COLORADO
Department of Public Health & Environment

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To: Members of the State Board of Health

From: Lorraine Dixon-Jones, Policy Advisor

Through: D. Randy Kuykendall, Director, Health Facilities and Emergency Medical Services Division

Date: February 21, 2018

Subject: **Rulemaking Hearing**
Proposed Repeal of 6 CCR 1011-2 – Health Maintenance Organizations to occur in February 2018

The Colorado Department of Public Health and Environment is proposing to repeal 6 CCR 1011-2, Health Maintenance Organizations in response to Senate Bill (SB) 17-249. Prior to the bill's enactment, HMOs were regulated by both the Division of Insurance (DOI) and CDPHE. SB 17-249 repealed CDPHE's oversight responsibilities and consolidated them within DOI effective June 1, 2017. Since the statutory basis for the department's oversight responsibilities has been eliminated, the HMO regulations have become obsolete.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1011-2 – Health Maintenance Organizations

The regulations pertaining to the oversight of health maintenance organizations (HMOs) are being repealed in conformance with legislation enacted in 2017. Senate Bill 17-249 repeals the department's oversight authority and transfers the responsibilities to the Division of Insurance (DOI), which is housed within the Department of Regulatory Agencies. As the lead agency in Colorado for HMO oversight, DOI issues certificates of authority - similar to licenses - that allow HMOs to conduct operations in the state.

The statutory repeal was enacted in response to the findings of a DOI sunset review in 2016. One of the recommendations in the sunset review report[1] reads as follows:

> Recommendation 2. Repeal the duties related to reviewing health maintenance organization certificates of authority and conducting periodic reviews of health maintenance organizations that are assigned to the Executive Director of the Colorado Department of Public Health and Environment and reassign them to the Commissioner [of Insurance] and repeal any provisions that are otherwise duplicative.

The rationale for the recommendation included that: a) the regulation of HMOs in most states falls under the insurance regulator; b) splitting the duties between two state agencies creates an additional layer of regulation that appears to be unnecessary; and c) CDPHE has indicated that it does not have the funds to conduct oversight.

Background. Prior to the repeal enacted by SB 17-249, CDPHE was responsible for overseeing the quality and availability of the health care services delivered by HMOs. Department responsibilities were supplementary to DOI's oversight role, with significant overlap of jurisdiction. CDPHE's duties included:

- ensuring the availability, accessibility and continuity of care for enrollees. (As a corollary, DOI is responsible for monitoring network adequacy.)
- ensuring that the HMO had a quality assurance program.
- ensuring that the HMO had a procedure for evaluating statistics regarding cost of operations, pattern of service utilization, and availability of services.
- providing consultation to DOI regarding the adequacy of the complaint system to address enrollee concerns.

CDPHE was charged with reviewing compliance when a) HMOs applied for a certificate of authority and b) during examinations to be conducted no less frequently than once every three years. However, lack of funding meant that instead of conducting comprehensive oversight, CDPHE relied primarily on attestations as proof of compliance.

Specific Statutory Authority:
These rules are promulgated pursuant to the following statutes:
Section 25-1-108(1)(c)(I), C.R.S

[1] 2016 Sunset Review: Division of Insurance. October 14, 2016. Colorado Office of Policy, Research & Regulatory Reform. Department of Regulatory Agencies. p.58

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

___X___ Yes, the bill number is SB 17-249.

_____ No

Does this rulemaking incorporate materials by reference?

_____ Yes ___ URL or ___ Sent to State Publications Library

___X___ No

Does this rulemaking create or modify fines or fees?

_____ Yes

__X____ No

Does the proposed rule create (or increase) a state mandate on local government?

_X__ No. This rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed. Though the rule does not contain a state mandate, the rule may apply to a local government if the local government has opted to perform an activity, or local government may be engaged as a stakeholder because the rule is important to other local government activities.

