OFFICE OF THE SECRETARY OF STATE

BEV CLARNO 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 309

OREGON HEALTH AUTHORITY

HEALTH SYSTEMS DIVISION: BEHAVIORAL HEALTH SERVICES

FILED

10/27/2020 11:35 AM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: INFORMED CONSENT TO TREATMENT AND TRAINING BY PATIENTS IN STATE INSTITUTIONS

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/23/2020 11:00 AM

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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HEARING(S)

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

DATE: 11/16/2020

TIME: 11:00 AM - 11:30 AM
OFFICER: Adina Canales
ADDRESS: Conference Line
Call in number: 1 971-277-2343
Call in participation number: 224 691

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Salem, OR 97301

NEED FOR THE RULE(S):

These rules provide the framework for the hospital to treat patients who lack capacity to consent to treatments the amendments will continue to ensure that patients have the right to request a review by an administrative law judge not affiliated with the hospital. The rule would allow for OSH staff who are not on the patients treatment team to provide a second opinion consultation on requests for treatments with good cause. Currently the hospital is using contractors at the cost of approximately \$15,000.00/month. Using staff instead of contractors would allow the hospital to more responsibly expend funds and help mitigate the budget impact of the corona virus pandemic. Having a larger group of physicians to provide these consultations will help to speed up the initial review process, giving patients the opportunity to request hearings sooner. Completing the process faster can potentially shorten the length of hospital stays, speeding up the admission/discharge of patients. Both of which support treatment excellence and business rigor. The sooner this amendment can be made the more funds the hospital can save.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

OAR 309-114-0000 through 309-114-0030

https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1061

FISCAL AND ECONOMIC IMPACT:

Budget shortfalls across the state have forced the hospital to look for alternative ways to provide services to patients during the pandemic. The hospital currently pays approximately \$300 per second opinion consultation for patients who lack capacity to consent to treatment. By shifting this work to employees who are stationed at home or to those who are not a part of the treatment team, the hospital could save around \$15,000.00 per month (50 consultations per month on average) by utilizing state employees. Not all of the consultations will be able to be completed by an employee, some will still need to be seen by contractors depending the available staffing of the hospital to provide these services.

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).

Contractors who are currently providing these services will receive fewer referrals and as a result, receive less funds. Contractor services are to be provided on an as needed basis. The need for their services will decrease.

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

Contractors who are currently providing these services will receive fewer referrals and as a result, receive less funds.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

309-114-0005, 309-114-0020

AMEND: 309-114-0005

RULE SUMMARY: Adds definition for "Independent examining physician". The rule update would allow for OSH staff who are not on the patients treatment team to provide a second opinion consultation on requests for treatments with good cause.

CHANGES TO RULE:

309-114-0005 Definitions ¶

As used in these rules: ¶

- (1) "Authorized Representative" or "representative" means an individual who represents a party in a contested case hearing; the representative must be supervised by an attorney that is licensed by the Oregon State Bar. \P
- (2) "Chief Medical Officer" means the physician designated by the superintendent of each state institution pursuant to ORS 426.020(2) who is responsible for the administration of medical treatment at each state institution. ¶
- (3) "Committed" or "Commitment" means an individual is admitted under ORS 161.327, 161.328, 161.370, 426.701, 426.130, 427.215 or 426.220 when the individual's guardian or health care representative is unavailable or unable to consent \P
- (4) "Dangerousness" means either: ¶
- (a) A substantial risk that physical harm will be inflicted by an individual upon his own person, as evidenced by threats, including verbal threats or attempts to commit suicide or inflict physical harm on him or herself. Evidence of substantial risk may include information about historical patterns of behavior that resulted in serious harm

being inflicted by an individual upon him or herself as those patterns relate to the current risk of harm; ¶
(b) A substantial risk that physical harm will be inflicted by an individual upon another individual, as evidenced by recent acts, behavior or threats, including verbal threats, which have caused such harm or which would place a reasonable person in reasonable fear of sustaining such harm. Evidence of substantial risk may include information about historical patterns of behavior ¶

