

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 332
OREGON HEALTH AUTHORITY
HEALTH LICENSING OFFICE, BOARD OF DIRECT ENTRY MIDWIFERY

FILED

02/28/2023 9:00 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Amend peer review, indication for consult and legend drugs rule.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 03/28/2023 12:00 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.

CONTACT: Samie Patnode
503-373-1917
samie.patnode@oha.oregon.gov

1430 Tandem Ave. NE Suite 180
Salem, OR 97301

Filed By:
Samantha Patnode
Rules Coordinator

HEARING(S)

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

DATE: 03/16/2023

TIME: 9:00 AM - 10:00 AM

OFFICER: Samie Patnode

HEARING LOCATION

ADDRESS: Health Licensing Office, 1430 Tandem Ave. NE Suite 180, Salem, OR 97301-1287

REMOTE MEETING DETAILS

PHONE NUMBER: 503-934-3605

CONFERENCE ID: 530340

NEED FOR THE RULE(S)

Amend the peer review requirements to clarify that licensed direct entry midwives (LDMs) who "attend" births must present at least two cases per year for peer review with an Oregon midwifery peer review organization or midwifery quality improvement organization that maintains a charter and standards for peer review. The current rule requires that at least one peer review be conducted through an "entity". The only specifications for an "entity" are that the entity must have more than five LDMs and that the "entity" must review the quality of professional midwifery care provided by the LDM.

Add "fetal growth restriction" to indication for consult during pregnancy (antepartum.) There has been confusion in the midwifery community that the indication to transfer during pregnancy (antepartum) regarding abnormal fetal surveillance testing, including, but not limited to, biophysical profile, non-stress test, and auscultated acceleration testing, includes "fetal growth restriction." The Rules Advisory Committee (RAC) determined that there are enough variables in regard to "fetal growth restriction" that it should be separate from abnormal fetal surveillance testing and added to the indication to consult which requires the LDM either transfer care or consult with an Oregon licensed

health care provider, communicate to the birthing person all recommendations, obtain informed consent, and make a plan for the birthing person. Consultation information must be documented in the birthing person's record of care.

Add Tranexamic Acid (TXA) to the list of legend drugs for maternal use by DEMs to stop bleeding.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

- Oregon Revised Statutes and Oregon Administrative Rules related to licensed direct entry midwifery and the Health Licensing Office (HLO).
- Legend Drugs and Devices committee recordings and materials.
- RAC materials.
- Information provided by the Oregon Midwifery Council in relation to peer review.

All documents are available at the HLO, 1430 Tandem Ave NE, Suite 180, Salem, OR 97301-2192. To obtain information or copies of information please contact Samie Patnode, Policy Analyst, at 503-373-1917 or by email at samie.patnode@oha.oregon.gov, during normal business hours Monday through Friday between 7 a.m. to 2:30 p.m.

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

Regarding peer review, all LDMs, regardless of race, gender, or ethnic background must participate in and attend peer review.

When a birthing person's fetus is given a diagnosis of "fetal growth restriction," the race and ethnicity must be taken into consideration, because if "fetal growth restriction" results, the LDM can determine if transfer of care is necessary or if consultation with an Oregon licensed health care provider to determine next steps is warranted. Concerns were voiced that, generally, health care providers are using Caucasian "fetal growth restriction" guidelines, which are problematic for patients who are non-Caucasian. Current studies have shown that use of Caucasian based "fetal growth restriction" guidelines has resulted in the incorrect diagnosis of "fetal growth restriction" for normal babies in up to 15% of pregnancies in some racial and ethnic groups, especially in Asian patients. Adding "fetal growth restriction" to the indication to consult allows the LDM to take race and ethnicity into consideration before transferring care.

TXA is being added to the list of legend drugs for maternal use as an option for an LDM to use to stop bleeding.

FISCAL AND ECONOMIC IMPACT:

There may be a fiscal impact to LDMs and the public if these proposed rules become permanent.

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 does not appear to be any state agencies or units of local government likely to be economically affected by the rule changes.

