Review Act.

In conclusion, many provisions of the proposed regulation violate the clearly expressed legislative intent of Act 68. This failure to comply with statutory authority could negatively impact on the health and safety of the citizens of Pennsylvania. We trust that corrections will be made in the final-form regulations. Thank you for giving your full consideration to our comments.

Sincerely,

Rep. Frank Oliver, Democratic Chairman
Health & Human Services Committee



Rep. Leo Trich, Sub-Committee Chair on Health
Health & Human Services Committee

H. William DeWeese, Democratic Leader

Michael R. Veon, Democratic Whip

cc: IRRC ✓