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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
08/12/2020 5:00 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Waiver of OARs Based on CMS §1135 Waiver and Emergency Declarations

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/21/2020 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.

A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.

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NEED FOR THE RULE(S):

On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services' (DHHS) Secretary's declared a public health emergency, and on March 13, 2020, the President of the United States declared an emergency, allowing the Centers for Medicare and Medicaid Services (CMS) to issue §1135 Waivers. This type waiver allows health care facilities and providers to deliver sufficient health items and services to patients and clients and seek reimbursement if providers cannot comply with specific regulatory requirements due to the emergency circumstances. The Oregon Health Authority (Authority) is proposing to amend and make permanent this rule, which was adopted as a temporary rule on April 10, 2020, that will ensure that any Oregon administrative rule that is inconsistent with an §1135 waiver issued by CMS is suspended while an §1135 waiver is in effect.

This rule reduces any barriers that would prevent facilities and providers from providing timely, appropriate and necessary services in an emergency declared by the President and Secretary of DHHS and when CMS issues an §1135 Waiver.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Documents Relied Upon, and where they are available:

- CMS 1135 Waivers:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>

- CMS 1135 Waivers At-a-Glance:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/1135-Waivers-At-A-Glance.pdf>

- CMS Authority to Waive Requirements during National Emergencies:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/1135->

FISCAL AND ECONOMIC IMPACT:

The Authority is unable to quantify the possible fiscal or economic impact as a result of this proposed rule. The purpose of an §1135 Waiver is to ensure that licensed care facilities and providers are able to seek reimbursement if providers cannot comply with specific regulatory requirements due to the emergency circumstances. Adoption of this rule will suspend any rule that may conflict with a federal waiver issue by CMS and thus allow for reimbursement. Additionally, adoption of this rule will allow licensed care facilities and providers not to comply with certain rules which may result in costs savings.

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. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

There is no known impact to units of local government or to the general public. The Authority is currently responsible for ensuring that health care facilities comply with state and federal regulations.

2. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:

The Authority does not collect data on the number of persons employed by any licensed health care facility and therefore cannot estimate with accuracy how many facilities may be a small business.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

The Authority does not anticipate any change in reporting, recordkeeping or other administrative activities with respect to this rule.

c. Equipment, supplies, labor and increased administration required for compliance:

No additional equipment, supplies or labor is anticipated to comply with the proposed rule.

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

Small businesses were not involved in the development of this rule given the continued emergency conditions in responding to the COVID-19 outbreak.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Health care facilities are acutely aware of the CMS §1135 Waiver and the steps the Authority has taken in allowing flexibilities under the federal waiver.

ADOPT: 333-003-1050

RULE SUMMARY: The Oregon Health Authority is proposing to permanently amend and make permanent OAR 333-003-1050 which will give flexibility to licensed health care facilities, home health agencies, hospice, ambulance service agencies, EMS providers and hemodialysis technicians to provide appropriate and necessary services during a declared emergency that is in alignment with waivers issued by the federal Centers for Medicare and Medicaid Services (CMS).

Adopt OAR 333-003-1050 – Amend and make permanent this rule originally adopted as a temporary rule on April 10, 2020, which will allow health care facilities and providers to deliver sufficient health items and services to patients and clients and seek reimbursement if providers cannot comply with specific regulatory requirements due to emergency circumstances.

The Oregon Health Authority is proposing to permanently amend and make permanent OAR 333-003-1050 which will give flexibility to licensed health care facilities, home health agencies, hospice, ambulance service agencies, EMS providers and hemodialysis technicians to provide appropriate and necessary services during a declared emergency that is in alignment with waivers issued by the federal Centers for Medicare and Medicaid Services (CMS).

Adopt OAR 333-003-1050 – Amend and make permanent this rule originally adopted as a temporary rule on April 10, 2020, which will allow health care facilities and providers to deliver sufficient health items and services to patients and clients and seek reimbursement if providers cannot comply with specific regulatory requirements due to emergency circumstances.

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

CHANGES TO RULE:

333-003-1050

Declared Emergency: Waiver of Rules Applicable to Acute Care Health Care Facilities, Outpatient Renal Dialysis, Hospice, Home Health, Emergency Medical Services, and Hemodialysis Due to Federal 1135 Waivers

(1) This rule applies to:

(a) Hospitals;

(b) Ambulatory surgical centers;

(c) Special inpatient care facilities;

(d) Outpatient renal dialysis facilities;

(e) Hospice;

(f) Home health agencies;

(g) Emergency medical services providers;

(h) Ambulance service providers; and

(i) Hemodialysis technicians.

(2) The purpose of this rule is to ensure that the entities listed in section (1) of this rule have the flexibility to provide appropriate and necessary services during an emergency declared by the President of the United States and a Public Health Emergency declared by the Secretary for Health and Human Services, and when the Centers for Medicare and Medicaid Services (CMS) has approved temporary modifications and waivers that apply to Oregon under Section 1135 of the Social Security Act.

(3) In order to accomplish the purposes identified in section (2) of this rule, all rules in OAR chapter 333, divisions 027, 035, 071, 076, 250, 255, 265, 275, 500 through 535, and 700 that are inconsistent with an §1135 waiver issued by the CMS are suspended for all entities and facilities covered by the waivers. ¶

(4) The Oregon Health Authority (Authority), as time and resources permit, shall issue guidance concerning the rules affected by this rule. ¶

(5) The Authority shall post any guidance issued under this rule at: <http://www.healthoregon.org/hflc> or <http://www.healthoregon.org/ems>. ¶

(6) If an §1135 waiver described in section (2) of this rule is rescinded or terminated by CMS, any rule that was suspended based on this rule will again be effective at the time the §1135 waiver ends.

Statutory/Other Authority: ORS 413.014, ORS 441.025, 441.086, 443.085, 443.860, 682.017, 688.635, 688.650

Statutes/Other Implemented: ORS 441.025, 441.086, 443.085, 443.860, 682.017, 688.635, 688.650