STATE 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 *D.R.K.*

Date: May 21, 2014

Subject: Proposed Amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Chapter XXI, Hospices and Chapter XXVI, Home Care Agencies, with a Request for the Rulemaking Hearing to occur on July 16, 2014

The Division is proposing amendments to its licensing standards for hospices and home care agencies in order to accommodate services offered by the Department of Health Care Policy and Financing through a new waiver program entitled Home and Community Based Services for Children with Life Limiting Illness. The Department of Health Care Policy and Financing (HCPF) is also amending its regulations at 10 CCR 2505-10, section 8.504 regarding these waiver services.

The services provided under this waiver program are frequently not provided on a continuous basis and often not strictly medical in nature. The program allows for services that are intermittent, sometimes consumer driven, and often provided by a therapist rather than a physician. The Division's proposed amendments will allow hospices and home care agencies leeway to deliver these services under the Children with Life Limiting Illness waiver program rather than having to conform to existing regulations that were intended for continuous medical care.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY

For Rules Pertaining to the Standards for Hospitals and Health Facilities
6 CCR 1011, Chapter XXI, Hospices and Chapter XXVI, Home Care Agencies
May 21, 2014

Basis and Purpose:

The Health Facilities and Emergency Medical Services Division is proposing amendments to the above referenced rules in order to accommodate services offered by the Department of Health Care Policy and Financing through a new waiver program entitled Home and Community Based Services for Children with Life Limiting Illness. The Department of Health Care Policy and Financing (HCPF) is also amending its regulations at 10 CCR 2505-10, section 8.504 regarding these waiver services which are not always continuous or strictly medical in nature.

The Division's proposed amendments will allow hospices and home care agencies leeway to deliver qualifying services under the Children with Life Limiting Illness waiver program without being constrained by existing regulations that were intended for the delivery of continuous medical care. The Division's proposed amendments will also add two definitions that are consistent with definitions used by HCPF in their regulations.

These rules are promulgated pursuant to the following statutes:

Section 25-1.5-103, C.R.S. (2013).
Section 25-1.5-108, C.R.S. (2013).
Section 25-27.5-104, C.R.S. (2013).

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

___ Yes
__X__ No

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

_____ Yes
__X__ No

Does this rule incorporate materials by reference?

_____ Yes
__X__ No

Does this rule create or modify fines or fees?

_____ Yes
__X__ No

REGULATORY ANALYSIS

For Rules Pertaining to the Standards for Hospitals and Health Facilities
6 CCR 1011-1, Chapter XXI, Hospices and Chapter XXVI, Home Care Agencies

May 21, 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.

The primary class of persons who will be affected by the proposed amendments are the patients receiving care under the Medicaid waiver program entitled Home and Community Based Services for Children with Life Limited Illness Waiver. The amendments will allow these patients to receive care that providers might otherwise be hindered from providing under the existing rules.

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 proposed amendments will have a positive qualitative impact on the patients eligible for care under the Children with Life Limiting Illness waiver because the amendments will remove any obstacles to the provision of that care by hospices or home care agencies.

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 costs and benefits of the proposed amendments are detailed above. There is no benefit to inaction. Inaction would result in conflict between agency rules that would hinder the delivery of essential services. Therefore, the probable costs and benefits of the proposed rule outweigh the probable costs and benefit of inaction.

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 resolving potential conflicts in various agency regulations. 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 anticipated short-term consequence will be that licensed hospices and home care agencies must acquaint themselves with the amended rules and make any necessary changes to their existing policies and procedures. The long-term consequences are updated regulations that align with those of other agencies and that allow the provision of services to children who are eligible under the waiver program.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities Regulation Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES

CHAPTER XXVI - HOME CARE AGENCIES

6 CCR 1011-1 Chap 26

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Section 3. DEFINITIONS

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3.15 "LIFE-LIMITING ILLNESS" MEANS A MEDICAL CONDITION THAT, IN THE OPINION OF THE MEDICAL SPECIALIST INVOLVED, HAS A PROGNOSIS OF DEATH THAT IS HIGHLY PROBABLE BEFORE A CHILD REACHES ADULTHOOD AT AGE 19.

