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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

FILED
10/17/2017 2:17 PM
ARCHIVES DIVISION
SECRETARY OF STATE

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Administration of Vitamin K to newborns

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 12/08/2017 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.

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Filed By:
Brittany Hall
Rules Coordinator

HEARING(S)

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

DATE: 12/05/2017
TIME: 1:00 PM
OFFICER: Jana Fussell
ADDRESS: Portland State Office Building
800 NE Oregon St. Room 1E
Portland, OR 97232

NEED FOR THE RULE(S):

The Oregon Health Authority, Public Health Division is proposing to permanently amend OAR 333-021-0800 relating to the administration of vitamin K to newborns due to the passage of HB 2644 (Oregon Laws 2017, chapter 162) during the 2017 legislative session. HB2644 requires the Oregon Health Authority to establish by rule the appropriate dosage of vitamin K and the most effective procedures for administering vitamin K.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

HB 2644 (2017) https://olis.leg.state.or.us/liz/2017R1/Measures/Overview/HB2644

FISCAL AND ECONOMIC IMPACT:

ORS 433.306 already requires physicians or midwives attending the mother at the birth of a child to ensure that a newborn infant receives Vitamin K within 24 hours after birth. As such it is not expected that hospitals, birthing centers or providers attending a birth will be impacted economically. The rule proposes that the most effective procedure for administering Vitamin K is by a single intramuscular dose which many providers and facilities currently administer. Since an intramuscular dose is less expensive than an oral dose, costs savings may be experienced. There will be a minimal fiscal impact to the Oregon Health Authority and licensing boards in terms of educating providers about the

new rules.

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) The Oregon Health Authority, in cooperation with the licensing boards shall notify licensing boards' licensees and any association of midwives of rules. There will be minimal impact to workload of agency staff. There is no anticipated cost of compliance impact on units of local government or the public.

(2)(a) The Oregon Health Authority does not collect data on the number of small clinical practices providing care to mothers at the time of birth or the number of staff each birthing center employs and therefore cannot estimate with accuracy how many providers or facilities may be a small business subject to this rule.

(b) The proposed amendments do not change current standard practice therefore reporting and recordkeeping is not expected to be impacted by this rule change.

(c) The proposed rule change could result in an increase of newborns receiving an intramuscular dose of Vitamin K instead of an oral dose. The intramuscular dose is less expensive than the oral dose therefore facilities and providers could experience cost savings.

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

A small business owner participated in the Rules Advisory Committee.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

AMEND: 333-021-0800

RULE SUMMARY: Proposed changes to include the appropriate dosage of vitamin K to be administered and the most effective procedures for administering vitamin K.

CHANGES TO RULE:

333-021-0800
Administration of Vitamin K to Newborns ¶

(1) The purpose of ORS 433.303 to 433.314 is to protect newborn infants against ~~hemorrhagic disease of the newborn.¶~~
~~(2) The Vitamin K forms suitable for use are forms of Vitamin K1 (Phytonadione), available in injectable or oral forms: as Mephyton for oral use, or as aquamephyton or konakion for injectable use. Menadione (Vitamin K3) is not recommended for prophylaxis and treatment of hemorrhagic disease of the newborn:¶~~
~~(a) The dose of any of the Vitamin K1 forms to be administered is one dose of 0.5 to 1.0 mg., if given by injection, or~~

~~one dose of 1.0 to 2.0 mg. if given orally. Additional or larger doses may be administered on an individual basis as judged medically necessary;~~¶
~~(b)~~Vitamin K Deficiency Bleeding (VKDB). ¶
(2) Physicians licensed under ORS chapters 677, 684 and 685 (medical, osteopathic, naturopathic and chiropractic physicians) or a midwife attending the mother at the birth of a child are responsible for ensuring that Vitamin K is administered to the newborn. The Vitamin K dose is to be administered within the first 24 hours ~~of delivery~~after birth. If for any reason ~~this is not done, the administration of Vitamin K1 to the newborn at a later date is recommended.~~¶
~~(3) The forms of Vitamin K listed in section (2) of this rule are prescription drugs, and because no forms of Vitamin K1 appropriate for oral~~Vitamin K is not administered within 24 hours, it should be done at the earliest opportunity. A physician or midwife ensures that Vitamin K is administ~~ration~~ered to a newborn ~~infants which are not prescription drugs have been identified, Vitamin K may be administered only by persons authorized by law to administer prescription drugs.~~by: ¶
(a) Administering the Vitamin K themself; ¶
(b) Directing another person who is legally authorized and who is able to administer the Vitamin K; or¶
(4c) ~~Physicians licensed under ORS Chapters 677, 684 and 685 (medical, osteopathic, naturopathic and chiropractic physicians) or midwives attending the mother at the birth of the child are responsible for ensuring that~~Referring the infant's family to a practitioner legally authorized to obtain and administer Vitamin K.¶
(3) The appropriate dose of Vitamin K ~~is administered to the newborn. This may be accomplished by a person legally authorized to~~(phytonadione) for a newborn is 0.5 to 1.0 mg and the most effective procedure for administer ~~Vitamin K, or by directing another person who is legally authorized and in a position to administer Vitamin K, or by referring the infants family to the local health department, hospital, or practitioner legall~~ing is through a single intramuscular dose. Smaller, larger or additional doses may be administered on an individual basis as judged medically necessary. This rule is not intended to prevent a physician or midwife from ensuring that Vitamin K is administered by a~~uthorized to obtain and administer Vitamin K.~~nother method after seeking informed consent from the parent. ¶
(~~5~~4) The person administering the Vitamin K to the newborn shall keep a record of the administration for a minimum of six months. ¶
(~~6~~5) A parent may, after being provided a full and clear explanation, decline to permit the administration of Vitamin K. ~~In this event, t~~¶
(a) The parent shall sign a form acknowledging ~~his/her~~ understanding of the reason for administration of Vitamin K and possible adverse consequences ~~in the presence of a.~~¶
(b) A person ~~who~~must witness~~ed~~ the ~~instruc~~explanation t~~of~~ the parent, and ~~who will~~must also sign the form. ¶
(c) The form shall become a part of the medical record of the newborn infant.
Statutory/Other Authority: ORS 433.312
Statutes/Other Implemented: ORS 433.303-433.314