



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
Office of Health Care Quality
Bland Bryant Building • Spring Grove Center
55 Wade Avenue • Catonsville, Maryland 21228

To: All Health Maintenance Organizations

From: Carol Benner, Director Licensing and Certification Administration

Date: March 8, 1999

Please find attached COMAR 10.07.11.11 -- Complaint System for Quality of Care Issues. The regulations became effective on March 3, 1999. These new procedures require each HMO to develop a written procedure to assist and respond to enrollees concerning quality of care issues. The written procedure must include certain criteria that must be followed. These are delineated in the regulations. The Department must approve these written procedures.

To comply with COMAR 10.07.11.11, you must submit your written procedure **no later than April 15, 1999**. These should be sent to me at Licensing and Certification Administration, 4201 Patterson Avenue, Baltimore, Maryland 21215-2299. If you have any questions, please call Thomas Russell at 410-764-4979.

Thank you for your cooperation.

cc: Martin P. Wasserman

Attachment: COMAR 10.07.11.11

M:99003

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 07 HOSPITALS

10.07.11 Health Maintenance Organizations

Authority: Health-General Article, § 19-701 et seq.;

Insurance Article, §2-109(a)-(c), Annotated Code of Maryland

Notice of Proposed Action

The Secretary of Health and Mental Hygiene proposes to repeal in its entirety Regulation .11 and to adopt new Regulation .1I under **COMAR 10.07.11 Health Maintenance Organizations.**

Statement of Purpose

The proposed action outlines HMO complaint procedures as required by recent statutory changes as a result of HB 3, Maryland General Assembly, 1998.

Comparison to Federal Standards

(Check one option)

There is no corresponding federal standard to this proposed regulation.

or

There is a corresponding federal standard to this proposed regulation, but the proposed regulation is not more restrictive or stringent.

or

Incompliance with Executive Order 01.01.1996.03, this proposed regulation is more restrictive or stringent than corresponding federal standards as follows:

1. Regulation citation and manner in which it is more restrictive than the applicable federal standard:
2. Benefit to the public health, safety or welfare, or the environment:
3. Analysis of additional burden or cost on the regulated person:
4. Justification for the need for more restrictive standards:

Impact Statements

Part A

(check one option)

Estimate of Economic Impact

The proposed action has no economic impact.

or

The proposed action has an economic impact.

Complete the following form in its entirety.

1. Summary of Economic Impact.

HMOs already have procedures for internal complaint resolution; so the proposed action places no additional administrative burdens on the industry.

NOT OFFICIAL TEXT

Types of Revenue (R+/R-)

Economic Impacts. Expenditure (E+/E)-Magnitude

A. On issuing agency:

B. On other State agencies:

C. On local governments: Benefit (+) Cost (-) Magnitude

D. On regulated industries or trade groups:

E. On other industries or trade groups:

F. Direct and indirect effects on public:

Assumptions. (Identified by Impact Letter and Number from Section II.)

Part B

(check one option)

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

or

The proposed action has a meaningful economic impact on small businesses. An analysis of this economic impact follows.

Opportunity for Public Comment

Written comments on the proposed action may be sent to Michele Phinney, Regulations Coordinator, Department of Health and Mental Hygiene, Room 538, 201 West Preston Street, Baltimore, Maryland 21201, fax (410) 333-7687, or call (410) 767-6499. These comments must be received by

Part C

(For legislative use only; not for publication)

A. Fiscal Year in which regulations will become effective: FY 1999.

B. Does the budget for the fiscal year in which the regulations become effective contain funds to implement the regulations?

Yes No N/A

C. If "yes", state whether general, special (exact name), or federal funds will be used:

D. If "no", identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

Recent legislation established the Maryland Insurance Administration as the single point of entry for all complaints filed by an HMO enrollee to State government. The proposed action clarifies the roles of HMOs and State government agencies regarding investigating and resolving complaints concerning HMO care and treatment. HMOs already have procedures for internal complaint resolution; so the proposed action places no additional administrative burdens on the industry.

F. If these regulations have minimal or no economic impact on small businesses

under Part B, indicate the reason and attach small business worksheet.

HMOs are not considered small business.

BEGIN ALL NEW MATERIAL

.11 Complaint System for Quality of Care Issues.

A. The HMO shall have a:

(1) Written procedure to assist and respond to enrollees, families and providers on complaints concerning quality of care issues; and

(2) Designated department to handle complaints.

B. Quality of care issues include, but are not necessarily limited to:

(1) Bad outcomes related to poor care;

(2) Failure to follow-up on diagnostic procedures;

(3) Failure to provide treatment for presenting complaints consistent with standard of care;

(4) Failure to appropriately document medical records;

(5) Confidentiality and privacy issues related to medical records or provision of care;

(6) General dissatisfaction with care;

(7) Qualifications of individuals who are employees of the HMO or who are under contract with the HMO to provide services to enrollees;

(8) Misdiagnosis;

(9) Inappropriate referral to meet enrollees' needs;

(10) Environmental issues related to infection control and hazardous medical waste;

(11) Failure of a provider to perform adequate medical screening, assessments, or timely care in emergency situations;

(12) Failure to provide an adequate internal enrollee complaint process concerning quality of care issues;

(13) Failure to comply with policies and procedures concerning delivery of care; or

(14) Inadequate credentialing and performance appraisal for physicians.

C. The HMO shall:

(1) Submit the written procedure to the Department for approval before distributing to enrollees;

(2) Obtain Departmental approval of any revision to the written procedure before implementing the proposed change; and

(3) Distribute the approved written procedure to all enrollees.

D. The written complaint procedure shall include, at a minimum:

(1) The department of the HMO that the enrollee or family member may contact if the enrollee wishes to make a complaint or obtain information concerning a complaint;

(2) The complaint department's address and telephone number;

(3) The procedure for investigating the complaint;

(4) The time frame in which the HMO shall provide a final response

to or resolve the enrollee's complaint, not to exceed 60 days; and

(5) The telephone number of the Maryland Insurance

Administration if the enrollee wishes to pursue a complaint regarding quality of care issues outside of the HMO's complaint system.

E. The HMO shall treat the enrollee with dignity, courtesy and due regard for the individual's privacy.

F. The HMO shall maintain a written record of complaints and responses for at least 5 years following the date the complaint was received by the HMO.

G. Investigation by the Department.

(1) The Maryland Insurance Administration is the single point of entry for all complaints filed by an HMO enrollee to State government. The Maryland Insurance Administration shall refer all quality of care complaints as defined in Regulation .11 B of this chapter to the Department for investigation.

(2) The Department may refer a complaint directly to an HMO for resolution, or conduct an independent investigation.

(3) If the Department refers the complaint to an HMO, the HMO shall provide the following information in writing to the Department within 30 days of receipt of the complaint:

(a) The results of the investigation;

(b) Any change or proposed change to HMO policies or procedures as a result of the investigation; and

(c) The HMO's method to prevent recurrence of the problem.

(4) If the HMO has not completed the investigation within 30 days, the HMO shall send the Department an interim report with a summary of the investigation to date and the expected date of completion. The expected date of completion may not be longer than 60 days from receipt of the complaint.

**END ALL NEW MATERIAL MARTIN P. WASSERMAN, M.D.
Secretary of Health and Mental Hygiene**