If an LDM is considered the public, there could be travel expenses and loss of work to attend "peer review" through an Oregon midwifery peer review organization or midwifery quality improvement organization that maintains a charter and standards for peer review instead of participating in peer review through an "entity that has more than five LDMs," which could be within the LDMs practice.

A birthing person's financial obligation may be decreased if "fetal growth restriction" is diagnosed and the LDM can consult with an Oregon licensed health care provider rather than transfer care to a higher level of care, for example, emergency medical services or hospitals.

There are currently 97 LDMs in Oregon that will likely be affected by the rule changes. Many LDMs are sole proprietors with small businesses in the practice of midwifery. There are also 13 licensed birthing centers in Oregon, which are also likely considered small businesses with fewer than 50 employees.

There may be a minimal fiscal impact related to projected reporting. LDMs must currently attest to having participated in peer reviews as required by the rule, and this will not change.

There may be an increase in administration for LDMs attending births in terms of record keeping due to having to attend an additional peer review with an Oregon midwifery peer review organization or midwifery quality improvement organization that maintains a charter and standards for peer review.

Adding "fetal surveillance testing" to the list of indications to consult for mothers during pregnancy would require additional record-keeping for the LDM. An LDM must either transfer care or consult with an Oregon-licensed health care provider, communicate all recommendations to the birthing person, obtain informed consent, and make a plan for the birthing person. The components of the "consultation" must be documented in the birthing person's record of care.

The cost for professional services, equipment supplies, labor, and increased administration cannot be determined. The likelihood of an LDM having to pay for professional services, equipment supplies, labor, and increased administration is very low.

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

Members of the Board of Direct Entry Midwifery are small business owners as well as RAC members. One RAC member is the owner of a birthing center which would be considered a small business.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

332-025-0015, 332-025-0021, 332-026-0000, 332-026-0010

AMEND: 332-025-0015

RULE SUMMARY: Clarify peer review requirements.

CHANGES TO RULE:

332-025-0015

Peer Review and Sentinel Events

(1) Pursuant to ORS 687.480, an LDM must participate in peer review.¶

(2) "Peer review" means the candid review and evaluation, subject to ORS 41.675, of midwifery practice. The objective of peer review includes: reviewing the care provided, making recommendations for quality improvement, and identifying areas where additional education or skills training is needed.¶

(3) An LDM must participate in at least two peer review sessions per year, regardless of the number of births attended.¶

(a4) Each peer review must be conducted with at least two other LDMs, one of which must be outside the LDM's practice.¶

~~(b5) Each peer review must be conducted with providers who perform community births.~~

~~(4) At least one of the peer review sessions discussed in subsection (3) of this rule must be conducted through an entity. The~~An LDM who is attending births must present at least two cases ~~peer review must meet the following requirements:~~

~~(a) The entity through which the peer review occurs must consist of more than five LDMs.~~

~~(b) The entity through which the peer review occurs must be an entity that reviews the quality of professional midwifery care provided by the LDM.~~

~~(c) The peer review must be conducted with at least two other LDMs, one of which must be outside the LDMs practice.~~

~~(d) The peer review must be conducted with providers who perform community birth~~year for peer review with an Oregon midwifery peer review organization or midwifery quality improvement organization that maintains a charter and standards for peer review.

~~(56) An LDM who has had one of the following sentinel events must have the sentinel event reviewed within 90 days of the event by the~~entity/organization ~~described under subsection (45) of this rule:-~~

~~(a) Maternal hospitalization for infection;~~

~~(b) Maternal hospitalization requiring blood transfusion;~~

~~(c) Uterine rupture;~~

~~(d) Maternal or neonatal death;~~

~~(e) Neonate admitted to Neonatal Intensive Care Unit within 72 hours (except for observation or anomaly); or~~

~~(f) Transfer care deemed emergent by the LDM.~~

Statutory/Other Authority: ORS 676.615, ORS 687.425, ORS 687.480

Statutes/Other Implemented: ORS 687.425, ORS 687.480

AMEND: 332-025-0021

RULE SUMMARY: Add fetal growth restriction to indication for consult.

