PUBLIC HEALTH DIVISION Office of the State Public Health Director

Tina Kotek, Governor



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DATE: January 25, 2023

TO: Hearing Attendees and Commenters – OAR chapter 333, division 35,

"Hospice Program Licensure Requirements"

FROM: Brittany Hall, Hearing Officer and Administrative Rules Coordinator

cc: Dana Selover, MD, MPH; Section Manager

Health Care Regulation and Quality Improvement

SUBJECT: Presiding Hearing Officer's Report on Rulemaking Hearing and Public

Comment Period

Hearing Officer Report

Date of Hearing: December 20, 2022, via Microsoft Teams.

Purpose of Hearing: The purpose of this hearing is to receive testimony regarding the Oregon Health Authority (Authority), Public Health Division, Health Care Regulation and Quality Improvement's proposed permanent amendments to OAR chapter 333, division 35 related to Hospice program licensure requirements.

These administrative rules have not been amended since their initial adoption in 2010 and are being revised to align with other licensed facility and agency types regulated by the Health Care Regulation and Quality Improvement Program and changes to Oregon and federal regulations. The proposed amendments seek to:

- Update language and terms to reflect current processes, terminology, technology and statutory references;
- · Streamline the organization of the rules;
- Provide clarity on the requirement that a Hospice program must comply with federal regulations prescribed by the Centers for Medicare and Medicaid Services;
- Provide clarity on the actions taken by the Authority in reviewing a license application, issuing a license, or denying, suspending, or revoking a license;
- Clarify the geographic service area in which a Hospice may operate;
- Add requirement for health care interpreter services, clinical records, infection control, and quality assessment and performance improvement; and

Add provision for requesting a waiver from rule, including, but not limited to, if a
parent Hospice program proposes to provide hospice services to an underserved
area or population in Oregon. Defines the term underserved area or population.

Hearing Officer: Brittany Hall

Testimony Received: One individual provided oral testimony at the hearing. This testimony is briefly summarized as follows:

<u>Barbara Hansen</u>, Chief Executive Officer, Oregon Hospice and Palliative Care Association

Barbara Hansen provided comments for future rulemaking, stating that this was the first opportunity to review the rules since they were adopted in 2010 and proposing that a review and subsequent amendments are done more often than every 12 years so that as issues come up, there is an opportunity to get input.

Barbara Hansen suggested that the State of Oregon can go above and beyond what CMS requires in the Medicare/Hospice Conditions of Participation in order to address issues or areas of concern in our state, such as equity issues and to encourage hospices to do more outreach to underserved communities. They provided some examples of ways Oregon can go above and beyond what CMS requires in their oral testimony for future considerations for rulemaking.

Agency response: The Authority thanks Barbara Hansen for their comments and is encouraged to hear about future ideas on addressing equity and how hospice programs may better serve underserved communities. Given these suggestions and possible future state legislation, the Authority anticipates that these rules will be opened again, and a RAC convened in the future.

Other Comments: Two individuals or organizations submitted written comments to the Authority within the period allotted for public comment, which closed at 5:00 PM on December 21, 2022. These comments are briefly summarized as follows:

Allison Tonge, MPH, BSN, RN, Operations and Policy Analyst, Office of Program Integrity, Fiscal and Operations Division, Oregon Health Authority

Allison Tonge submitted comments on behalf of the Oregon Health Authority, Fiscal and Operations Division, Office of Program Integrity (OPI) that detail OPI's recommendations and suggested language throughout the proposed rules.

The Office of Program Integrity's written comments are attached to this report as Exhibit 1.

Agency response: The Authority thanks its Fiscal and Operations Division agency partner and Allison Tonge for their careful and thorough review of these rules. In reviewing the comments provided and existing hospice program licensing statutes, it was determined that the Authority may not have the necessary statutory authority to make many of the suggested changes and legal counsel will need to be consulted. Additionally, a RAC did not have the opportunity to consider any of the suggested changes, many of which may benefit from community input. As indicated in the response to Barbara Hansen, the Authority anticipates future discussions on the hospice administrative rules and will consider these changes further after statutory authority has been determined. Lastly, the Authority would like to note that the Health Facility Licensing and Certification (HFLC) program and its licensing rules focus on health and safety. The HFLC program does not have any regulatory oversight over payment and such requirements should be addressed by other Division rules.

The changes were made in the following rules based on comments provided:

OAR 333-035-0125

Application for Licensure

- (2)(a) A person wishing to applying for a new or renewal license to operate a hospice program shall submit...
- (2)(b)(B) A complete application for an initial license includes, but is not limited to documentation that patient care and documentation systems have been developed.
- (5)(a) Within 30 days of the change, a hospice program must inform the Authority in writing of any change in:
- (A) Ownership;
- (B) Ownership category (for example, corporation, partnership, sole proprietorship);
- (C) Administrator;
- (D) Business name;
- (E) Medicare certification number;
- (F) Primary and multiple locations; or
- (G) Physical location; or
- (F) Mailing address.

OAR 333-035-0155

Return of License and Hospice Program Closure

- (2) A hospice program that discontinues operations must:
- (b) Provide information about how an individual may obtain a copy of their clinical records.
- (c) Notify the Authority at least 14 calendar days prior to closure and submit plans for the transfer, storage and disposal of clinical records and how stored

records can be accessed, including the name of the entity responsible for handling access requests.

- (3)(a) Clinical records not claimed that are less than seven years old from the last date of discharge shall be stored for a minimum of until they are more than seven years old from last date of discharge. Clinical records that are greater than seven years old from last date of discharge may be destroyed.
- (b) The clinical records of a patient less than 18 years of age shall be kept at least seven years after the patient reached the age of 18.
- (c) Storage and destruction of clinical records shall comply with 45 CFR Part 160, subparts A and E of 45 CFR Part 164, and ORS 192.553 through 192.581.

OAR 333-035-0180 Clinical Records

(2) In the event of dissolution of a hospice program, the hospice program administrator shall notify the Authority where the clinical records will be stored and how clinical records may be accessed in accordance with OAR 333-035-0155.

OAR 333-035-0190 Infection Control

A hospice program shall develop, implement and maintain an infection control program to prevent and control infections and communicable diseases. The program shall include at a minimum:

(3) Development and maintenance of policies and procedures that include, at a minimum:

OAR 333-035-0210 Criminal Records Check

- (7)(a) A hospice program shall require a SI to report to the hospice program within 10 days :(a) A-any criminal conviction, a-arrest, indictment, or charge for a sexual offense or property crime, or and any disciplinary action taken by a health professional regulatory board or agency.
- (b) A hospice program shall conduct a fitness determination in accordance with section (3) to determine whether the SI is fit to continue to hold position.

Bernadette Nunley, National Director of Policy, Compassion & Choices

Bernadette Nunley submitted written comments on behalf of Compassion & Choices, thanking the agency for the opportunity to serve on the Rules Advisory Committee for Hospice Program Licensure Requirements. They wrote that Compassion & Choices strongly supports OAR 333-035-0125(5) "requiring notice of change of ownership, particularly as small, locally-owned hospices are increasingly bought by private equity firms and organizations that may refuse to provide or allow certain end-of-life care

options." They further wrote that "we encourage data collection and public release of information when changes in ownership and policies limit access to the full range of end-of-life care options."

Bernadette Nunley wrote that "we support the intentions to reconvene this RAC following CMS rules release relating to minimum requirements such as providing services regardless of ability to pay and minimum demonstration outreach efforts. Until then, while we support the waiver language for the geographic service areas (OAR 333-035-0160(4)), we recommend specifically including protections for 'sexual orientation or gender identity-related barriers to hospice services'." They cited that "studies show that lesbian, gay and bisexual older adults are more likely than their heterosexual peers to experience health disparities, discrimination from healthcare providers based on sexual orientation and rejection from their family of origin, all of which can complicate medical care and decision making, as well as end-of-life arrangements. As a result, this population should be included as an 'underserved population'."