3.15 6 "Nurse aide" means a nurse aide certified by the Colorado Department of Regulatory Agencies or a nurse aide who has completed the requisite training and is within four (4) months of achieving certification.

3.167 "Parent home care agency" means the agency that develops and maintains administrative control of branch offices.

3.178 "Personal care services" means assistance with activities of daily living, including but not limited to bathing, dressing, eating, transferring, walking or mobility, toileting, and continence care. It also includes housekeeping, personal laundry, medication reminders, and companionship services furnished to a home care consumer in the home care consumer's temporary or permanent home or place of residence, and those normal daily routines that the home care consumer could perform for himself or herself were he or she physically capable, which are intended to enable that individual to remain safely and comfortably in the home care consumer's temporary or permanent home or place of residence.

3.189 "Plan of correction" means a written plan prepared by the HCA and submitted to the department for approval that specifies the measures the HCA shall take to correct all cited deficiencies.

3.1920 "Primary agency" means the agency responsible for the consumer's direct care coordination when a secondary or subcontracted agency is also providing care and services.

3.201 "Qualified Early Intervention Service Provider" has the same meaning set forth in section 27-10.5-702, C.R.S.

3.22 "RESPITE CARE" MEANS SERVICES PROVIDED TO A CONSUMER WHO IS UNABLE TO CARE FOR HIMSELF OR HERSELF ON A SHORT TERM BASIS BECAUSE OF THE ABSENCE OR NEED FOR RELIEF OF THOSE PERSONS NORMALLY PROVIDING CARE.

3.213 "Service Agency" means an individual or any publicly or privately operated programs, organization, or business providing services or supports for persons with developmental disabilities.

3.224 "Service note" means a written notation that is signed, with date and time, by an employee of the home care agency furnishing the non-medical services.

3.2~~3~~5 "Skilled home health services" means health and medical services furnished in the consumer's temporary or permanent place of residence that include wound care services; use of medical supplies including drugs and biologicals prescribed by a physician; in-home infusion services; nursing services; or certified nurse aide services that require the supervision of a licensed or certified health care professional acting within the scope of his or her license or certificate; occupational therapy; physical therapy; respiratory care services; dietetics and nutrition counseling services; medication administration; medical social services; and speech-language pathology services. "Skilled home health services" does not include the delivery of either durable medical equipment or medical supplies.

3.2~~4~~6 "Subdivision" means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the licensure requirements for HCAs. A subdivision that has branch offices is considered a parent agency.

3.2~~5~~7 "Summary report" means the compilation of the pertinent factors of a home care consumer's clinical notes that is submitted to the consumer's physician by the skilled home health care agency.

3.2~~6~~8 "Supervision" means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity.

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Section 7. SKILLED CARE

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7.9 Initial and comprehensive assessments

(A) Initial assessment visit

(1) A registered nurse shall conduct an initial assessment visit to determine the immediate care and support needs of the consumer. The initial assessment visit shall be held either within 48 hours of referral, or within 48 hours of the consumer's return home, or on the ~~attending provider-~~ordered start-of-care date.

(2) When an alternate professional healthcare service is the only service ordered, the initial assessment visit may be made by the appropriate ~~skilled~~ healthcare professional.

(B) Comprehensive assessment of consumers

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(6) WHEN NURSING SERVICES ARE PROVIDED, ~~T~~ the comprehensive assessment shall include a review of all medications the consumer is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy and noncompliance with drug therapy.

(a) The HCA shall report any concerns to the attending physician, and the director of nursing and these reports shall be acted upon.

(7) FOR CONSUMERS RECEIVING INTERMITTENT RESPITE AND WAIVER SERVICES THAT ARE NOT PROVIDED WITHIN A CONTINUOUS 60 DAY PERIOD, A COMPREHENSIVE ASSESSMENT SHALL BE ACCOMPLISHED BEFORE REINITIATING SERVICES RATHER THAN THE MINIMUM TIME FRAMES SET FORTH BELOW.