CHANGES TO RULE:

332-025-0021

Risk Assessment Practice Standards ¶¶

(1) Recognizing the importance of collaborative maternal health care, when determining the appropriateness of community birth, an LDM must assess risks, including ongoing and cumulative risks, by using clinical skills and expertise, relevant state rules and laws, principles of informed choice, midwifery core competencies, the setting of practice and access to higher levels of care, and careful consideration of selection criteria.¶¶

(2) ~~W~~"Indication for transfer": means when an indication to transfer presents the LDM must transfer care as defined in OAR 332-015-0000(13). If the birthing person or newborn present with any of the following indications the LDM must:-¶¶

(a) During the antepartum period, plan for transfer of care and an in-hospital birth; ¶¶

(b) During the intrapartum period, arrange transportation to the hospital and transfer of care unless the birth is imminent;¶¶

(c) When the birth is imminent, take the health and condition of the birthing person and baby and conditions for transport into consideration in determining whether to proceed with out-of-hospital birth or to arrange for transportation to a hospital and transfer of care; ¶¶

(d) During the postpartum period arrange for transfer of care.¶¶

(3) The timing for when arranging transportation and transfer of care in subsection (2) of this rule must occur is tied to the degree of risk of the indication to transfer. ¶¶

(4) If a client refuses transfer of care, the midwife must terminate midwifery care. The timing for when termination of care must occur is tied to the degree of risk of the indication to transfer. The LDM may immediately terminate midwifery care orally and then provide written notice to the client or relinquish care to a licensee under ORS 682.¶¶

(5) After transferring care, an LDM may continue to provide supportive care to the client including, but not limited to, nutritional advice, education, emotional, and psychosocial support.¶¶

(6) Upon documented resolution of an indication to transfer, an LDM may resume primary care and responsibility for the client or newborn, or both, and proceed with midwifery care.¶¶

(7) When transferring care, the LDM must provide the following at the time of transfer, to the hospital or licensees under ORS Chapter 682: medical history, prenatal flow sheet, diagnostic studies, laboratory findings, and maternal and baby care notes through time of transfer. ¶¶

(8) In cases of emergency, at the time of transfer, the LDM must provide the records required in subsection (7) of this rule to the hospital or licensees under ORS Chapter 682, including notes for care provided during the emergency, if available. If notes are not available, an oral summary of care during the emergency must be made available to the hospital or licensees under ORS Chapter 682. ¶¶

(9) Indication to transfer - Pre-existing and historical conditions:¶¶

(a) Chronic renal disease.¶¶

(b) Acquired immune deficiency syndrome (AIDS).¶¶

(c) Diabetes currently requiring oral medication or insulin.¶¶

(d) Previous classical uterine incision, T-incision, extensive transfundal surgery or prior uterine rupture.¶¶

(e) Three (3) cesarean sections without previous successful vaginal birth.¶¶

(f) Four (4) or more cesarean sections.¶¶

(10) Indication to transfer - Antepartum:¶¶

(a) Active cancer.¶¶

(b) Acquired Immune Deficiency Syndrome (AIDS).¶¶

(c) Ectopic pregnancy.¶¶

(d) Active substance abuse.¶¶

(e) Deep venous or any treated thromboembolic disease.¶¶

(f) Higher order multiples (three or more).¶¶

(g) Monochorionic, monoamniotic twins.¶¶

(h) Twin-to-twin transfusion.¶¶

(i) Presenting twin transverse.¶¶

(j) Hypertension at or above 140 systolic or at or above 90 diastolic on two (2) separate occasions that are more than four (4) hours apart, or hypertension at or above 160 systolic or at or above 110 diastolic on one (1) occasion.¶¶