Bernadette Nunley further wrote that "we support the addition of advance care planning in OAR 333-035-0170. We encourage reducing the time period for this requirement. Individuals enrolling in hospice should be offered advance directive materials and encouraged to designate a health care representative at enrollment. We also recommend the State develop a standardized advance directive that must be offered to hospice patients."

Bernadette Nunley's written comments, submitted on behalf of Compassion & Choices, are attached to this report as Exhibit 2.

Agency response: The Authority thanks Bernadette Nunley for their comments. With regards to change of owner, the Health Care Market Oversight (HCMO) program established within the Oregon Health Authority, Health Policy and Analytics Division, Office of Health Policy is responsible for the oversight of health care consolidation in Oregon. The HCMO is responsible for reviewing business deals involving health care entities, including hospitals, coordinated care organizations, or any other person or business entity that has as a primary function the provision of health care items or services, including physical, behavioral or dental health items or services. One of the aims of this program is to support statewide priorities including ensuring that health care consolidation in Oregon supports statewide goals related to health equity, lower costs, increase access, and better quality. Transactions subject to review, as well as requirements for review, are found under OAR chapter 409, division 070. The Public Health Division will share Compassion and Choices' written comments with the Health Policy and Analytics Division for future consideration.

The Authority appreciates the information forwarded regarding advance care and endof-life planning among lesbian, gay and bisexual older adults and barriers to palliative care for these communities. The Authority is amenable to changing the definition of 'underserved population' under OAR 333-035-0160(5) to include references to sexual orientation and gender identity as follows:

(5) As used in this rule, "underserved area or population" means an area in which residents have a shortage of available hospice services or a group of persons who face economic, racial, cultural, linguistic, religious, sexual orientation, gender-identity, or age-related barriers to hospice services.

Lastly, advance care planning regulations and specifically the adoption of the form used is the responsibility of the Advance Directive Advisory Committee (ADAC) established pursuant to ORS 127.532. The form must be reviewed every four years by the ADAC, and any changes adopted by the ADAC must be ratified by the Oregon Legislature. During the 2021 legislative session, the Oregon Legislature ratified the ADAC adopted advance directive form with passage of SB 199. This form is available at: https://www.oregon.gov/oha/PH/ABOUT/Pages/ADAC-Forms.aspx as well as a user guide to help persons complete the form and includes the answers to many questions that a person may have about the form.

The timing of when a hospice program must provide information about an advance directive is established under ORS 127.652(3) which states, "The written information described in ORS 127.649(1) shall be provided by a home health agency or a hospice program, not later than 15 days after the initial provision of care by the agency or program but in any event before ceasing to provide care."

OFFICE OF THE SECRETARY OF STATE

SHEMIA FAGAN SECRETARY OF STATE

CHERYL MYERS DEPUTY SECRETARY OF STATE



ARCHIVES DIVISION

STEPHANIE CLARK **DIRECTOR**

800 SUMMER STREET NE **SALEM, OR 97310** 503-373-0701

NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333 OREGON HEALTH AUTHORITY PUBLIC HEALTH DIVISION

FILED

11/21/2022 11:35 AM **ARCHIVES DIVISION** SECRETARY OF STATE

FILING CAPTION: Hospice program licensure requirements

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 12/21/2022 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Filed By:

Public Health Division

Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 12/20/2022 TIME: 10:00 AM **OFFICER: Staff**

ADDRESS: Microsoft Teams - Video/teleconference call

Due to COVID-19 some public meetings are

being held virtually Portland, OR 97232

SPECIAL INSTRUCTIONS:

Due to COVID-19, some public meetings are being held remotely. To provide oral testimony during this hearing, please contact publichealth.rules@odhsoha.oregon.gov to register and receive the link for the Microsoft Teams video conference. Alternatively, you may dial 971-277-2343, Phone Conference ID 223 229 490# for audio only.

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide free help. Some examples are: sign language and spoken language interpreters, real-time captioning, braille, large print, audio, and written materials in other languages. If you need help with these services, please contact the Public Health Division at 971-673-1222, 711 TTY or publichealth.rules@odhsoha.oregon.gov at least 48 hours before the meeting. All relay calls are accepted. To best ensure our ability to provide a modification please contact us if you are considering attending the meeting and require a modification. The earlier you make a request the more likely we can meet the need.

NEED FOR THE RULE(S)

The Oregon Health Authority (Authority), Public Health Division, Health Care Regulation and Quality Improvement (HCRQI) section is proposing to permanently adopt, amend, and repeal Oregon Administrative Rules in chapter 333, division 035 relating to the licensing requirements for hospice programs in Oregon. These administrative rules have not been updated since 2010 and are being revised to align with other acute and continuing care license types and changes

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

- ORS chapter 443: https://www.oregonlegislature.gov/bills_laws/ors/ors443.html
- 42 CFR 418: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-418?toc=1

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Hospice programs provide hospice services to fragile Oregon citizens which are frequently provided in the client's home. Hospice services include palliative care and supportive services that affect both clients and their families during the final stages of life, including periods of illness, dying, and bereavement. The Authority, in accordance with ORS 443.860, is required to and responsible for licensing hospice programs in Oregon and ensuring that hospice services are safe and comply with regulatory standards.

In Oregon and nationally, systemic racism, oppression, discrimination, and bias have created significant barriers for people of color, LGBTQIA2S+, people experiencing poverty, and people with disabilities trying to access all forms of healthcare, including palliative care, and quality end-of-life care.

These rules prescribe minimum requirements for licensure and do not address payment or access to hospice care. Members of the Rule Advisory Committee (RAC) acknowledged that hospice programs traditionally have not done a good job serving communities of color or underserved populations. It was further noted that people living in poverty is a barrier to obtaining hospice services as a hospice program may refuse to serve a patient based on ability to pay. It is anticipated that the federal Centers for Medicare and Medicaid Services (CMS) will be releasing final rules soon that may include measures such as outreach requirements and other factors to increase access to services. The RAC encouraged the Authority to reconvene the RAC after those CMS rules have been released in order to strengthen Oregon requirements relating to minimum requirements such as providing services regardless of ability to pay and minimum demonstration outreach efforts. The Authority has created waiver language for the geographic service areas with the intention of making it possible for hospice programs that serve historically underserved populations to serve a larger service area.

FISCAL AND ECONOMIC IMPACT:

There are currently 72 licensed hospice programs in Oregon; 58 hospice programs are currently certified by the Centers for Medicare and Medicaid Services (CMS) and 14 are license only. While current regulations require compliance with 42 CFR Part 418, agencies are not required to be CMS certified. Compliance with federal regulation therefore is not expected to cause a fiscal or economic impact. The following additional elements may create a financial burden on currently licensed hospice programs:

- Staff time necessary to track and report changes to ownership, organizational structure or other information noted on the application form to the Authority within 30 days of the change;
- Staff time and costs associated with notifying patients within 14 calendar days if the hospice program closes or its license is suspended or revoked and the necessary storage of clinical records;
- Staff time necessary and costs associated with development of additional infection control policies and procedures that address standard precautions and availability of personal protective equipment;
- Staff time necessary to document in writing quarterly quality assessment and performance improvement activities; and
- Costs associated with providing health care interpreter services to persons who prefer to communicate in a language other than English which is currently required under OAR 333-002-0010.

COST OF COMPLIANCE:

- (1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).
- (1) The Oregon Health Authority, Public Health Division is not anticipating any increased costs as it is already responsible for licensing, surveying and conducting complaint investigations relating to hospice programs. There are no anticipated increased costs to local government or the public.
- (2)(a) The Oregon Health Authority, Public Health Division does not collect or have access to data on the number of persons employed by licensed hospice programs and therefore cannot estimate with any accuracy how many agencies are a small business.
- (b) Additional reporting, recordkeeping and other administrative duties are anticipated for the following requirements, but the Authority acknowledges that many hospice programs may already comply with these provisions:
- Reporting changes to ownership, organizational structure or other information noted on the application form to the Authority within 30 days of the change;
- Notifying patients within 14 calendar days if the hospice program closes or its license is suspended or revoked and necessary storage of clinical records;
- Development of additional infection control policies and procedures that address standard precautions and availability of personal protective equipment; and
- Written documentation of quarterly quality assessment and performance improvement activities.
- (c) The Authority anticipates there would be additional costs for the items below, but acknowledge that many hospice programs may already comply with these provisions:
- Providing health care interpreter services to persons who prefer to communicate in a language other than English which is currently required under OAR 333-002-0010; and
- Availability of personal protective equipment and other equipment necessary to implement a plan of care.