The comprehensive assessment shall be updated and revised as frequently as the consumer's condition warrants due to a major decline or improvement in the consumer's health status. At a minimum, it shall be updated and revised:

(a) Every 60 days beginning with the start-of-care date; and

(b) Within 48 hours of the consumer's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests or, for non-certified agencies, as ordered by the physician or intermediate care provider.

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7.10 Plan of care

(A) Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine. Care plans established by a nurse practitioner, ~~or~~ physician assistant OR OTHER THERAPISTS WITHIN THEIR SCOPE OF PRACTICE may be accepted by an HCA that is not federally certified as a home care agency. For PACE participants, the interdisciplinary team shall establish, follow and periodically review the plan of care.

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(C) The total plan of care shall be reviewed by the attending physician or attending intermediate care provider and HCA personnel as often as the severity of the consumer's condition requires, but at least once every 60 days or more frequently when there is a significant change in condition.

(1) FOR CONSUMERS RECEIVING INTERMITTENT RESPITE AND WAIVER SERVICES THAT ARE NOT PROVIDED WITHIN A CONTINUOUS 60 DAY PERIOD, THE TIME FRAME FOR REVIEW BEGIN UPON THE RE-INITIATION OF CARE.

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7.12 Coordination

(A) Care coordination shall be demonstrated for each consumer at least every ~~30~~ 60 days for cases where there is more than one agency sharing the provision of the same home health services. The minutes of these case conferences shall reflect discussion and input by all the disciplines providing care to the consumer.

(B) The HCA shall be responsible for the coordination of consumer services both with internal staff and known external services providing care and services to the same consumer.

(C) All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care and as delineated through outside home care services.

(D) The clinical record, care coordination notes or minutes of case conferences establish that effective interchange, reporting and coordination of consumer care do occur.

(E) A written summary report for each consumer shall be documented and sent to the attending primary care provider, AS APPROPRIATE, at least every 60 days.

7.13 Extended care

Extended care is defined as a total of six (6) or more hours of home health services provided in a 24-hour period by a licensed agency that provides skilled health services ON A CONTINUOUS BASIS.

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DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES

CHAPTER XXI - HOSPICES

6 CCR 1011-1 Chap 21

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SECTION 2 DEFINITIONS

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2.8 "Interdisciplinary Group (IDG)" means a group of qualified individuals, consisting of at least a physician, registered nurse, social worker, chaplain or other counselor who collectively have expertise in meeting the special needs of the hospice patient/family.

2.9 "LIFE-LIMITING ILLNESS" MEANS A MEDICAL CONDITION THAT, IN THE OPINION OF THE MEDICAL SPECIALIST INVOLVED, HAS A PROGNOSIS OF DEATH THAT IS HIGHLY PROBABLE BEFORE A CHILD REACHES ADULTHOOD AT AGE 19.

2.~~9~~10 "Palliative Care" means specialized medical care for people with serious illnesses. This type of care is focused on providing patients with relief from the symptoms, pain and stress of serious illness, whatever the diagnosis. The goal is to improve quality of life for both the patient and the family. Palliative care is provided by a team of physicians, nurses and other specialists who work with a patient's other health care providers to provide an extra layer of support. Palliative care is appropriate at any age and at any stage in a serious illness and can be provided together with curative treatment. Hospice providers may perform palliative care services that are separate and distinct from hospice care services.

2.1~~0~~1 "Patient/Family" means the patient and those individuals who are closely linked with the patient including the immediate family, the primary caregiver and/or other individuals with significant personal ties.

2.12 "RESPITE CARE" MEANS SERVICES PROVIDED TO A PATIENT WHO IS UNABLE TO CARE FOR HIMSELF OR HERSELF ON A SHORT TERM BASIS BECAUSE OF THE ABSENCE OR NEED FOR RELIEF OF THOSE PERSONS NORMALLY PROVIDING CARE.