- (k) Pre-eclampsia or eclampsia.¶
- (l) Placenta less than 2.0 centimeters from internal os not resolved by onset of labor and as determined by ultrasound evidence.¶
- (m) Evident or suspected placenta accreta.¶
- (n) Hemoglobin under nine (9) unresponsive to treatment at term.¶
- (o) Abnormal fetal surveillance testing including, but not limited to, biophysical profile, non-stress test and auscultated acceleration testing.¶
- (p) Pregnancy lasting longer than 43 weeks 0 days gestation (21 days past the due date). ¶
- (q) Gestational diabetes requiring oral medication or insulin.¶
- (r) Chronic renal disease.¶
- (11) Indication to transfer - Intrapartum:¶
 - (a) Labor or premature rupture of membrane less than 36 and 0 weeks gestation.¶
 - (b) Evident or suspected footling or kneeling breech and birth is not imminent.¶
 - (c) Transverse or oblique lie at onset of labor.¶
 - (d) Prolapsed cord or cord presentation.¶
 - (e) Active genital herpes in the vaginal, perineal, or vulva areas in labor or with ruptured membranes.¶
 - (f) Two (2) temperatures at 100.4 degrees Fahrenheit or 38 degrees Celsius or greater within one (1) hour or one (1) temperature at 102.2 degrees Fahrenheit or 39 degrees Celsius or greater.¶
 - (g) Signs or symptoms of chorioamnionitis or suspected chorioamnionitis.¶
 - (h) Excessive vomiting, dehydration, acidosis or exhaustion unresponsive to treatment.¶
 - (i) Hypertension at or above 140 systolic or at or above 90 diastolic on two (2) separate occasions that are more than four (4) hours apart or hypertension at or above 160 systolic at or above 110 diastolic on one (1) occasion.¶
 - (j) Pre-eclampsia or eclampsia.¶
 - (k) Signs or symptoms of complete or partial placental abruption.¶
 - (l) Signs or symptoms of placenta previa or suspected placenta previa.¶
 - (m) Signs or symptoms of uterine rupture.¶
 - (n) Persistent inability to auscultate fetal heart tones.¶
 - (o) Persistent non-reassuring fetal status.¶
 - (p) Thick meconium stained amniotic fluid and birth is not imminent.¶
 - (q) Lack of adequate progress in second stage in breech presentation, which means no progress in descent after a maximum of one (1) hour of active pushing in cases with complete dilation and ruptured membranes.¶
 - (r) Lack of adequate progress in second stage with cephalic presentation, which means no descent after a maximum of three (3) hours of active pushing in cases with complete dilation and ruptured membranes.¶
 - (s) Significant hemorrhage unresponsive to treatment with or without sustained vital sign instability or shock.¶
 - (t) Signs or symptoms of shock.¶
 - (u) Vital sign instability or altered level of consciousness unresponsive to treatment.¶
 - (v) Retained placenta.¶
- (12) Indication to transfer - Postpartum:¶
 - (a) Significant hemorrhage unresponsive to treatment with or without sustained vital sign instability or shock.¶
 - (b) Laceration requiring transfer of care for repair including but not limited, to 3rd and 4th degree lacerations.¶
 - (c) Increasingly painful or enlarging hematoma.¶
 - (d) Pre-eclampsia or eclampsia.¶
 - (e) Signs or symptoms of uterine infection.¶
 - (f) Postpartum depression or mood disorder with suspicion of possible endangerment of self or others. Notwithstanding the definition of transfer of care the LDM may continue clinical postpartum care for the birthing person unless another licensed health care provider assumes clinical postpartum care.¶
- (13) Indication to transfer - Newborn Care:¶
 - (a) Apgar less than seven (7) at 10 minutes of age.¶
 - (b) Apnea.¶
 - (c) Persistent nasal flaring, grunting or retraction after one (1) hour of life without improvement.¶
 - (d) Persistent inability to maintain temperature between 97 to 100 degrees Fahrenheit or 36 to 37 degrees Celsius. ¶
 - (e) Seizures.¶
 - (f) Central cyanosis.¶
 - (g) Weight less than 2,270 grams (five pounds.)¶
 - (h) Significantly distended abdomen.¶
 - (i) Unresolved pallor at birth.¶
 - (j) Jaundice at birth or in the first 24 hours.¶
 - (k) Persistent projectile or bilious vomiting or emesis of fresh blood.¶