Hospice programs may see a cost savings, especially in rural Oregon, given the removal of the requirement that a hospice aide must be a certified nursing assistant (CNA).

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

A RAC was convened that included programs from rural Oregon. The Authority sent multiple correspondence seeking participants from hospice programs, communities of color, tribal nations, and other communities to participate.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

333-035-0105, 333-035-0110, 333-035-0115, 333-035-0120, 333-035-0125, 333-035-0130, 333-035-0135, 333-035-0140, 333-035-0145, 333-035-0150, 333-035-0155, 333-035-0160, 333-035-0170, 333-035-0175, 333-035-0180, 333-035-0190, 333-035-0200, 333-035-0210, 333-035-0220, 333-035-0230, 333-035-0240, 333-035-0250, 333-035-0260, 333-035-0270, 333-035-0280, 333-035-0290, 333-035-0300

REPEAL: 333-035-0105

RULE SUMMARY: Repeal OAR 333-035-0105 – Repeals the rule relating to applicability as the dates no longer apply.

CHANGES TO RULE:

333-035-0105

Applicability of Rules

- (1) A hospice program already in operation on September 1, 2010 shall apply to the Division for a license and pay the applicable fee by October 1, 2010.¶
- (2) The Division shall allow a hospice program already in operation on September 1, 2010, three months from its date of application before an on-site inspection is conducted, in order to allow a hospice program to come into compliance with these rules.¶
- (3) A hospice program already in operation on September 1, 2010 shall conduct criminal background checks in accordance with OAR 333-035-0060 prior to September 1, 2012.

RULE SUMMARY: Amend 333-035-0110 (renumbered from 333-035-0045) – Minor corrections made for readability CHANGES TO RULE:

333-035-0110 Purpose ¶



These rules establish the authority of the Oregon Health Authority, Public Health Division to license hospice programs in order to ensure the health and safety of individuals who are experiencing the last phases of life purpose of these rules is to establish the standards for licensure of hospice programs.

RULE SUMMARY: Adopt 333-035-0115 – Places requirement that a hospice program must comply with federal Conditions of Participation that govern hospice programs under its own rule for clarity.

CHANGES TO RULE:

333-035-0115

Compliance with CMS Conditions of Participation

(1) Hospice programs must comply with the Conditions of Participation governing hospice programs prescribed by CMS, under 42 CFR Part 418, adopted by reference. A licensed hospice program that is not currently certified by CMS must ensure that it complies with this rule no later than [insert six months from effective date of rule.]¶
(2) In addition to the requirements of 42 CFR 418, hospice programs must also comply with OAR 333-035-0110 through 333-035-0300.

RULE SUMMARY: Amend 333-035-0120 (renumbered from 333-035-0050) – Amends definitions for clarity. Removes definition for "Division" and replaces with "Authority." Removes requirement that a hospice aide must be certified by the Oregon State Board of Nursing as a nursing assistant to align with federal regulations. Aligns definitions with Oregon statute and clarifies purpose of interdisciplinary team. Adds definition for "Parent hospice program," "Palliative care." and "These rules."

CHANGES TO RULE:

333-035-0120 Definitions ¶

As used in OAR chapter 333, division 35, the following definitions apply:

- (1) "Accreditation" means a designation by an accrediting organization that a hospice program has met standards that have been developed to indicate a quality program.¶
- (2) "Administrator" means a $\frac{\text{person}}{\text{hospice employee}}$ responsible for the administrative functions and $\frac{\text{day-to-day}}{\text{operations}}$ of the hospice program.
- (3) "Authority" means the Oregon Health Authority, Public Health Division. ¶
- (4) "CMS" means Centers for Medicare and Medicaid Services.¶
- (45) "Certification" means a state agency's official recommendations and findings to CMS regarding a hospice program's compliance with federal CMS regulations.¶
- (56) "Conditions of Participation" mean the applicable federal regulations that hospice programs are required to comply with in order to participate in the federal Medicare and Medicaid programs.
- (67) "Division" means the Oregon Health Authority, Public Health Division. Hospice aide" means a person: ¶
 (a) Certified by the Oregon State Board of Nursing as a certified nursing assistant (CNA) under ORS 678.442; ¶
- (7<u>b</u>) "Hospice aide" has the same meanWho has successfully completed a training program and competency evaluation in accordance with 42 CFR 418.76(a); or ¶
- (c) Who has successfully completed a competency evaluation in gas nurse's aide. ccordance with 42 CFR 418.76(c). \P
- (8) "Hospice program" means a coordinated program of home and inpatient care, available 24 hours a day, that utilizes an interdisciplinary team of personnel trained to provide palliative and supportive services to a patient-family unit experiencing a life-<u>-</u>threatening disease with a limited medical prognosis. A hospice program is an institution for purposes of ORS 146.100.¶
- (9) "Hospice services" means items and services provided to a patient-family unit by a hospice program or by other individuals or community agencies under a consulting or contractual arrangement with a hospice program. Hospice services include home care, inpatient care for acute pain and symptom management or respite, and bereavement services provided to meet the physical, psychosocial, emotional, spiritual and other special needs of a patient-family unit during the final stages of illness, dying and the bereavement period.¶
- (10)(a) "Interdisciplinary team" means a group of individuals working together in a coordinated manner to provide hospice care. An interdisciplinary team includes, but is not limited to, the patient-family unit, the patient's attending physician or clinician and one or more of the following hospice program personnel:¶

(a who are trained and experienced to provide hospice care: ¶

- (A) Physician;¶
- (B) Physician assistant;¶
- (bC) Nurse practitioner;¶
- (\underline{eD}) Nurse;¶
- (dE) Nurse's aide or hospice aide;¶
- (eF) Occupational therapist:¶
- (fG) Physical therapist;¶
- (gH) Trained lay volunteer:¶
- (hl) Clergy or spiritual counselor; or ¶
- $(i\underline{J})$ Credentialed mental health professional such as psychiatrist, psychologist, psychiatric nurse or social worker: or¶
- (K) Naturopathic physician.¶
- (b) The interdisciplinary team is not the same as the interdisciplinary group as that term is defined under 42 CFR 418.56; however, interdisciplinary team members may be included in the interdisciplinary group meetings. The purpose of the interdisciplinary team is to include the patient, patient's family, and the patient's attending physician or clinician when formulating a plan of care to ensure that the full range of needs of the patient and

family are met. ¶

- (11) "Medicare Certification Number" means the unique identification number, also referred to as the Medicare Provider Number, assigned to a qualifying hospice program by CMS.¶
- (12) "Nurse's Aaide" means a person CNA certified as a nursing assistant under ORS 678.442 who has received special hospice training in accordance with CMS Conditions of Particip by the Oregon State Board of Nursing under ORS 678.442.¶
- (13) "Palliative care" has the meaning given that term in ORS 413.273. ¶
- (14) "Parent hospice program" means the program that provides supervision and administrative control to multiple locations providing care that are within a 60-mile radius from the parent hospice program's physical location.¶



- (135) "Patient-family unit" includes an individual who has a life-threatening disease with a limited prognosis and all others sharing housing, common ancestry or a common personal commitment with the individual.
- (146) "Person" includes individuals, organizations and groups of organizations.¶
- (157) "Survey" means an inspection of an applicant for a hospice program license or a hospice program to determine the extent to which the applicant or hospice program is in compliance with state hospice program statutes, these rules and CMS Conditions of Participation.
- (18) "These rules" means OAR 333-035-0110 through 333-035-0300.

