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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

BHS 7-2022

CHAPTER 309

OREGON HEALTH AUTHORITY

HEALTH SYSTEMS DIVISION: BEHAVIORAL HEALTH SERVICES

FILED

05/27/2022 10:33 AM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Informed Consent Procedures for COVID-19 Vaccination of Incapacitated Persons

EFFECTIVE DATE: 05/27/2022 THROUGH 11/22/2022

AGENCY APPROVED DATE: 05/26/2022

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NEED FOR THE RULE(S):

The rule was needed due to the public health emergency resulting in several executive orders and due to the Emergency Use Authorization status of COVID-19 vaccine in place at the time the rule was implemented. The COVID-19 vaccines have since been granted full FDA approval for the age range of the Oregon State Hospital's patient population. Because this rule applied only to the vaccine when it had emergency use approval rather than full approval, the rule is obsolete.

JUSTIFICATION OF TEMPORARY FILING:

Emergency Use Authorization from the Federal Food and Drug Administration. The COVID-19 vaccines have since been granted full FDA approval for the age range of the Oregon State Hospital's patient population. Because this rule applied only to the vaccine when it had emergency use approval rather than full approval, the rule is no longer needed.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/distributing/steps-ensure-safety.html?s_cid=11700:covid%20vaccine%20fda%20approval:sem.ga:p:RG:GM:gen:PTN:FY22

https://www.oregon.gov/gov/eo/eo_22-03.pdf

SUSPEND: 309-114-0035

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

RULE SUMMARY: 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.

RULE TEXT:

(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, patient 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