(l) Evident or suspected infection.¶

(14) "Indication for Consult" means a condition or clinical situation that places a birthing person or newborn at increased obstetric or neonatal risk but does not automatically exclude a birthing person or newborn from a community birth or midwifery care.¶

(15) When a birthing person or newborn present with one (1) or more indications for consult the LDM must:¶

(a) Arrange for transfer of care; or¶

(b) Comply with all the following:¶

(A) Consult with an Oregon licensed health care provider, as defined in OAR 332-025-0021(20) and (21) of this rule, who is experienced and knowledgeable about the indication for consult unless a different Oregon licensed health care provider is otherwise stated specifically within this rule;¶

(B) Communicate to the birthing person the recommendations given by the consulting Oregon licensed health care provider if the birthing person was not present at the consultation;¶

(C) Obtain informed consent in accordance with OAR 332-025-0120;¶

(D) Make a plan with the birthing person about the indication; and¶

(E) Document the recommendations, consultation, discussion, informed consent and plan.¶

(16) Indication for Consult - Preexisting or historical medical conditions:¶

(a) Three (3) cesarean sections with a previous successful vaginal birth. Consult must be with a physician who provides cesarean delivery.¶

(b) One (1) or two (2) cesarean sections without previous successful vaginal birth. ¶

(c) Current treatment with prescription medication for any ongoing or chronic medical conditions.¶

(d) Human Immunodeficiency Virus (HIV) positive.¶

(e) Syphilis.¶

(f) Cardiac condition.¶

(g) Active or chronic liver disease.¶

(h) Hyperthyroidism.¶

(i) Pulmonary disease being currently treated or is symptomatic.¶

(j) Hypertension at or above 140 systolic or at or above 90 diastolic outside of pregnancy.¶

(k) Deep venous thrombosis or any treated thromboembolic event.¶

(l) Thrombophlebitis.¶

(m) Family history of thrombophilia.¶

(n) Hemoglobinopathies.¶

(o) Bleeding disorder.¶

(p) Psychiatric disorders with concern for maternal and fetal safety.¶

(q) Isoimmunization to blood factors.¶

(r) Previous myomectomy.¶

(s) Placental abruption with adverse outcomes.¶

(t) Preterm pre-eclampsia.¶

(u) Preterm delivery less than 34 weeks.¶

(v) Obstetric hemorrhage requiring transfusion.¶

(w) Fetal demise.¶

(17) Indication for consult - Antepartum:¶

(a) Dichorionic, diamniotic twins. Consult must be with a physician who provides cesarean delivery.¶

(b) Monochorionic, diamniotic twins. Consult must be with a physician who provides cesarean delivery.¶

(c) Substance use disorder.¶

(d) Incomplete spontaneous abortion.¶

(e) Primary genital herpes.¶

(f) Known fetal anomalies that may require medical attention.¶

(g) Second or third trimester bleeding.¶

(h) Gestational diabetes or blood glucose dysregulation well-controlled with diet and exercise.¶