Statutory/Other Authority: ORS 443.860

Statutes/Other Implemented: ORS 443.850, 443.867

RULE SUMMARY: Amend 333-035-0125 (renumbered from 333-035-0055 – Amends application requirements and clarifies that the Authority may reject an application that is incomplete. Specifies that a hospice program must report to the Authority within 30 days of any change in ownership and other business information. Clarifies that a hospice program may provide palliative care. Clarifies requirements for a hospice located in a border state to provide care to an Oregon patient. Specifies that license fees may not be prorated and are non-refundable. Moves information about surveys to new rule number 333-035-0240. Information on issuing a license was removed and placed under new rule number 333-035-0135. Information on expiration and renewal of a license was removed and placed under new rule number 333-035-0145. Requirements for providing care at multiple locations was removed and placed under new rule number 333-035-0135. Mileage radius and waiving mileage guidelines was removed and placed under new rule 333-035-0160.

CHANGES TO RULE:

333-035-0125

Application for Licensingure and Fees ¶

- (1) A person may not establish, conduct or maintain a hospice program providing hospice services, or hold itself out to the public as a hospice program, without obtaining a license from the DivisionAuthority. ¶

 (2)(a) A person may applywishing to apply for a new or renewal license to operate a hospice program by shall submitting a complete application on a form prescribed by the DivisionAuthority, accompanied by the fee establishspecified in ORS 443.860. An application that is incomplete or that is not accompanied by the correct fee will be returned to the person applying. ¶
- (3) In order for a license application to be considered complete, it shall include, but is not limited to: ¶
 (a) Business name; ¶
- (b) Medicare Certification Number (Medicare Provider Number)(if applicable); ¶
- (c) Prim¶
- (b) A complete application for an initial license includes, but is not limited to: ¶
- (A) Documentation of written policies and procedures, including any forms and curricula to direct all administrative, personnel, and patient care operations;¶
- (B) Documentation that patient carye and multiple locations (if any); documentation systems have been developed; and ¶
- (dC) Tax status; ¶
- (e) Ownership category (for example corporation, partnership, sole proprietorship); ¶
- (f) Physical and mailing addresses: ¶
- (g) Owner information; Documentation that sufficient, qualified, and trained employees or contractors are available to provide hospice services and that personnel records have been prepared for each employee or contractor.¶
- (h3) Descriptions of services; ¶
- (i) Staffing levels; and ¶
- (i) Average daily census. ¶
- (4) The Division shall conduct an initial survey prior to licensure. ¶
- (5) In lieu of an initial survey required under The Authority may deem an application incomplete if it does not include the information required by the Authority, is not accompanied by the appropriate fee, or at the time of initial survey fails to comply with subsection (42)(b) of this rule, the Division may accept a CMS certification or a survey conducted within the previous three years by an accrediting organization approved by the Division. ¶
 (6) A hospice program licensed in Washington, Idaho or California must be licensed in Oregon in order to provide care in Oregon within a 60 mile radius of the parent agency in the other state. A hospice program licensed in these other states shall pay the required fee and the Division:.¶
- (4) The Authority may reject an application that is incomplete.¶
- (5)(a) Within 30 days of the change, a hospice program must inform the Authority in writing of any change in:¶ (A) Ownership;¶
- (B) Ownership category (for example, corporation, partnership, sole proprietorship);¶
- (C) Administrator; ¶
- (aD) Shall conduct a licensing survey; or Business name; ¶
- (bE) May accept a CMS certification or a survey conducted within the previous three years by an accrediting

organization approved by the Division. edicare certification number;¶

(F) Primary and multiple locations; or ¶

(7G) The Division may waive the Physical and maileage guideline in section (6ing address. ¶

- (b) o<u>l</u>f this rule if the parentownership of a hospice program proposchanges, to providhe hospice services to an underserved area of the state and adequately demonstrates the ability to manage and control the services. program must submit a new license application indicating change of ownership along with the required fee.¶
 (8c) The Division shall issue a license to an applicant that has the necessary qualifications, meets all requirements established by the Division, meets the CMS Conditions of Participation for hospice programs found in 42 CFR Part 418, and has paid the <u>lf</u> a parent hospice program moves 30 miles or more from its current physical location, the parent hospice program must apply for a new license and pay the required fee.-¶
- (96) A license issued under this section is valid for one year and is not transferable. ¶
- (10) A licensee may apply for renewal of a license by completing a renewal application on a form prescribed by the Division and submission of the applicable fee. The Division shall renew a license if the licensee is in compliance with ORS 443.850 through 443.869, these rules, and CMS Conditions of Participation, 42 CFR Part 418.¶ (11) The Division may permit a hospice program providing care at multiple locations, to operate under one license for all locations, if: ¶
- (a) All locations are operating under the same Medicare Certification Number; The Authority may issue a civil penalty for failure to timely notify the Authority of any changes under section (5) of this rule or suspend, revoke or deny the license. ¶
- (7) A hospice program may provide palliative care in addition to hospice services as defined in these rules. A hospice program providing palliative care is not subject to licensure as an in-home care agency under ORS 443.867. ¶
- (b8) The multiple location provides the same full range of care and services that is required by the hospice program issued the Medicare Certification Number; and \P
- (c) The locations are located within a 60 mile radius of the parent A hospice program licensed in a bordering state must be licensed in Oregon to provide care to patients located in Oregon. The hospice program applying for licensure. ¶
- (12) The Division may waive the mileage guideline in subsection (11)(c) of this rule if the parent hospice program proposes to provide hospice services to an undermust apply and be licensed in accordance with these rules. The hospice program is subject to these rules including, the geographic serviced area of the state and adequately demonstrates the ability to manage and control the services restrictions specified in OAR 333-035-0160. ¶ (139) An applicant or licensee may be required by CMS to obtain a survey by a CMS deemed accrediting organization in addition to any survey conducted by the Division under section (4) of this rule or OAR 333-035-0075 hospice program license is nontransferable. ¶

(10) Licensure fees are not prorated and are non-refundable.

Statutory/Other Authority: ORS 443.860

Statutes/Other Implemented: ORS 443.860, 443.867

RULE SUMMARY: Adopt 333-035-0130 – Specifies the responsibilities of the Authority in reviewing a license application.

CHANGES TO RULE:



333-035-0130

Review of License Application

In reviewing an application for a hospice program license, the Authority shall:

(1) Confirm receipt of the required fee and determine if the application is complete; ¶

(2) Verify that the program is primarily engaged in providing hospice services and complies with hospice program licensing laws under ORS 443.860 through 443.869 and these rules; and ¶

(3) Assess capacity for compliance with the Conditions of Participation prescribed by CMS, under 42 CFR 418. ¶

(4) Conduct a survey of the hospice program in accordance with OAR 333-035-0240.¶

(5) If a hospice program is in compliance with ORS chapter 443 and these rules and intends to provide hospice services to patients, a license may be issued for the operation of the hospice program.

RULE SUMMARY: Adopt 333-035-0135 – Identifies the responsibilities of the Authority and an applicant when a license is approved.

CHANGES TO RULE:

333-035-0135

Approval of License Application

- (1) The Authority shall notify an applicant in writing if a license application is approved.
- (2) A license shall be issued only for the hospice program and person(s) named in the application and may not be transferred or assigned. ¶
- (3) The license shall be posted in a clearly visible location in an office that is open to the public. ¶
- (4) A licensed hospice program shall not in any manner or by any means assert, represent, offer, provide or imply that the program is or may render care or services other than that is permitted or within the scope of the issued license. A licensed hospice program shall not offer or provide any service that is not authorized within the scope of the license. ¶
- (5) The Authority may permit a hospice program providing care at multiple locations, to operate under one license for all locations, if: ¶
- (a) All locations are operating under the same Medicare Certification Number; ¶
- (b) All locations provide the same full range of care and services that is offered by the CMS certified hospice program issued the Medicare Certification Number; and \P
- (c) The locations comply with OAR 333-035-0160.