- (5) "Division" means the State Hospitals Division of the Oregon Health Authority. ¶
- (6) "Guardian" means a legal guardian who is an individual appointed by a court of law to act as guardian of a minor or a legally incapacitated person. ¶
- (7) "Health Care Representative" means a person who has authority to make health care decisions for a patient. ¶
- (8) "Independent examining physician" is a board-eligible psychiatrist, who shall have been subjected to review by the medical staff executive committee as to qualifications to make such an examination, shall have been provided with a copy of administration rules OAR 309-114-0000 through 309-114-0030 and shall have participated in a training program regarding these rules, their meaning and application. The independent examining physician shall not be directly involved in the patient's current or past treatment or diagnosis, excluding time spent solely as an on-call provider.¶
- (9) "Legally Incapacitated" means having been found by a court of law under ORS 426.295 to be unable, without assistance, to properly manage or take care of one's personal affairs, or who is a person under guardianship. \P ($9\underline{10}$) "Material Risk." A risk is material if it may have a substantial adverse effect on the patient's psychological or physical health, or both. Tardive dyskinesia is a material risk of neuroleptic medication. Other risks include, but are not limited to raised blood pressure, onset of diabetes and metabolic changes. \P
- (101) "Patient" means an individual who is receiving care and treatment in a state institution for the mentally ill. \P (142) Patient with a "grave disability" means a patient who: \P
- (a) Is in danger of serious physical harm to his or her health or safety absent the proposed significant procedures; or \P
- (b) Manifests severe deterioration in routine functioning evidenced by loss of cognitive or volitional control over his or her actions which is likely to result in serious harm absent the proposed significant procedures. \P (123) "Person Committed to the Division" or "Person" means an individual committed under ORS 161.327, 161.328, 426.701, 426.220, 161.370, 426.130, or 427.215. \P
- (134) "Psychiatric Nurse Practitioner," means a registered nurse with prescription authority who independently provides health care to clients with mental and emotional needs or disorders. \P
- (14<u>5</u>) "Routine Medical Procedure" means a procedure customarily administered by facility medical staff under circumstances involving little or no risk of causing injury to a patient including, but not limited to physical examinations, blood draws, influenza vaccinations, tuberculosis (TB) testing, human immunodeficiency virus (HIV) testing and hygiene. ¶
- (156) "Significant Procedure" means a diagnostic or treatment modality and all significant procedures of a similar class that pose a material risk of substantial pain or harm to the patient such as, but not limited to psychotropic medication and electro-convulsive therapy. Significant procedures do not include routine medical procedures. ¶ (167) "Significant Procedures of a Similar Class" means a diagnostic or treatment modality that presents substantially similar material risks as the significant procedure listed on the treating physician's or psychiatric nurse practitioner's informed consent form and is generally considered in current clinical practice to be a substitute treatment or belong to the same class of medications as the listed significant procedure. ¶
- (a) For purposes of these rules, medications listed in subsections 167 (a)(A) through 167(a)(F) of this rule will be considered the same or similar class of medication as other medications in the same subsection: \P
- (A) All medications used under current clinical practice as antipsychotic medications including typical and atypical antipsychotic medications; \P
- (B) All medications used under current clinical practice as mood stabilizing medications; ¶
- (C) All medications used under current clinical practice as antidepressants; ¶
- (D) All medications used under current clinical practice as anxiolytics; ¶
- (E) All medications used under current clinical practice as psychostimulants; and ¶

- (F) All medications used under current clinical practice as dementia cognitive enhancers. \P
- (b) Significant procedures of the same or similar class do not need to be specifically listed on the treating physician's or psychiatric nurse practitioner's form. \P
- (178) "State Institution" or "Institution" means all Oregon State Hospital campuses. [DBL*D1] (189)

"Superintendent" means the executive head of the state institution listed in section 178 (18) of this rule, or the superintendent's designee.

Statutory/Other Authority: ORS 179.040, 413.042

Statutes/Other Implemented: ORS 179.321, 183.458, 426.070, 426.385

AMEND: 309-114-0020

RULE SUMMARY: Remove language for Independent Review. The rule update would allow for OSH staff who are not on the patients treatment team to provide a second opinion consultation on requests for treatments with good cause.

CHANGES TO RULE:

309-114-0020

Involuntary Administration of Significant Procedures to Persons Committed to the Division with Good Cause ¶