(i) Uterine anomaly.¶

(j) Platelet count of less than 115,000.¶

(k) Isoimmunization to blood factors.¶

(l) Psychiatric disorders with concern for maternal and fetal safety.¶

(m) Syphilis.¶

(n) Human Immunodeficiency Virus (HIV) positive.¶

(o) Suspected thromboembolic event.¶

(p) Hemoglobinopathies. ¶

(q) Thrombophilia.¶

(r) Confirmed or suspected cholestasis.¶

- (s) Breech presentation after 36 weeks. Consult for breech presentation after 36 weeks must be with a physician who provides cesarean delivery.¶¶
 - (t) Hemoglobin under 10 unresponsive to treatment.¶¶
 - (u) Oligohydramnios or polyhydramnios.¶¶
 - (v) Abnormal fetal cardiac rate or rhythm.¶¶
 - (w) Abnormally decreased fetal movement.¶¶
 - (x) Abnormal hepatic or renal function test.¶¶
 - (y) Active renal disease.¶¶
 - (z) Fetal growth restriction.¶¶
 - (18) Indication for consult - Intrapartum:¶¶
 - (a) Hypertension at or above 140 systolic or at or above 90 diastolic.¶¶
 - (b) Frank or complete breech identified in labor and without previous consult unless birth is imminent.¶¶
 - (19) Indication for consult - Postpartum:¶¶
 - (a) Hypertension at or above 150 systolic or at or above 100 diastolic on two (2) separate occasions which are more than four (4) hours apart or hypertension at or above 160 systolic or at or above 110 diastolic on one (1) occasion.¶¶
 - (b) Ongoing or unresolved urinary retention.¶¶
 - (c) Evident or suspected infection unresponsive to treatment.¶¶
 - (20) Indication for consult - Newborn:¶¶
 - (a) Gestational age assessment of less than 36 weeks and 0 days.¶¶
 - (b) Excessive ruddiness at birth.¶¶
 - (c) Any generalized rash at birth.¶¶
 - (d) Persistent hypotonia.¶¶
 - (e) Heart rate less than 80 or greater than 160 (at rest) without improvement.¶¶
 - (f) Birth injury such as facial or brachial palsy, suspected fracture or severe bruising.¶¶
 - (g) Evident or suspected major congenital anomaly.¶¶
 - (h) Direct Coomb's positive. Consultation for Direct Coomb's positive newborns must be with a pediatric care provider.¶¶
 - (i) Evident or suspected neonatal opioid withdrawal syndrome.¶¶
 - (j) Failure to urinate within 24 hours after birth or pass stool within 48 hours after birth.¶¶
 - (k) Pulse oximeter reading of less than 90 percent on right hand at greater than 24 hours.¶¶
 - (l) Persistent cardiac murmur.¶¶
 - (m) Persistent poor feeding.¶¶
 - (n) Weight loss greater than 10 percent of birth weight that is unresponsive to treatment.¶¶
 - (o) Newborn with Human Immunodeficiency Virus (HIV)-positive mother. Consultation must be with a pediatric care provider.¶¶
 - (p) Respiration rate greater than 100 within the first two (2) hours postpartum, and greater than 80 thereafter, lasting more than one (1) hour without improvement.¶¶
 - (q) Evident or suspected abnormally elevated bilirubin.¶¶
 - (21) For the purpose of this rule "consultation" means a dialogue for the purpose of obtaining information or advice, with an Oregon licensed health care provider who has direct experience handling complications of the risk(s) present, as well as the ability to confirm the indication for consult, which may include, but is not limited to confirmation of a diagnosis and recommendation(s) regarding management of medical, obstetric, or fetal problems or conditions. Consultation may be by phone, in person, or in writing.¶¶
 - (22) For the purpose of this rule "Oregon licensed health care provider" means a physician or physician assistant licensed under ORS 677, a nurse practitioner who is licensed as a nurse midwife under ORS 678 or nurse practitioner licensed under ORS 678, a naturopath licensed under ORS 685, or a licensed direct entry midwife licensed under ORS 687.
- Statutory/Other Authority: ORS 676.615(1), ORS 687.480(1), ORS 687.405, ORS 676.615(2), ORS 687.480(2)
 Statutes/Other Implemented: ORS 676.615(1), ORS 687.480(1), ORS 687.405, ORS 676.615(2), ORS 687.480(2)

AMEND: 332-026-0000

RULE SUMMARY: Clarify requirements for use of legend drugs and devices.