RULE SUMMARY: Adopt 333-035-0140 – Specifies that the Authority will use the process described in ORS chapter 183 if it intends to deny a license application.

CHANGES TO RULE:

333-035-0140

Denial of License Application

If the Authority intends to deny a license application, it shall issue a Notice of Intent to Deny in accordance with ORS 183.411 through 183.470.

RULE SUMMARY: Adopt 333-035-0145 – Specifies when a license will expire and renewal application requirements.

CHANGES TO RULE:

333-035-0145

F



Expiration and Renewal of License

(1) Each license to operate a hospice program expires 12 months from the date of issue. ¶

(2) A hospice program shall submit a completed application for renewal on a form prescribed by the Authority, accompanied by the required fee, to the Authority not less than 30 days prior to the license expiration date. (3) A hospice program is not eligible for renewal if a complete renewal application and fee have not been submitted to the Authority within 30 days after the license has expired. To be licensed, the hospice program must submit a new application under OAR 333-035-0125.

(4) The Authority may deny a renewal license if the hospice program failed to timely notify the Authority of any changes specified under OAR 333-035-0125(5) or if there are violations of ORS chapter 443 or these rules. ¶

(5) The Authority may deem an application incomplete if it does not include the information required by the Authority or is not accompanied by the appropriate fee. The Authority may reject an application that is incomplete.¶

(6) If the ownership of a hospice program changes, other than at the time of the annual renewal, the hospice program shall comply with OAR 333-035-0125(5) and submit a change of ownership form along with the fee for a new license.

RULE SUMMARY: Adopt 333-035-0150 – Specifies that the Authority will use the process described in with ORS chapter 183 if it intends to deny, suspend or revoke or license or issue a civil penalty.

CHANGES TO RULE:





333-035-0150

Denial, Suspension, or Revocation of License

(1) The Authority may impose a civil penalty or deny, suspend or revoke a program's license for failure to comply with ORS chapter 443 or these rules.¶

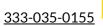
(2) If the Authority intends to impose a civil penalty or deny, suspend or revoke a hospice program license, it shall do so in accordance with ORS 183.411 through 183.745.

Statutory/Other Authority: ORS 443.860

Statutes/Other Implemented: ORS 443.864, 443.869

RULE SUMMARY: Adopt 333-035-0155 – Specifies a hospice licensee's responsibility to return a license if the license is suspended or revoked. Specifies that if the hospice program decides to discontinue its operations it must return license, notify patients and a patient's representative, and provide for storage of clinical records.

CHANGES TO RULE:





Return of License and Hospice Program Closure

(1) If a hospice program's license is suspended, revoked, or if the hospice program decides to discontinue operations, the license certificate in the licensee's possession shall be returned to the Authority immediately.¶ (2) A hospice program that discontinues operations must:¶

(a) Inform patients or the patient's representative about the closure at least 14 calendar days prior to closure;¶ (b) Provide information about how an individual may obtain their clinical records;¶

(c) Notify the Authority at least 14 calendar days prior to closure and submit plans for the transfer, storage and disposal of clinical records. ¶

(3) Clinical records not claimed that are less than seven years old from the last date of discharge shall be stored until they are more than seven years old from last date of discharge. Clinical records that are greater than seven years old from last date of discharge may be destroyed. The clinical records of a patient less than 18 years of age shall be kept at least seven years after the patient reached the age of 18.

<u>Statutory/Other Authority: ORS 443.860</u> <u>Statutes/Other Implemented: ORS 443.860</u>

RULE SUMMARY: Adopt 333-035-0160 – Defines the geographic service area for a hospice program to operate. Allows multiple locations within a portion of the area served and specifies criteria for a hospice program to operate multiple locations under one license. Specifies requirements of a licensee that moves its physical location. Allows mileage guidelines to be waived under specified circumstances.

CHANGES TO RULE:

333-035-0160

Geographic Service Area

- (1) A hospice program serves a geographic service area that is within a 60-mile radius from the physical location of the hospice program. ¶
- (3) The Authority may permit a hospice program providing care at multiple locations, to operate under one license for all locations, if: ¶
- (a) All locations are operating under the same Medicare Certification Number; ¶
- (b) All locations provide the same range of care and services offered by the parent hospice program certified by CMS; and \P
- (c) The multiple locations are located within a 60-mile radius of the parent hospice program applying for licensure. \P
- (4) The Authority may waive the geographical restrictions specified in this rule in accordance with OAR 333-035-0300, including but not limited to, if the parent hospice program proposes to provide hospice services to an underserved area or population of the state and adequately demonstrates the ability to manage and control the services. ¶
- (5) As used in this rule, "underserved area or population" means an area in which residents have a shortage of available hospice services or a group of persons who face economic, racial, cultural, linguistic, religious or age related barriers to hospice services.

RULE SUMMARY: Adopt 333-035-0170 – Specifies that a hospice program must maintain written policies and procedures relating to advance directives in accordance with ORS 127.649 and must provide patients with material in accordance with ORS 127.652.

CHANGES TO RULE:

333-035-0170

Advance Directives

(1) A hospice program shall comply with ORS 127.649 relating to written policies and procedures on providing information to patients on a patient's right to make health care decisions. ¶

(2) In accordance with ORS 127.652, a hospice program shall provide to a patient the materials necessary to execute an advance directive or a form appointing a health care representative no later than 15 days after the initial provision of care by the hospice program, but in any event before ceasing to provide care to the patient. Statutory/Other Authority: ORS 443.860

Statutes/Other Implemented: ORS 127.649, 127.652, 443.860

RULE SUMMARY: Adopt 333-035-0175 – Specifies that a hospice program must comply with health care interpreter services as defined in OAR 333-002-0010 for a patient who prefers to communicate in a language other than English.

CHANGES TO RULE:

333-035-0175

Health Care Interpreter Services

A hospice program shall comply with ORS 413.559 and OAR 333-002-0250 to provide health care interpreting services as defined in OAR 333-002-0010 to a patient who prefers to communicate in a language other than English.

Statutory/Other Authority: ORS 443.860

Statutes/Other Implemented: ORS 413.559, 413.561, 443.860

RULE SUMMARY: Adopt 333-035-0180 – Specifies requirements related to retaining clinical records including when a hospice program changes ownership or closes.

CHANGES TO RULE:

333-035-0180

Clinical Records

(1) If a hospice program changes ownership, the hospice program shall retain all clinical records in written or electronic form, and it shall be the responsibility of the successor hospice program to protect and maintain these records in accordance with OAR 333-035-0155(3).¶

(2) In the event of dissolution of a hospice program, the hospice program administrator shall notify the Authority where the clinical records will be stored in accordance with OAR 333-035-0155.¶

(3) A hospice program shall comply with 45 CFR Part 160, subparts A and E of 45 CFR Part 164, and ORS 192.553 through 192.581.

<u>Statutory/Other Authority: ORS 443.860</u> <u>Statutes/Other Implemented: ORS 443.860</u>

RULE SUMMARY: Adopt 333-035-0190 – Requires a hospice program to develop an infection control program and specifies requirements.

CHANGES TO RULE:

333-035-0190

Infection Control

A hospice program shall develop an infection control program to prevent and control infections and communicable diseases. The program shall include at a minimum: ¶

- (1) A tuberculosis infection control plan in accordance with OAR 333-019-0041;¶
- (2) Appropriate disposal of sharp instruments in accordance with OAR 333-056-0050; ¶
- (3) Development of policies and procedures that include, at a minimum: ¶
- (a) Standard precautions such as hand hygiene, respiratory hygiene and cough etiquette, and personal protective equipment;¶
- (b) Availability of personal protective equipment and other equipment necessary to implement plan of care; and ¶
- (c) Exposure to bloodborne pathogens such as Hepatitis B and HIV and other potentially infectious agents. ¶
- (4) Education and training on infection control measures to staff, patients, and caregivers.