- (1) Good cause: Good cause exists to administer a significant procedure to a person committed to the Division without informed consent if in the opinion of the treating physician or psychiatric nurse practitioner after consultation with the treatment team, the following factors are satisfied: \P
- (a) Pursuant to OAR 309-114-0010(2), the person is deemed unable to consent to, refuse, withhold or withdraw consent to the significant procedure. This determination must be documented on the treating physician's or psychiatric nurse practitioner's informed consent form and the independent examining physician's evaluation form. It must include the specific questions asked and answers given regarding the patient's ability to weigh the risks and benefits of the proposed treatment, alternative treatment and no treatment including, but not limited to all relevant factors listed in 309-114-0010(3)(a). \P
- (b) The proposed significant procedure will likely restore or prevent deterioration of the person's mental or physical health, alleviate extreme suffering or save or extend the person's life. This factor is established conclusively for purposes of a hearing under OAR 309-114-0025 by introducing into evidence the treating physician's or psychiatric nurse practitioner's informed consent form and the independent examining physician's evaluation form, unless this factor is affirmatively raised as an issue by the patient or his or her representative at the hearing. ¶
- (c) The proposed significant procedure is the most appropriate treatment for the person's condition according to current clinical practice all other less intrusive procedures have been considered and all criteria and information set forth in OAR 309-114-0010(3)(a) were considered. This factor is established conclusively for purposes of a hearing under 309-114-0025 by introducing into evidence the treating physician's or psychiatric nurse practitioner's informed consent form and the independent examining physician's evaluation form, unless this factor is affirmatively raised as an issue by the patient or his or her representative at the hearing. ¶

 (d) The institution made a conscientious effort to obtain informed consent from the patient. This factor is
- established conclusively for purposes of a hearing under OAR 309-114-0025 by introducing into evidence the treating physician's or psychiatric nurse practitioner's informed consent form unless this factor is affirmatively raised as an issue by the patient or his or her representative at the hearing. If the institution has reason to believe a patient has limited English language proficiency or the patient requests it, the institution will make reasonable accommodations to provide the patient with meaningful access to the informed consent process, such as providing the patient with the opportunity to have an interpreter orally translate written materials into the patient's native language and provide translation during the treating physician's or psychiatric nurse practitioner's attempts to obtain informed consent. A "conscientious effort" to obtain informed consent means the following: ¶

 (A) The patient's treating physician or psychiatric nurse practitioner made at least two good faith attempts to obtain informed consent by attempting to explain the procedure to the patient and documenting those efforts in the patient's record. ¶
- (e) Because of the preliminary nature of their commitment, the following additional findings must be made for patients under ORS 161.370 jurisdiction in order to show good cause under this rule: \P
- (A) Medication is not requested for the sole purpose of restoring trial competency; and \P
- (B) The patient is being medicated because of the patient's dangerousness or to treat the patient's grave disability. \P
- (2) Independent Review: Prior to granting approval for the administration of a significant procedure for good

cause to a person committed to the Division, the superintendent or chief medical officer of a state institution for the mentally ill shall obtain consultation and approval from an independent examining physician, or if a patient refuses to be examined, the superintendent or chief medical officer shall document that an independent examining physician made at least two good faith attempts to examine the patient. The superintendent or chief medical officer shall maintain a list of independent examining physicians and shall seek consultation and approval from one of these independent examining physicians selected on a rotating basis from the list. The independent examining physician shall not be an employee of the Division, shall be a board-eligible psychiatrist, shall have been subjected to review by the medical staff executive committee as to qualifications to make such an examination, shall have been provided with a copy of administration rules OAR 309-114-0000 through 309-114-0030 and shall have participated in a training program regarding these rules, their meaning and application. ¶

- (3) The superintendent or chief medical officer shall provide to a patient to whom a significant procedure is proposed to be administered written advance notice of the intent to seek consultation and approval of an independent examining physician for the purpose of administering the procedure without the patient's consent. ¶
- (4) The physician selected to conduct the independent consultation shall: \P
- (a) Review the person's medical chart including the records of efforts made to obtain the person's informed consent and \P
- (A) Personally examine the person at least one time; or \P
- (B) If the patient refuses to be examined, the physician shall make two good faith attempts to examine the patient. If the patient refuses to be examined during these two good faith attempts, the independent consultation and approval requirement outlined in subsection (4)(a)(A) and (4)(b) of this rule shall be deemed to be fulfilled. \P
- (b) Discuss the matter with the person to determine the extent of the need for the procedure and the nature of the person's refusal, withholding or withdrawal or inability to consent to the significant procedure. This determination as well as the supporting evidence in the form of the specific questions asked and answers given regarding the patient's ability to weigh the risks and benefits of the proposed treatment, alternative treatment and no treatment must be documented in the patient's record; ¶
- (c) Consider additional information, if any, presented prior to or at the time of examination or interview as may be requested by the person or anyone on behalf of the person; and \P
- (d) Make a determination whether the factors required under these rules exist for the particular person or that one or more factors are not present and complete a report of his or her findings which provides their approval or disapproval of the proposed significant procedure. The written report must be provided to: ¶
- (A) The superintendent or chief medical officer; and ¶
- (B) The person to whom a significant procedure is proposed to be administered with a copy being made part of the person's record. ¶
- (5) Superintendent's Determination: ¶
- (a) The superintendent or chief medical officer shall approve or disapprove of the administration of the significant procedure to a person committed to the Division based on good cause provided that if the examining physician or psychiatric nurse practitioner found that one or more of the factors required by section (1) of this rule were not present or otherwise disapproved of the procedure; the superintendent or chief medical officer shall not approve the significant procedure and it shall not be performed; ¶
- (b) Approval of the significant procedure shall be only for as long as no substantial increase in risk is encountered in administering the significant procedure or significant procedure of a similar class during the term of a person's commitment, but in no case longer than 180 days. Disapproval shall be only for as long as no substantial change occurs in the person's condition during the term of commitment, but in no case longer than 180 days; \P
- (c) Written notice of the superintendent's or chief medical officer's determination shall be provided to the patient and made part of the individual's record. This notice must be delivered to the patient and fully explained by facility medical staff. This notice must include a clear statement of the decision to treat without informed consent, specific basis for the decision, what evidence was relied on to make the decision and include a clear notice of the opportunity to ask for a contested case hearing with an administrative law judge if the patient disagrees with the decision. Attached must be a form with a simple procedure to request a hearing. The patient indicating in writing