2.1~~1~~3 "Terminally Ill" means that the individual has a medical prognosis that includes a limited life expectancy of days, weeks or months if the illness runs its anticipated course. Palliative care patients may fall outside of a payer's coverage guidelines for the hospice benefit.

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SECTION 6 PATIENT CARE SERVICES

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6.2 Admission Criteria:

(A) Upon admission to the hospice there shall be an evaluation of the patient's immediate needs related to their terminal condition. An initial plan of care shall be developed based upon the results of the immediate needs evaluation.

(B) An initial assessment of the patient's physical, psychosocial, spiritual and emotional status related to the patient's terminal illness and related conditions shall be completed by a registered nurse within forty-eight (48) hours.

(1) FOR PATIENTS RECEIVING PALLIATIVE CARE SERVICES UNDER THE CHILDREN WITH LIFE LIMITING ILLNESS WAIVER PROGRAM, THE INITIAL ASSESSMENT SHALL BE COMPLETED BY A REGISTERED NURSE WITHIN FOURTEEN (14) CALENDAR DAYS OF ADMISSION.

6.3 Within five (5) calendar days following admission, depending upon the patient's immediate needs, a comprehensive assessment shall be completed by the interdisciplinary group. FOR PATIENTS RECEIVING PALLIATIVE CARE SERVICES UNDER THE CHILDREN WITH LIFE LIMITING ILLNESS WAIVER PROGRAM, A COMPREHENSIVE ASSESSMENT SHALL BE COMPLETED BY AN APPROPRIATE INTERDISCIPLINARY TEAM MEMBER WITHIN 30 CALENDAR DAYS.

The comprehensive assessment shall identify the patient's physical, psychosocial, emotional and spiritual needs related to the terminal illness and related conditions that shall be addressed in order to promote the patient's well-being, comfort and dignity throughout the dying process. This includes a thorough evaluation of the caregiver's and family's willingness and capability to care for the patient.

The comprehensive assessment shall be updated as frequently as the patient's condition requires but no less than every ~~fifteen (15)~~ 30 CALENDAR days. FOR PATIENTS RECEIVING INTERMITTENT RESPITE AND WAIVER SERVICES THAT ARE NOT PROVIDED WITHIN A CONTINUOUS 30 DAY PERIOD, THE COMPREHENSIVE ASSESSMENT SHALL BE UPDATED BEFORE REINITIATING SERVICES.

6.4 An individualized written plan of care shall be developed to reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive and updated comprehensive assessments. The plan of care shall include all services necessary for the palliation and management of the terminal illness and include but not be limited to:

(A) Interventions to manage pain and symptoms;

(B) A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs;

(C) Measurable outcomes anticipated from implementing and coordinating the plan of care;

(D) Drugs and interventions necessary to meet the needs of the patient;

(E) Medical supplies and appliances necessary to meet the needs of the patient;

(F) Coordination of care;

(G) Patient/family understanding and agreement with the plan of care, and

(H) When applicable, plans to meet the special needs of patients who are infants, children and adolescents.

6.5 ~~A designated registered nurse~~ THE APPROPRIATE INTERDISCIPLINARY GROUP MEMBER shall coordinate the overall plan of care for each patient.

6.6 EXCEPT AS SET FORTH IN PARAGRAPH (A) BELOW ,~~T~~ The interdisciplinary group (in collaboration with the individual's attending physician or nurse practitioner) shall review, revise and document the individualized plan as frequently as the patient's condition requires, but no less frequently than every ~~15~~ 30 calendar days. A revised plan of care shall include information from the patient's updated comprehensive assessment and shall note the patient's progress toward outcomes and goals specified in the plan of care.

(A) FOR PATIENTS RECEIVING INTERMITTENT RESPITE AND WAIVER SERVICES THAT ARE NOT PROVIDED WITHIN A CONTINUOUS 30 DAY PERIOD, THE TIME FRAME FOR REVIEW BY AN APPROPRIATE INTERDISCIPLINARY GROUP MEMBER BEGINS UPON THE RE-INITIATION OF CARE

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