RULE SUMMARY: Adopt 333-035-0200 – Adds state specific requirements to the existing federal requirement for quality assessment and performance improvement activities.

CHANGES TO RULE:

333-035-0200

Quality Assessment and Performance Improvement

A hospice program must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished to a patient. A hospice program must document this information at least quarterly and record any performance improvement activities at least quarterly.

RULE SUMMARY: Amend 333-035-0210 (renumbered from 333-035-0060) – Adds definitions for 'disqualifying condition,' 'subject individual,' and 'fitness determination.' Clarifies weigh test requirements. Clarifies that a hospice program does not need to complete a background check on contracted staff if the agency the hospice program contracts with has conducted a background check. Minor corrections made for readability.

CHANGES TO RULE:

333-035-0210

Criminal Background Records Checks ¶ [=]



- (1) Except as provided in section (7) of this rule, As used in this rule: ¶
- (a) "Disqualifying condition" means a non-criminal personal history issue that makes a subject individual unsuitable for employment, contracting or volunteering for a hospice program-must obtain a criminal background check for the following prior to employment, entering into a contract, or permitting a volunteer to have direct patient contact and every three years thereafter:, including but not limited to discipline by a licensing or certifying agency, or drug or alcohol dependency; ¶
- (b) "Subject individual (SI)" means an individual on whom a hospice program may conduct a criminal records check including:¶
- (A) An employee or prospective employee;¶
- (B) A contractor, temporary worker, or volunteer who may have contact with patients or access to personal information about patients, including but not limited to Social Security numbers, dates of birth, driver license numbers, medical information, personal financial information, or criminal background information; and ¶
- (C) A prospective contractor, temporary worker, or volunteer who may have contact with patients or access to personal information about patients including but not limited to Social Security numbers, dates of birth, driver license numbers, medical information, personal financial information, or criminal background information. (ac) Hospice program employees; ¶
- (b) Individuals who contract with the hospice program and who have direct patient contact or access to patient records; and ¶
- (c) V"Fitness determination" means a decision made by a hospice program pursuant to the policy established in accordance with section (3) of this rule, that a subject individual is or is not fit to hold a position, paid or not paid, have direct access, or otherwise provide services to a patient.¶
- (2) Except as provided in section (8) of this rule, a hospice program must conduct a criminal records check on a subject individual and make a fitness determination prior to employment, and prior to entering into a contract, or permitting a volunteers wh to have direct patient contact or access to patient records ersonal information about a patient.¶
- (23) A hospice program must have written policies and procedures for conducting <u>a</u> criminal background checksrecords check and making a fitness determination in accordance with section (12) of this rule including a description of <u>any</u> criminal convictions that <u>or other</u> disqualifies an individual ying condition that would disqualify <u>a SI</u> from being employed, contracted with or working as a volunteer.¶
- (3) If the criminal background check or other information obtained by a hospice program indica The policies and procedures must include at a minimum:¶
- (a) Provisions for performing a weigh test; an employee, contractor or volunteerd¶
- (b) Weigh test actions should a criminal records check indicate that a SI has been convicted of a-crimes against a person or property that reasonably raises questions about the ability of that individual to safely provide services or care, the hospice program shall notify the individual in writing that they have been found unfit to be employed, contracted with or to be a volunteer.n individual or property, or other disqualifying condition.¶
- (4) In performing a weigh test, the hospice program shall consider circumstances regarding the nature of the potentially disqualifying conviction or condition using the criteria established under ORS 181A.195(10)(c). ¶
- (4<u>5</u>) If an individual <u>SI</u> has been found unfit in accordance with section (3<u>2</u>) of this rule, the hospice program shall provide that individual notify the <u>SI</u> and provide the <u>SI</u> with information on how to appeal to the source of the criminal background records check if the individual <u>SI</u> believes the records are in error.¶
- (56) A hospice program shall keep the information obtained from <u>a</u> criminal background checks confidential and use it solely to determine an individual <u>SI</u>'s eligibility to be employed, contracted with or to be a volunteer.¶
- (67) A hospice program shall require the individuals described in subsection (1)(a) through (c) of this rule a SI to report within 10 days:¶
- (a) Any criminal conviction; ¶

- (b) Any arrest, indictment, or charge for a sexual offense or property crime; and ¶
- (c) Any disciplinary action taken by a health professional regulatory board or agency. ¶
- (78) An individual Notwithstanding section (2) of this rule, a hospice program is not required to complete a background check on: ¶
- (a) A SI licensed by a health professional regulatory board as defined in ORS 676.160-is not subject to the criminal background checks described in section (1) of this rule; or¶
- (b) A contractor employed by a company that has completed a criminal records check on the contractor and has determined the contractor is fit to have contact with patients, have access to personal information about the patient, or otherwise provide services to a patient on behalf of the hospice program.¶
- (89) A hospice program shall have policies and procedures that ensure the entities it contracts with have conducted criminal background checks for individuals records checks on a SI that will have direct contact with a patient of the hospice program's patients or access to hospice program patient record or access to personal information about a hospice patient.¶
- (10) A hospice program shall ensure that a criminal records check is performed on a SI every three years from the date of the SI's last criminal records check in accordance with these rules.

RULE SUMMARY: Amend 333-035-0220 (renumbered from 333-035-0065) – Minor grammatical changes and rule number update.

CHANGES TO RULE:

333-035-0220 Complaints ¶

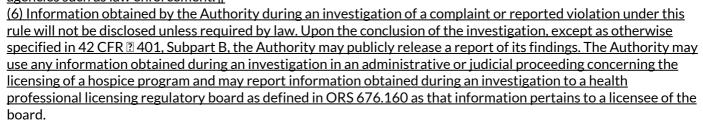
- (1) Any person may make a complaint verbally or in writing to the <u>DivisionAuthority</u> regarding an allegation as to the care or services provided by a hospice program or violations of any hospice program laws or regulations.¶
- (2) The identity of a person making a complaint will be kept confidential.¶
- (3) An investigation will be carried out as soon as practicabl Authority may investigate after the receipt of a complaint in accordance with OAR 333-035-0 $\frac{723}{23}$ 0.
- (43) If the complaint involves an allegation of criminal conduct or an allegation that is within the jurisdiction of another local, state, or federal agency, the <u>Division will Authority may</u> refer the matter to that agency.

RULE SUMMARY: Amend 333-035-0230 (renumbered from 333-035-0070) – Minor corrections made for readability. Specifies that a complaint investigation may be unannounced. Adds caregivers and patient representative to the list of persons that may be interviewed during an investigation. Specifies that all requested documents must be made available to Authority surveyor. Clarifies that a hospice program must cooperate with other agencies investigating allegations of abuse including the Oregon Department of Human Services, Authority's Adult Protective Services, and law enforcement.

CHANGES TO RULE:

333-035-0230 Investigations ¶

- (1) As soon as practicable after receiving a complaint, taking into consideration the nature of the complaint, Division Authority staff may begin an conduct an unannounced complaint investigation.
- (2) A hospice program shall permit <u>DivisionAuthority</u> staff access to any location from which it is operating its program or providing services during an investigation.¶
- (3) An investigation may include but is not limited to: ¶
- (a) Interviews of the complainant, patients of the hospice program, caregivers, patients, a patient's representative, a patient's family members, witnesses, and hospice program management and staff;¶
- (b) On-site observations of the patients and(s), staff performance, or patient environment; and ¶
- (c) Review of documents and records.¶
- (4) Except as otherwise specified in 42 CFR 401, Subpart B, the Division shall draft an investigation report and may make publicly available a copy of that report that does not contain any information that could lead to the identification of the complainant, a patient, or any other information that is confidential under state law hospice program shall timely make all requested documents and records available to the surveyor for review and copying.
- (5) The hospice program shall cooperate with investigations of allegations of abuse and neglect conducted by the Oregon Department of Human Services (ODHS), Oregon Health Authority, Adult Protective Services, and other agencies such as law enforcement.¶



RULE SUMMARY: Amend 333-035-0240 (renumbered from 333-035-0075) – Clarifies that site inspections are inperson. Clarifies that a survey is conducted at time of initial license and every three years thereafter. Describes requirements for the Authority to accept a survey conducted by a federal agency or approved accrediting organization. Specifies that a hospice program administrator must immediately notify the Authority if the deemed status of hospice program changes or if the program decides not to renew its affiliation with the accrediting organization. Removes requirement that an administrator must return a signed copy of the written notice that the agency complies with licensing laws.

