

STATE OF COLORADO

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Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

To: Members of the State Board of Health

From: Laurie Schoder, Policy Analyst, Health Facilities and Emergency Medical Services Division

Through: D. Randy Kuykendall, MLS; Director

Date: July 16, 2014

Subject: Proposed Amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Chapter 2, General Licensure Standards- Quality Management Plans and Chapter 8, Facilities for Persons with Developmental Disabilities- Administrator Requirements, with a Request for the Rulemaking Hearing to occur on October 15, 2014

The Division is proposing amendments to its general licensure rules concerning the review and approval of quality management plans which must be developed by all licensed health care entities. The Division's rules have not been updated since the statute regarding health facility quality management was enacted in 1988. Consistent with Governor Hickenlooper's Executive Order D2012-002 regarding regulatory efficiency reviews, the Division undertook a thorough review of this rule and determined that changes were necessary.

Section 25-3-109, C.R.S. does not exempt any licensed health care entity from the requirement of having a quality management plan. Therefore, the current rule language exempting certain health care entities has been stricken. In addition, the current rule language regarding submission of written quality management plans for Division approval is outdated and is being revised to align with the Division's new tiered inspection process, which was implemented to comply with House Bill 12-1294.

**STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY**

For Amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities
Chapter II, General Licensure Standards; with conforming changes to Chapter VIII,
Facilities for Persons with Developmental and Intellectual Disabilities
July 16, 2014

Basis and Purpose:

In 1988, the Colorado General Assembly declared that the implementation of quality management functions to evaluate and improve patient and resident care was essential to the operation of health care facilities licensed or certified by the Department. To that end, the legislature enacted Section 25-3-109, C.R.S. regarding the quality management functions of health care entities. Included in that legislation was language that required the Department to review and approve a health facility's quality management program. The Division's general licensure requirements regarding the quality management functions of licensed facilities have not been updated since the statute was enacted in 1988. Pursuant to the Governor's Executive Order D2012-002 regarding regulatory efficiency reviews, the Division undertook a thorough review of this rule and determined that changes were necessary.

The proposed changes are two-fold. First of all, the statute does not exempt any licensed health care entity from the requirement of having a quality management program. Therefore, the current rule language exempting certain health care entities has been stricken. Secondly, the current rule language regarding submission of written quality management plans for Division approval is outdated and is being revised to align with the new survey processes mandated by House Bill 12-1294.

These rules are promulgated pursuant to the following statutes:

Section 25-1.5-103, C.R.S. (2013).

Section 25-3-109, C.R.S. (2013).

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

Yes
 No

Is this rulemaking due to a federal statutory or regulatory change?

Yes
 No

Does this rule incorporate materials by reference?

Yes

No

Does this rule create or modify fines or fees?

Yes

No

REGULATORY ANALYSIS

For Rules Pertaining to 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Chapter II, General Licensure Standards; with conforming changes to Chapter VIII, Facilities for Persons with Developmental and Intellectual Disabilities
July 16, 2014

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

All health care entities seeking an initial license from the Department will be affected by the rule amendment, as will currently licensed assisted living facilities with 19 or fewer residents and group homes for persons with developmental and intellectual disabilities that have previously been exempt from the rule. The affected health care entities will bear the cost of the proposed amendment. The classes that will benefit from the proposed amendment are the patients, residents and consumers of the affected health care entities. As the general assembly noted in the statutory language regarding quality management programs, the implementation of such functions is necessary to evaluate and improve patient and resident care.

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

The probable quantitative impact of the proposed amendment is primarily economic in that the administration of the affected health care entities will need to expend some time and energy to develop a quality management plan that meets the criteria set forth in the rule. The quantitative impact of the proposed rule will be improved patient, resident and consumer care due to the quality management plan requirements which stress continuing evaluation and investigation of facility care issues in a confidential manner designed to foster corrective action and improvement.

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.