REGULATORY ANALYSIS
for Amendments to
6 CCR 1011-2 Health Maintenance Organizations

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

   This rulemaking deletes an obsolete rule. The elimination of CDPHE oversight is expected to benefit HMOs, since oversight for these entities has been consolidated by statute under the Division of Insurance (DOI). DOI codified various duties previously conducted by CDPHE under 3 CCR 702-4, Regulation 4-7-1 effective on October 1, 2017. DOI has indicated that additional regulations regarding the transfer of responsibilities are underway, with an anticipated effective date of June 1, 2018.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   The repeal of this rule means that instead of being regulated by two state agencies, HMOs will only be regulated by one, namely DOI.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   There are no costs associated with the repeal of this regulation.

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   The benefit of repeal is the elimination of an obsolete regulation. There are no costs or benefits associated with inaction.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   There are no less costly or less intrusive methods of achieving the purpose of the rulemaking.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

   No alternatives were considered, since the intent of this rulemaking is conformance with statute.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

   Not applicable.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1011-2 Health Maintenance Organizations

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were notified of the repeal of 6 CCR 1011-2, Health Maintenance Organizations:

- Cindy Hathaway, Director of Corporate Affairs, Division of Insurance
- Matt Mortier, Director and Custodian of Records and Compliance
- Health Maintenance Organizations

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

No major factual or policy issues were encountered.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

No determinants of health or other health equity and environmental justice concerns were identified.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HEALTH MAINTENANCE ORGANIZATIONS

6 CCR 1011-2

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

I. AUTHORITY

These regulations are promulgated by the Executive Director pursuant to the provisions of Colorado Revised Statutes 10-16-402 and 10-16-416.

II. PURPOSE

The purpose of these regulations is to comply with the provisions of the Colorado Health Care Coverage Act, which require that the Executive Director determine whether each health maintenance organization (HMO) that is licensed is delivering quality health care services and each HMO seeking licensure in Colorado has an ongoing quality assurance program and procedures to compile, evaluate and report measures and statistics relating to the costs of its operation, pattern of utilization of services, the availability and accessibility of services, outcomes of care, and such other matters as may be reasonably required by the Executive Director.

III. APPLICABILITY AND SCOPE

This regulation shall apply to all HMOs that are licensed or seeking licensure in Colorado.

IV. DEFINITIONS

For the purposes of this regulation:

A. "Adverse determination" means a determination by an HMO that an admission, availability of care, continued stay or other health care service has been reviewed and, based upon the information provided, does not meet the HMO's requirement for medical necessity, appropriateness, health care setting, level of care or effectiveness, and the requested service or coverage for the requested service is therefore denied, reduced or terminated.

B. "Executive Director" means the Executive Director of the Colorado Department of Public Health and Environment or the director's designee.

C. "Facility" means an entity providing health care services or a health care setting, including but not limited to hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

D. "Health care professional" means a physician or other health care practitioner licensed, accredited, or certified to perform specified health services consistent with state and federal statutes.

E. "Provider" means a health care professional or a facility.

V. QUALITY ASSURANCE

~~Each HMO shall establish and maintain an ongoing program for quality assurance accountable to the HMO's governing body. The quality assurance program shall systematically monitor and evaluate the quality and appropriateness of health care services; shall develop and implement methods to resolve identified problems; and shall monitor the implementation of corrective measures to ensure their effectiveness. The evaluation of the quality and appropriateness of health care services shall be prospective, concurrent, and retrospective. The program shall be designed to improve the delivery of health care services and outcomes.~~

~~A. The quality assurance program shall implement a written plan that is evaluated at least annually and updated as necessary. The plan shall describe:~~

~~1. The program's mission, philosophy, goals and objectives;~~

~~2. The program's organizational structure and the job titles of the personnel responsible;~~

~~3. Specific diagnoses, conditions or treatments targeted for review by the program and focused studies designed to improve health care services and health outcomes;~~

~~4. Mechanisms to evaluate the health of enrollees and the results of treatment and outcomes of health care services in relation to reference data bases, such as current medical research, knowledge, standards and practice guidelines;~~

~~5. Mechanisms by which the findings generated by the quality assurance program, including preventive services, shall be used on a continuing basis by providers and other staff to improve the health of enrollees;~~