CHANGES TO RULE:

332-026-0000

Access to and Administration of Legend Drugs and Devices ¶¶

(1) An LDM is prohibited from purchasing or administering legend drugs and devices, until the continuing education listed in OAR 332-020-0010 has been completed and attestation submitted to the Office upon renewal.¶¶

(2) Pursuant to ORS 687.493, an LDM who completes the continuing education listed in OAR 332-020-0010 is authorized to purchase and administer legend drugs and devices listed in OAR 332-026-0010, 332-026-0020, and 332-026-0030.¶¶

(3) An LDM must comply with all local, state and federal laws and regulations regarding the administration, distribution, storage, transportation and disposal of legend drugs and devices listed in OAR 332-026-0010, 332-026-0020, 332-026-0030.¶¶

(4) Approved legend drugs must be inventoried and securely stored when the product is not in use, including samples or any remaining portion of a drug.¶¶

(5) Records regarding approved legend drugs and devices must be maintained for five years. Records must be kept on the business premises and available for inspection upon request by the Office. Upon request by the Board or Office, an LDM must provide a copy of records. Records must include, but are not limited, to the following:¶¶

(a) Name of drug, amount received, date of receipt, and drug expiration date;¶¶

(b) Name of drug and to whom it was administered; date and amount of drug administered to client;¶¶

(c) Name of drug, date and place or means of disposal.¶¶

(6) Expired, deteriorated or unused legend drugs must be disposed of in a manner that protects the LDM, client and others who may come into contact with the material during disposal.¶¶

(7) An LDM is required to obtain ~~the continuing education for intravenous antibiotics for Group B Streptococcal prophylaxis, however a LDM is not required to administer the antibiotic education and training before administering or purchasing any legend drug or device.~~¶¶

(8) An LDM is not required to administer and purchase any legend drugs or devices.

Statutory/Other Authority: ORS 676.615, ORS 687.793

Statutes/Other Implemented: ORS 687.793

AMEND: 332-026-0010

RULE SUMMARY: Add tranexamic acid to the list of legend drugs for maternal use.

CHANGES TO RULE:

332-026-0010

Approved Legend Drugs For Maternal Use ¶¶

An LDM may administer the following legend drugs as approved by the Board for maternal use:¶¶

(1) Anti-Hemorrhagics for use by intramuscular injection includes:¶¶

(a) Synthetic Oxytocin (Pitocin, Syntocin and generic);¶¶

(b) Methylergonovine (Methergine); or¶¶

(c) Ergonovine (Ergotrate); ~~or~~¶¶

(2) Anti-Hemorrhagics by intravenous infusion is limited to:¶¶

(a) Synthetic Oxytocin (Pitocin, Syntocin, and generic); or¶¶

(b) Tranexamic acid.¶¶

(3) Anti-Hemorrhagics for oral administration is limited to:¶¶

(a) Methylergonovine (Methergine);¶¶

(b) Misoprostol (Cytotec).¶¶

(4) Anti-Hemorrhagics for rectal administration is limited to Misoprostol (Cytotec).¶¶

(5) Resuscitation is limited to medical oxygen and intravenous fluid replacement.¶¶

(6) Intravenous fluid replacement includes:¶¶

(a) Lactated Ringers Solution;¶¶

(b) 0.9% Saline Solution;¶¶

(c) D5LR (5% Dextrose in Lactated Ringers); or¶¶

(d) D5W (5% Dextrose in water).¶¶

(7) Anaphylactic treatment by subcutaneous injection is limited to Epinephrine.¶¶

(8) Local anesthetic includes:¶¶

(a) Lidocaine HCl (1% and 2%) (Xylocaine and generic);¶¶

(b) Topical anesthetic;¶¶

(c) Procaine HCl (Novocain, benzocaine, cetacane and generic); and¶¶

(d) Sterile water papules.¶¶

(9) Rhesus Sensitivity Prophylaxis is limited to Rho(d) Immune Globulin (RhoGAM, Gamulin Rh, Bay Rho-D and others).¶¶

(10) Tissue adhesive (Dermabond or generic).¶¶

(11) Intravenous antibiotics for Group B Streptococcal prophylaxis is limited to the following and is only to be used solely for the purpose of Group B Streptococcal prophylaxis:¶¶

(a) Penicillin;¶¶

(b) Ampicillin;¶¶

(c) Cefazolin; or¶¶

(d) Clindamycin.

Statutory/Other Authority: ORS 676.615, ORS 687.493

Statutes/Other Implemented: ORS 687.493