The Division does not anticipate any significant additional costs will be incurred by it or any other agency.

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

The probable benefits of the proposed amendments outweigh inaction which would have no benefit. The probable cost of the proposed amendments are more than if no action was taken, but action is required in order to comply with the statutory language which requires that all licensed health care entities develop a quality management program for Departmental review and approval.

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

The determination is that there is no less costly or less intrusive method for achieving the purpose of the amendments.

6. A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

Written guidance and policy documents were considered, but those items alone would not achieve the desired result of eliminating regulatory exemptions for certain facility types so that the Department's regulations align with statutory language. Therefore, no other alternatives are deemed appropriate at this time.

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.

The Department estimates that in the short-term, the proposed rule amendments will affect approximately 125 currently licensed assisted living facilities and 167 currently licensed group homes for persons with developmental and intellectual disabilities. In the long-term, the proposed amendments will affect only new assisted living facilities and group homes applying for an initial license, a number that the Department predicts will be around 25 per year.

STAKEHOLDER Comment for Amendments to
6 CCR 1011-1, Chapter II, General Licensure Standards; with conforming changes to
Chapter VIII, Facilities for Persons with Developmental and Intellectual Disabilities

The following individuals and/or entities were included in the development of these proposed rules:
All licensed health care entities, the 1294 stakeholder forum group.

The following individuals and/or entities will be notified if this proposed rule-making is scheduled for consideration by the Board of Health: All currently licensed health care entities, all subscribers to the Division's health facilities blog, the Colorado Hospital Association, the Colorado Ambulatory Surgery Center Association, the Home Care Association of Colorado, Alliance and the Colorado Health Care Association.

On or before the date of publication of the notice in the Colorado Register, the Division will send notice to persons and/or groups considered by the division to be interested parties to the proposed rule-making, and those who have requested notification/information from the division regarding the proposed rule-making.

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 have been encountered thus far. The majority of the proposed amendments are required in order to comply with Colorado statutes.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

The Division is unaware of any health equity or environmental justice impacts.

1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2 Health Facilities and Emergency Medical Services Division

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4 STANDARDS FOR HOSPITALS AND HEALTH FACILITIES CHAPTER II - General Licensure Standards

5 6 CCR 1011-1 Chap 02

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8 PART 3. QUALITY MANAGEMENT, OCCURRENCE REPORTING, PALLIATIVE CARE

9
10 3.1 QUALITY MANAGEMENT PROGRAM. ~~Every licensed or certified facility, except personal care~~
11 ~~boarding homes of nineteen beds or fewer and except, community residential homes for persons with~~
12 ~~developmental disabilities~~ EVERY HEALTH CARE ENTITY LICENSED OR CERTIFIED BY THE DEPARTMENT
13 PURSUANT TO SECTION 25-1.5-103(1)(a), C.R.S., shall establish a quality management program
14 appropriate to the size and type of facility that evaluates the quality of patient or resident care and
15 safety, and that complies with this Part 3.

16
17 3.1.1 ~~Within 90 days of the effective date of this regulation for facilities licensed on the effective date~~
18 ~~of this regulation and within 90 days of the issuance of a license to a new facility, every facility~~
19 ~~defined in section 3.1 shall submit to the Department for its approval~~ EVERY HEALTH CARE ENTITY
20 IDENTIFIED IN SECTION 3.1 SHALL DEVELOP a plan for a quality management system PROGRAM THAT
21 SHALL BE AVAILABLE FOR DEPARTMENT REVIEW DURING THE INITIAL LICENSURE SURVEY AND EACH RE-
22 LICENSURE SURVEY. EACH PLAN SHALL includes the following elements:

- 23
24 (1) a A general description of the types of cases, problems, or risks to be reviewed and
25 criteria for identifying potential risks, including without limitation any incidents that may
26 be required by Department regulations to be reported to the Department;
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28 (2) iIdentification of the personnel or committees responsible for coordinating quality
29 management activities and the means of reporting to the administrator or governing
30 body of the facility.
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32 (3) a A description of the method for systematically reporting information to a person
33 designated by the facility within a prescribed time;
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35 (4) a A description of the method for investigating and analyzing the frequency and causes
36 of individual problems and patterns of problems;
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38 (5) a A description of the methods for taking corrective action to address the problems,
39 including prevention and minimizing problems or risks;
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41 (6) a A description of the method for the follow-up of corrective action to determine the
42 effectiveness of such action;
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44 (7) a A description of the method for coordinating all pertinent case, problem, or risk review
45 information with other applicable quality assurance and/or risk management activities,
46 such as procedures for granting staff or clinical privileges; review of patient or resident
47 care; review of staff or employee conduct; the patient grievance system; and education
48 and training programs;
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50 (8) d Documentation of required quality management activities, including cases, problems,
51 or risks identified for review; findings of investigations; and any actions taken to address
52 problems or risks; and

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(9) ~~a~~ A schedule for plan implementation not to exceed 90 days after the date OF THE INITIAL SURVEY. ~~the facility receives written notice of the Department's approval of the plan.~~

3.1.2 THE PLAN FOR A HEALTH CARE ENTITY'S QUALITY MANAGEMENT PROGRAM SHALL BE CONSIDERED APPROVED IF THE DEPARTMENT DOES NOT CITE ANY DEFICIENT PRACTICE RELATED TO IT. ~~If upon review of the facility's plan,~~ the Department finds that ~~it~~ A QUALITY MANAGEMENT PLAN does not meet the requirements of these regulations, the Department shall ~~return it to~~ INFORM the facility ~~along with~~ OF the specific reasons for disapproval and establish a reasonable date for resubmittal of a revised plan ~~meeting~~ THAT MEETS the requirements of these regulations.

3.1.3 ~~In lieu of requiring the submission of an entire plan for a quality management program as required under section 3.1.1, †~~ The Department may accept documented evidence of compliance with any or all applicable standards of the Joint Commission on Accreditation of Health Care Organizations, Medicare conditions of participation, or other acceptable standards regarding risk management and quality assurance functions. ~~The Department may accept submission of all or part of a plan or appropriate documentation regarding any or all elements required in section 3.1.1.~~

~~3.1.4~~ Any facility that makes a permanent and substantive change in its quality management plan shall submit a description of the change to the Department prior to implementation. The Department shall notify the facility if it determines that such change does not meet the requirements of these regulations along with the specific reasons therefor.

3.1.5~~4~~ The Department may audit the quality management program to determine its compliance with the approved plan.

(1) If the Department determines that an investigation of any incident or patient or resident outcome is necessary, it may, unless otherwise prohibited by law, investigate and review relevant documents to determine actions taken by the facility.

~~(2) This section shall be effective June 1, 1988.~~

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DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES

CHAPTER VIII - FACILITIES FOR PERSONS WITH DEVELOPMENTAL DISABILITIES

6 CCR 1011-1 Chap 08

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Section 5 – Administrator

5.1 The administrator shall be responsible on a full time basis to the governing body for planning, organizing, developing and controlling the operations of the facility.

5.2 The administrator shall develop a written plan of organization detailing the authority, responsibility, and functions of each category of personnel.

5.3 ~~RESERVED The administrator, in consultation with one or more physicians and one or more registered professional nurses and other related professional health care personnel, shall develop and at least annually review appropriate written policies and procedures for the care of the residents, including, but not limited to, admission and transfer of residents; dental, diagnostic, dietary, medical and emergency care; nursing, pharmaceutical, physical and occupational therapy, training and social services as applicable.~~

~~(A) A community residential home that submits a quality improvement plan to the Department for approval, and implements and maintains a quality management program in accordance with the approved plan shall be excluded from the requirement listed in section 5.3 of this chapter.~~

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