CHANGES TO RULE:

333-035-0240 Surveys ¶

- (1) The <u>DivisionAuthority</u> shall, in addition to any investigations conducted under OAR 333-035-007230, conduct at least one survey of each hospice program every three years in-person site inspection of each hospice program prior to licensure and once every three years thereafter as a requirement for licensure, and at such other times as the <u>DivisionAuthority</u> deems necessary.¶
- (2) In lieu of a survey required under section (1) of this rule, the Division may:¶
- (a) Accept certification by a federal agency; or ¶
- (b) Accept a survey perform Authority may accept deemed status by a CMS-approved accrediting organization following a survey conducted within the previous three years by that accrediting organization if:¶
- (a) The certification or accreditation is recognized by the Authority as addressing the standards and Condition for Participation requirements of the CMS and other standards set by the Authority;¶
- (b) The hospice program notifies the Authority to participate in any exit interview conducted by anthe accrediting organization approved by the Divisbody; and ¶
- (c) The hospice program provides copies of all documentation concerning the certification or accreditation requested by the Authority including: ¶
- (B) All progress reports; and ¶
- (C) The letter from CMS indicating its deemed status.¶
- (3) A hospice program administrator must notify the Authority within seven calendar days if: ¶
- (a) The deemed status of the hospice program changes; or ¶
- (b) The hospice program decides not to renew its affiliation with the accrediting organization. ¶
- (34) A hospice program shall permit <u>DivisionAuthority</u> staff access to any location from which it is operating its program or providing services during a survey.¶
- (45) A survey may include but is not limited to: \P
- (a) Interviews of patients, patient family members, hospice program management and staff; \P
- (b) On-site observations of patients and staff performance; ¶
- (c) Review of documents and records; and ¶
- (d) Patient audits.¶
- (56) A hospice program shall <u>timely</u> make all requested documents and records available to the surveyor for review and copying.¶
- (67) Following a survey, Division Authority staff may conduct an exit conference with the hospice program administrator or his or her the administrator's designee. During the exit conference Division Authority staff shall may: ¶
- (a) Inform the hospice program representative of the preliminary findings of the inspection; and ¶
- (b) Give the person a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings.¶
- (78) Following the survey, Division Authority staff shall prepare and provide the hospice program administrator or his or heradministrator's designee specific and timely written notice of the findings.¶
- (89) If the findings result in a referral to another regulatory agency, Division Authority staff shall submit the applicable information to that referral agency for its review and determination of appropriate action.¶
- (910) If no deficiencies are found during a survey, the Division Authority shall issue written findings to the hospice program administrator indicating that fact.¶
- (101) If the surveyor's written notice of findings indicates that the agency was in compliance with hospice program

 $\frac{\text{licensing laws and no }}{\text{deficiencies we}} \underline{\text{are cited}}, \\ \text{the agency administrator or administrator's designee shall sign the written notice and return it to the Division.} \\ \P$

(11) If deficiencies are found, the Division found, the Authority shall take informal or formal enforcement action in compliance with OAR 333-035-0085260 or 333-035-009270.

RULE SUMMARY: Amend 333-025-0250 (renumbered from 333-035-0080) – Minor corrections made for readability. Adds failure to report suspected abuse as a violation.

CHANGES TO RULE:

333-035-0250 Violations ¶

In addition to non-compliance with any <u>law that governs a</u> hospice program licensing law or CMS Conditions of Participation, it is a violation to:¶

- (1) Refuse to cooperate with an investigation or survey, including but not limited to failure to permit Division Authority staff access to the hospice program, its documents or records;¶
- (2) Fail to implement an approved plan of correction; ¶
- (3) Fail to comply with all applicable laws, lawful ordinances and rules relating to safety from fire;¶
- (4) Refuse or fail to comply with an order issued by the Division Authority; ¶
- (5) Refuse or fail to pay a civil penalty;¶
- (6) Fail to comply with rules governing the storage of records following the closure of a hospice program; ¶
- (7) Fail to report suspected abuse when required under ORS 124.060; or ¶

(78) Fail to obtain a license.

RULE SUMMARY: Amend 333-035-0260 (renumbered from 333-035-0085) – Updates term 'Division' to 'Authority.' Changes the number of days that a hospice program has to correct deficiencies from 45 days to 60 days from date of the exit conference. Adds requirements of the Authority if finding a plan of correction is unacceptable.

CHANGES TO RULE:

333-035-0260 Informal Enforcement ¶

- (1) I
 - (1) If during an investigation or survey <u>DivisionAuthority</u> staff document violations of hospice program licensing laws or conditions of participation, the <u>DivisionAuthority</u> may issue a statement of deficiencies that cites the law alleged to have been violated and the facts supporting the allegation.¶
 - (2) A signed plan of correction must be received by the <u>DivisionAuthority</u> within 10 business days from the date the statement of deficiencies was <u>mailreceived</u> to by the hospice program. A signed plan of correction will not be used by the <u>DivisionAuthority</u> as an admission of the violations alleged in the statement of deficiencies.¶
 - (3) A hospice program shall correct all deficiencies within 45<u>60</u> days from the date of the exit conference; unless an extension of time is requested from the <u>DivisionAuthority</u>. A request for such an extension shall be submitted in writing and must accompany the plan of correction.¶
 - (4) The <u>DivisionAuthority</u> shall determine if a written plan of correction is acceptable. If the plan of correction is not acceptable to the <u>Division</u>, the <u>DivisionAuthority</u>, the <u>Authority</u> shall notify the hospice program administrator in writing and ror by telephone:¶
 - (a) Identifying which provisions in the plan the Authority finds unacceptable;¶
 - (b) Citing the reasons the Authority finds them unacceptable; and ¶
 - (c) Requesting that the plan of correction be modified and resubmitted no later than 10 working days from the date the letter of non-acceptance was $\frac{\text{mail}}{\text{receiv}}$ the administrator. ¶
 - (5) If the hospice program does not come into compliance by the date of correction reflected on the plan of correction or 4560 days from date of the exit conference, whichever is sooner, the Division Authority may propose to deny, suspend, or revoke the hospice program license, or impose civil penalties.

RULE SUMMARY: Amend 333-035-0270 (renumbered from 333-035-0090) – Updates term 'Division' to 'Authority.' Specifies that the Authority may reinstate a license that has been suspended after it determines that the hospice program complies with OAR chapter 333, division 027.

CHANGES TO RULE:

333-035-0270 Formal Enforcement ¶

- (1) If during an investigation or survey <u>DivisionAuthority</u> staff document a substantial failure to comply with hospice program licensing laws or conditions of participation, or if a hospice program fails to pay a civil penalty imposed under ORS 443.869, the <u>Division and these rules</u>, the <u>Authority</u> may issue a Notice of Proposed Suspension or Notice of Proposed Revocation in accordance with ORS 183.411 through 183.4701. (2) The <u>DivisionAuthority</u> may issue a Notice of Imposition of Civil Penalty for violations of hospice program licensing laws.
- (3) At any time the Division Authority may issue a Notice of Emergency License Suspension under ORS 183.430(2).¶
- (4) If the <u>DivisionAuthority</u> revokes a hospice program license, the order shall specify when, if ever, the hospice program may reapply for a license.¶
- (5) The Authority may reinstate a hospice program license that has been suspended after the Authority determines that compliance with these rules have been achieved.

