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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 309
OREGON HEALTH AUTHORITY
HEALTH SYSTEMS DIVISION: BEHAVIORAL HEALTH SERVICES

FILED
05/04/2021 12:58 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Informed Consent Procedures for COVID-19 Vaccination of Patients Who Lack Capacity

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 06/21/2021 1:00 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:
Adina Canales
Rules Coordinator

HEARING(S)

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

DATE: 06/15/2021

TIME: 1:00 PM - 2:00 PM

OFFICER: Adina Canales

ADDRESS: Telephonic

OSH call in number: 888-273-3658

OSH participant code: 7476735

Salem, OR 97301

NEED FOR THE RULE(S):

The vaccine with EUA is not a routine or significant procedure, as those terms are defined in these rules. OSH needs a way to administer the vaccine to patients who lack capacity.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

NA

FISCAL AND ECONOMIC IMPACT:

Oregon received a Presidential Disaster Declaration on March 28, 2020 to help fight COVID-19 in the state. Governor Kate Brown declared a State of Emergency on February 7, 2020. On December 17, 2020 Governor Kate Brown today extended her declaration of a state of emergency regarding COVID-19 for an additional 60 days, until March 3, 2021. Oregon State Hospital became one of the few agencies to receive and administer the COVID-19 vaccine to both their patients and their staff. OSH is a 24 hour facility for criminally insane patients. We offer the vaccine to those who want to have it.

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).

There is no cost for OSH to comply with the new rule. OSH is already administering the vaccine, this is just a way for us to administer it to those patients who lack capacity.

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

This rule only impacts OSH staff and patients.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

ADOPT: 309-114-0035

RULE SUMMARY: 309-114-0035 The purpose of this rule is to set out a process for OSH to administer COVID-19 vaccinations with

Emergency Use Authorization (EUA) from the Federal Food and Drug Administration (FDA) to incapacitated patients, who do not have guardians or health care representatives, to help protect OSH patients during the COVID-19 public health emergency.

CHANGES TO RULE:

309-114-0035

Informed Consent Procedures for COVID-19 Vaccination of Patients Who Lack Capacity

(1) Purpose: The purpose of this rule is to set out a process for the Oregon State Hospital (OSH) to administer COVID-19 vaccinations with Emergency Use Authorization (EUA) from the Federal Food and Drug Administration (FDA) to patients who lack capacity, who do not have guardians or health care representatives, to help protect OSH patients during the COVID-19 public health emergency. ¶

(a) This process does not apply to patients who have capacity to provide informed consent to the vaccine, to patients who lack capacity with guardians or health care representatives, or to patients where a court order requires administration of the vaccine. ¶

(b) Unless adjudicated legally as lacking capacity for all purposes or for the purpose of making treatment decisions, a patient shall be presumed competent to consent to the administration of a COVID-19 vaccination. ¶

(2) Definitions: For purposes of this rule only. ¶

(a) "COVID-19 Vaccination" or "Vaccine" means a vaccine intended to prevent individuals from contracting COVID-19 (Coronavirus Disease 2019 caused by SARs-CoV-2) and that has received EUA from the FDA. The vaccine with EUA is not a routine or significant procedure, as those terms are defined in these rules. ¶

(b) "Patient" means an OSH patient who lacks capacity, who does not have a guardian or a health care representative, and is not subject to a court order that requires administration of the COVID-19 Vaccination. ¶

(c) "Lacks capacity to provide informed consent" for the administration of the COVID-19 vaccine means that the patient, due to a mental or physical illness or condition, ¶

(A) is unable to communicate the patient's preferences in a meaningful manner; ¶

(B) despite patient education, lacks factual understanding of the vaccination; or ¶

(C) lacks sufficient ability to rationally weigh the risks and benefits of accepting or declining the vaccination. ¶

(3) A COVID-19 vaccination may be administered to a patient when the treating physician or psychiatric nurse practitioner makes the following determination: ¶

(a) The patient lacks capacity to provide informed consent to the administration of a COVID-19 vaccine; ¶

(b) The vaccine would likely medically benefit the patient; and ¶

(c) The vaccine is not contraindicated for the patient. ¶

(4) The Chief Medical Officer (CMO) or designee shall review the treating physician's or psychiatric nurse practitioner's determination, and if the CMO or designee approves that determination, the CMO or designee shall issue a Notice of Action that OSH intends to administer the vaccine to the patient. ¶

(5) The treating physician or psychiatric nurse practitioner shall provide the patient with the Treating Practitioner Statement, CMO Form, Notice of Action, and EUA Fact Sheet and answer any questions the patient may have about the vaccine. ¶

(a) If the patient agrees to receive the vaccine, then OSH may immediately administer it to the patient. The Notice of Action will become the Final Order by Default immediately upon the patient's agreement to receive the vaccination. The patient may agree to receive the vaccine in writing by filling out the Patient Decision form attached to the Notice of Action or verbally by expressing their agreement to OSH treatment staff, who shall complete the form on the patient's behalf. ¶

(b) If the patient does not object to receiving the vaccine within 48 hours of the Notice of Action being issued, the Notice of Action shall become the Final Order by Default, and OSH may administer the vaccine to the patient. ¶

(c) If the patient objects to the vaccine within 48 hours of the Notice of Action being issued or at any time prior to the administration of the vaccine, the CMO or designee shall withdraw the Notice of Action or Final Order by Default, and OSH shall not administer the vaccine to the patient. The patient may object to the vaccine in writing by filling out the Patient Decision form attached to the Notice of Action or verbally by expressing their objection to OSH treatment staff, who shall complete the form on the patient's behalf. ¶

(6) Second dose of the COVID-19 vaccination: ¶

(a) If OSH is permitted to administer the first dose of a two-dose vaccine under subsection (5), OSH may administer the second dose of the vaccine under the Final Order by Default, except as otherwise provided in subsection (6)(b) or (6)(c) of this rule. ¶

(b) If, after receiving the first dose of a two-dose vaccine, the patient objects to receiving the second dose of the vaccine before it is administered, then the CMO or designee shall issue a Final Order that OSH shall not administer the second dose of the vaccine to the patient. The patient may object to the second dose of the vaccine in writing by filling out the Patient Decision form or verbally by expressing their objection to OSH treatment staff, who shall complete the form on the patient's behalf. ¶

(c) If, after receiving the first dose of a two-dose vaccine, the treating physician or psychiatric nurse practitioner determines that a second dose of the vaccine is contraindicated for the patient and the CMO or designee agrees with that determination, then the CMO or designee shall issue a Final Order that OSH shall not administer the second dose of the vaccine. ¶

(7) All Notices of Action, completed Forms and Final Orders, related to the process outlined in this rule, shall be placed in the patient's record.

Statutory/Other Authority: ORS 179.040

Statutes/Other Implemented: ORS 179.321, 426.070, 426.385