or verbally to any staff member a desire to challenge the institution's decision will be sufficient to request a contested case hearing pursuant to OAR 309 114 0025. The patient shall have 48 hours to request a contested case hearing after receiving this notice. If the patient does not request a hearing within the 48 hour period or the patient subsequently withdraws his initial hearing request and is not already receiving the significant procedure, the institution may involuntarily administer the significant procedure. A patient retains the right to request an initial hearing on the decision to administer a significant procedure without informed consent at any time. ¶

(d) If the patient withdraws his or her initial request for hearing or refuses to attend the initial hearing without good cause, the administrative law judge will issue a dismissal order pursuant to OAR 137-003-0672(3). A dismissal order will allow the institution to immediately administer the significant procedure without informed consent as if the patient had never requested a hearing. If a dismissal order is issued, the patient may request a second hearing. If the patient withdraws his second request for hearing or refuses to attend the second hearing without good cause, the hearing will occur as scheduled with the institution presenting a prima facie case pursuant to ORS 183.417(4) and the administrative law judge will issue a proposed order by default. The institution will then issue a final order by default. ¶

- (e) Records of all reports by independent examining physicians of the determinations of the superintendent or chief medical officer under this rule shall be maintained by the superintendent or chief medical officer in a separate file and shall be summarized each year. Such summaries shall show: ¶
- (A) Each type of proposed significant procedure for which consultation with an independent examining physician was sought; \P
- (B) The number of times consultation was sought from a particular independent examining physician for each type of proposed significant procedure; \P
- (C) The number of times each independent examining physician approved and disapproved each type of proposed significant procedure; and \P
- (D) The number of times the superintendent or chief medical officer approved and disapproved each type of proposed significant procedure. ¶
- (f) The summaries referred to in subsection (5)(e) of this rule shall be public records and shall be made available to the public during reasonable business hours in accordance with ORS Chapter 192. \P
- (6) When treatment is being administered without informed consent, the ward physician or psychiatric nurse practitioner will write a progress note addressing any changes in patient's capacity to give informed consent every 60 days. ¶
- (7) At any time that a patient's condition changes so that there appears to his or her treating physician or psychiatric nurse practitioner to be a substantial improvement in the patient's capacity to consent to or refuse treatment, a formal re assessment of the patient's capacity to consent shall occur as described in OAR 309-114-0010 and 309-114-0020. No order to administer treatment without informed consent in non-emergency situations shall be valid for longer than 180 days or the duration of the commitment, whichever is shorter, without re establishing the need for the order by following the procedures described in 309-114-0010 and 309-114-0020.
- (8) When an individual is transferred to a state institution from a community hospital or another state institution where he or she was already being treated with a significant procedure without informed consent, the receiving institution must apply OAR 309-114-0000 through 309-114-0030 no later than 7 days after the date of admission to the new institution. A state institution can honor an existing order for involuntary administration of a significant procedure without informed consent if procedures such as those outlined in 309-114-0010 through 309-114-0030 have already been applied and all necessary documentation is in the patient's file. Statutory/Other Authority: ORS 179.040, 413.042

Statutes/Other Implemented: ORS 179.321, 426.070, 426.385