~~6. Mechanisms for the evaluation of the clinical performance of providers; and~~

~~7. Confidentiality policies and procedures for enrollee health information considered under the quality assurance program.~~

~~B. The quality assurance program shall be directed by a licensed physician or alternatively there shall be substantial input from one or more licensed physicians. The clinical elements of the quality assurance program shall be under the direction of a licensed physician.~~

~~C. The quality assurance program shall include preventive services for enrollees that are designed to reduce the rate of occurrence or the likelihood of morbidity, disability or mortality resulting from illness or injury. The program shall strive to meet public and community health goals as well as to improve the health of the plan's enrollees. Programs may include, but are not limited to:~~

~~1. Prevention, screening and treatment of environmental diseases;~~

~~2. Prevention and treatment of communicable diseases, including vaccine preventable diseases and tuberculosis;~~

~~3. Prevention and treatment of tobacco, alcohol or drug addictions;~~

~~4. Prevention and treatment of injuries; and~~

~~5. Prevention and treatment of chronic diseases and disabilities, and the prevention of complications directly caused thereby.~~

~~D. In order for the HMO to conduct effective quality assurance and utilization review programs, each HMO shall develop written medical record policies and procedures and implement a medical records monitoring system that requires the maintenance of medical records by~~

providers that are current, organized, and detailed. Such medical records monitoring system shall facilitate documentation and retrieval of clinical information. The HMO shall institute procedures to safeguard the confidentiality of individual enrollee medical records. Such records shall include, at a minimum, the following information:

1. The enrollee's name, identification number, date of birth, gender and place of residence;

2. Services delivered, including when, where and by whom services were provided; and

3. Medical diagnoses, treatments and therapies prescribed, medications administered or prescribed, referrals and follow-up arrangements.

E. New, amended, and extended contracts between the HMO and providers managed, owned, under contract with or employed by the HMO shall include provisions requiring the sharing between providers, who are treating or who have treated the same enrollee, of medical record information which facilitates the continuity of health care services, consistent with state and federal statutes and regulations.

F. The quality assurance program shall foster the provision of enrollee education relating to the prevention of illness and injury and the management of chronic illnesses and disabilities.

G. Each HMO shall coordinate the quality assurance program with the utilization review and the credentialing functions conducted by the HMO.

H. Each HMO shall make available to the Executive Director, upon request and in the form prescribed, documentation demonstrating the capacity to implement and/or the implementation of the quality assurance program including, but not limited to, the quality assurance plan, policies and procedures, program minutes, annual summary reports of quality assurance activities and evaluations, and focused or special studies.

VI. ACCESS TO CARE

A. In accordance with the statutory requirements, each HMO shall develop and implement a written access plan for each managed care network. The access plan shall demonstrate that:

1. Enrollees have availability and access to the full range of covered services. The plan shall include the HMO's standard concerning waiting times for obtaining appointments with health care professionals and hours of operation of health care professionals, facilities, and suppliers of health care services; and

2. There is an adequate number of available providers within a reasonable distance or travel time, or both, to ensure availability and accessibility of covered services for all enrollees without unreasonable delay.

B. Each HMO shall submit to the Executive Director, upon request and in the form prescribed, documentation demonstrating the adequacy of the network, including but not limited to information concerning:

1. Primary care providers;

2. Specialty and subspecialty providers;

3. Open and closed practices; and

4. Continuity of health care services.

C. In order to increase access to care to enrollees, HMOs are encouraged to develop community outreach efforts, including but not limited to:

1. Making provisions for delivery of health care services, including community-based services, to persons with disabilities and chronic illnesses, and to high risk or underserved populations;

2. Establishing ongoing collaborative arrangements with public health services, school-based health centers, community clinics, social service agencies, or other health related services or agencies; and

3. Developing culturally competent systems of care.

VII. UTILIZATION REVIEW

A. Each HMO shall implement a written utilization review plan that describes all review activities for covered services provided. The utilization review program, which shall be accountable to the HMO governing body, shall be designed to improve health care outcomes; determine patterns of over- and under-utilization of tests, procedures, and services; monitor issues and data associated with adverse determinations; and implement improvements to health care services and delivery. The program shall include:

1. A medical director who is a licensed physician;

2. Procedures to evaluate concurrently, prospectively, and retrospectively the clinical necessity, appropriateness and efficacy of health services, procedures, or settings;

3. Review of medication usage;

4. Procedures to ensure that any denials of health care services are signed by a licensed physician as required by Colorado law;

5. Mechanisms to ensure consistent and fair application of utilization review criteria, including preauthorization criteria;

6. Data sources and documented clinical review criteria based on sound clinical evidence which are evaluated periodically to assure ongoing efficacy;

7. Mechanisms to assess periodically utilization review activities, report the results to providers and to the HMO's governing body and implement corrective measures as necessary; and

8. Confidentiality policies and procedures for enrollee health information considered under the utilization review program.

B. Each HMO shall make available to the Executive Director, upon request and in the form prescribed, documentation demonstrating the capacity to implement and/or the implementation of the utilization review program including, but not limited to, the utilization review plan, policies and procedures, program minutes, annual summary reports of its utilization review program activities and evaluations in different service areas.

VIII. CREDENTIALING AND ORGANIZATIONAL STRUCTURE

A. The Executive Director shall determine if the HMO has developed and implemented written policies and procedures to ascertain that health care services will be provided by qualified personnel in appropriate facilities. Each HMO shall:

1. Develop and implement a credentialing and recredentialing plan that verifies that all employed and contractual health care professionals who provide health care services to enrollees are licensed in the state in which the health care professionals are delivering health care services, if required, and have all the necessary and appropriate certification and accreditation. If the HMO contracts with health care professionals affiliated with an entity which conducts credentialing for its personnel, verification shall, at minimum, take the form of ascertaining that the entity's credentialing and recredentialing process is in compliance with the requirements of these regulations. The HMO shall reverify the credentials of health care professionals as often as necessary but not less frequently than once every three years. The HMO shall verify the credentials of health care professionals before employing or entering into contracts with such health care professionals;

2. Utilize health care facilities that are licensed in the state in which they are located, if required, and certified as a provider or supplier for Medicare or Medicaid, if required; and

3. Have, at minimum, a medical director who is a licensed physician designated by the governing body who shall oversee the quality of health care services rendered to enrollees.

B. Each HMO shall make available to the Executive Director, upon request and in the form prescribed, documentation demonstrating the capacity to implement and/or the implementation of the credentialing and recredentialing plan, and of methods used to ensure that facilities are licensed or certified, as appropriate. Documentation includes, but is not limited to, policies and procedures and program minutes.

IX. COST OF OPERATIONS

Upon request by the Executive Director, each HMO shall submit documentation on the cost of its operations in accordance with statutory requirements. Costs of operations include total administrative and medical costs.

X. CONTRACTING

Whenever an HMO elects to perform functions or deliver services indirectly through contracts, agreements or other arrangements, the HMO shall monitor the activities of the entity with which it contracts for compliance with the requirements specified under these regulations and in statute concerning quality assurance, access to care, utilization review, and credentialing.

XI. EXAMINATIONS

The Executive Director may conduct an examination concerning the quality of health care services of any health maintenance organization and providers with whom such organization has contracts, agreements, or other arrangements pursuant to its health care plan as often as the Executive Director deems it necessary for the protection of the interests of the people of this state but not less frequently than once every three years. The examination shall require that the HMO demonstrate compliance with these regulations and with statutory requirements concerning accessibility, availability and quality of care. The Executive Director may consider the results of a current accreditation review by a nationally recognized private accrediting entity or of another state entity, with established and maintained standards, as evidence of meeting some or all of the statutory and regulatory requirements concerning quality assurance, access to care, utilization review, and credentialing. The HMO shall submit documentation, as requested by the Executive Director, to demonstrate that the HMO meets or exceeds state requirements. The HMO shall submit a request for the consideration of the accreditation review results in the form prescribed by the Executive Director.

~~**Editor's Notes**~~

~~**History**~~

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