RULE SUMMARY: Amend 333-035-0280 (renumbered from 333-035-0095) – Updates term 'Division' to 'Authority.'

CHANGES TO RULE:

333-035-0280 Civil Penalties ¶

- (1) In addition to any other liability or penalty provided by law, the <u>DivisionAuthority</u> may impose a civil penalty of \$1,000 per day, up to \$10,000 in any 30-day period, for any of the following:¶
- (a) Violation of any of the terms or conditions of a license issued under these rules;¶
- (b) Violation of any of these rules or an order issued by the <u>DivisionAuthority</u> to a hospice program licensed under these rules;¶
- (c) Violation of any final order of the <u>directorAuthority</u> that pertains specifically to a hospice program owned or operated by the person incurring the penalty; or¶
- (d) Violation of ORS 443.860 or of the rules adopted under ORS 443.860.¶
- (2) In determining the amount of a civil penalty, the Division Authority shall consider whether: ¶
- (a) The Division Authority made repeated attempts to obtain compliance;¶
- (b) There is a history of noncompliance with hospice program licensing laws; \P
- (c) The violation poses a serious risk to the public's health;¶
- (d) The person or licensee gained financially from the noncompliance; and ¶
- (e) There are mitigating factors, such as a person or licensee's cooperation with an investigation or actions to come into compliance.¶
- (3) The Division Authority shall document its consideration of the factors in section (2) of this rule.¶
- (4) Each day a violation continues is an additional violation.¶
- (5) Civil penalties under this section shall be imposed in the manner provided by ORS 183.745.

RULE SUMMARY: Amend 333-035-0290 (renumbered from 333-035-0100) – Updates term 'Division' to 'Authority' and removes obsolete language.

CHANGES TO RULE:

333-035-0290

Approval of Accrediting Organizations ¶

- (1) An accrediting organization must request approval by the <u>DivisionAuthority</u> to accredit hospice programs in Oregon.¶
- (2) An accrediting organization shall request approval in writing and shall provide, at a minimum: ¶
- (a) Evidence that it is recognized as a deemCMS-approved accrediting organization by CMS; or ¶
- (b) Documentation of program policies and procedures that the accreditation meets standards and conditions established for hospice programs by CMS;¶
- (c) Accreditation history; and ¶
- (d) References from a minimum of two hospice programs currently receiving services from the organization.¶
- (3) If the <u>DivisionAuthority</u> finds that an accrediting organization's qualifications are equal to or exceed state licensing requirements in Oregon, the <u>Division willAuthority may</u> enter into an agreement with the accrediting organization permitting it to accredit hospice programs in Oregon.¶
- (4) CMS will not accept accreditation by an organization that is not a deemed organization by CMS, for purposes of CMS certification.

RULE SUMMARY: Adopt 333-035-0300 – Adds rule that allows a hospice program to request a waiver and specifies information that must be submitted for consideration. Specifies that the Authority may waive a rule that a hospice program is unable to meet for reasons beyond the hospice program's control.

CHANGES TO RULE:

333-035-0300

Waivers

(1) While all hospice programs are required to maintain continuous compliance with these rules, these requirements do not prohibit the use of alternative concepts, methods, procedures, techniques, equipment, facilities, personnel qualifications or the conducting of pilot projects or research. A request for a waiver from a rule must:¶

(a) Be submitted to the Authority in writing;¶

(b) Identify the specific rule for which a waiver is requested;¶

(c) Identify the special circumstances relied upon to justify the waiver;¶

(d) Explain why the hospice program is unable to comply, what alternatives were considered, if any, and why alternatives (including compliance) were not selected;¶

(e) Demonstrate that the proposed waiver is desirable to maintain or improve the health and safety of the patients, to meet the individual and aggregate needs of patients, and will not jeopardize patient health and safety; and ¶

(f) Include the proposed duration of the waiver.¶

(2) Upon finding that the hospice program has satisfied the conditions of this rule, the Authority may grant a waiver. ¶

(3) A hospice program may not implement a waiver until it has received written approval from the Authority.¶
(4) During an emergency the Authority may waive a rule that a hospice program is unable to meet, for reasons beyond the hospice program's control. If the Authority waives a rule under this section it shall issue an order, in writing, specifying which rules are waived, which hospice programs are subject to the order, and how long the order shall remain in effect.

<u>Statutory/Other Authority: ORS 443.860</u> <u>Statutes/Other Implemented: ORS 443.860</u>



December 20, 2022

COMMENT SENT VIA EMAIL

OHA, Public Health Division
Brittany Hall, Administrative Rules Coordinator
800 NE Oregon Street, Suite 930
Portland, Oregon 97232
Email: publichealth.rules@odhsoha.oregon.gov

RE: Hospice Program Licensure Requirements

Dear Coordinator Hall:

Thank you for the opportunity to serve on the Rules Advisory Committee for Hospice Program Licensure Requirements and to submit responsive comments.

Compassion & Choices is the nation's oldest, largest and most active nonprofit working to improve care and expand options at life's end, which includes access to quality hospice and palliative care, for all people, regardless of their race and ethnicity, gender identity, sexual orientation, age, geographic region or socioeconomic status.

We strongly support the rule (OAR 333-035-0125(5)) requiring notice of change of ownership, particularly as small, locally-owned hospices are increasingly bought by private equity firms and organizations that may refuse to provide or allow certain end-of-life care options. We are not opposed to these purchases generally but are concerned if a change in ownership and organizational policies limit access to all legal and authorized end-of-life care options, including palliative sedation, voluntarily stopping eating and drinking, and medical aid in dying. We encourage data collection and public release of information when changes in ownership and policies limit access to the full range of end-of-life care options.

We are heartened by the recognition in this Notice of Proposed Rulemaking that "In Oregon and nationally, systemic racism, oppression, discrimination, and bias have created significant barriers for people of color, LGBTQIA2S+, people experiencing poverty, and people with disabilities trying to access all forms of healthcare, including palliative care, and quality end-of-life care." We support the intentions to reconvene this RAC following CMS rules release relating to minimum requirements such as providing services regardless of ability to pay and minimum demonstration outreach efforts.

¹ Braun RT, Stevenson DG, Unruh MA. Acquisitions of Hospice Agencies by Private Equity Firms and Publicly Traded Corporations. *JAMA Intern Med.* 2021;181(8):1113–1114. doi:10.1001/jamainternmed.2020.6262

101 SW Madison Street, #8009 Portland, OR 97207 800 247 7421 phone CompassionAndChoices.org Until then, while we support the waiver language for the geographic service areas (ORS 333-035-0160(4)), we recommend specifically including protections for "sexual orientation or gender identity-related barriers to hospice services." Studies show that lesbian, gay and bisexual older adults are more likely than their heterosexual peers to experience health disparities, discrimination from healthcare providers based on sexual orientation and rejection from their family of origin, all of which can complicate medical care and decision making, as well as end-of-life arrangements.² As a result, this population should be included as an "underserved population."

Finally, we support the addition of advance care planning in OAR 333-035-0170. We encourage reducing the time period for this requirement. Individuals enrolling in hospice should be offered advance directive materials and encouraged to designate a health care representative at enrollment. We also recommend the State develop a standardized advance directive that must be offered to hospice patients.

Again, thank you for the opportunity to serve on the RAC. We look forward to next steps and continued engagement in this important work. If you have any questions, please contact Bernadette Nunley, National Director of Policy, bnunley@compassionandchoices.org.

Most sincerely, Bernadette Nunley National Director of Policy

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² Kristie L. Seelman et al., Motivations for advance care and end-of-life planning among lesbian, gay, and bisexual older adults, 18 Qualitative Soc. Work 1002 (2018)

https://journals.sagepub.com/doi/abs/10.1177/1473325018792396. See also, Kelly Haviland et al., Barriers to palliative care in sexual and gender minority patients with cancer: A scoping review of the literature 29 Health & Soc. Care in the Community 305 (2021) https://pubmed.ncbi.nlm.nih.gov/32767722/.