Policy Committee Agenda January 4, 2024 – 1st Revised



In accordance with the Open Public Meetings Act, this meeting notice was sent to individuals requesting notification of the Department of Health, Washington Medical Commission (WMC) meetings. This agenda is subject to change. The WMC will take public comment at the Policy: Interested Parties meeting. To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

The WMC is providing a virtual option for this meeting.

Virtual via Teams Webinar: Registration link can be found below.

Physical location: 111 Israel Rd SE, TC2 Room 236, Tumwater, WA 98501

Thursday – January 4, 2024

To attend virtually, please register here: WMC Policy Committee

Open Session			
10:00 am Agenda			
Agenda Items		Presented By:	Page(s)
1	Non-WMC Rulemaking: Midwifery Legend Drugs and Devices Review of draft rules and request for feedback.	Pam Kohlmeier, MD, JD	2-44
	Comments from Washington State Medical Association	NA	45-48
2	Guidance Document: Medical Records: Documentation, Access, Retention, Storage, Disposal, and Closing a Practice Review, discussion, and possible revisions to the current Guidance Document.	Pam Kohlmeier, MD, JD	49-63
	Comments from Washington Advocates for Patient Safety	NA	64-65

Public Comment

The public will have an opportunity to provide comments. If you would like to comment, please use the Raise Hand function or add your comments to the chat. Please identify yourself and who you represent, if applicable. If you would prefer to submit written comments send them to medical.policy@wmc.wa.gov by January 3, 2024.

AMENDATORY SECTION (Amending WSR 17-15-024, filed 7/7/17, effective 8/7/17)

WAC 246-834-010 Definitions. The following definitions apply throughout this chapter unless the context clearly indicates otherwise:

- (1) "Active practice" means ((twenty)) 20 hours per month in prenatal and postpartum clinical care, or minimum of six births annually as the primary midwife;
- (2) "Administer" means to dispense, apply, and manage drugs, medical devices, and implants;
- $((\frac{3}{3}))$ (4) "Directly assisted" means the act where a student midwife is learning the skills of a midwife through hands-on clinical experience in gradually increasing degrees of responsibility while under supervision of a licensed midwife or other obstetric provider;

(3) "Department" means the Washington state department of health;

 $((\frac{4}{1}))$ (5) "Lactation care and services" means evaluation, problem identification, treatment, education, and consultation regarding lactation and ((breastfeeding)) chest feeding to ((mothers)) gestational parents and neonates;

- $((\frac{5}{1}))$ (6) "Nursing education" means completion of courses for credit in a school that is approved to train persons for licensure as registered nurses or licensed practical nurses, or courses in other formal training programs which include instruction in basic nursing skills, excluding nursing assistant training;
- $((\frac{(6)}{(1)}))$ (7) "Postpartum" means the 12-month period beginning on the last day of the pregnancy.
- (8) "Practical midwifery experience" means performance of tasks within the midwifery scope of practice, that is verified by affidavit, testimony or other sworn written documentation that verifies that the experience and its documentation is equivalent to that required of students enrolled in an accepted midwifery education program;
- $((\frac{7}{1}))$ (9) "Preceptor" means a licensed midwife or other obstetric practitioner licensed by their state or jurisdiction to provide maternity care who assumes responsibility for supervising the practical (clinical obstetric) experience of a student midwife;
- $((\frac{(8)}{(8)}))$ (10) "Primary attendant" means a student midwife who acts as primary midwife making intrapartum clinical decisions while under supervision of a licensed midwife or other obstetric provider;
- $((\frac{(9)}{(9)}))$ (11) "Secretary" means the secretary of the Washington state department of health;

((\frac{(10)}{)}) (12) "Supervision" means the observation and evaluation of a student midwife's practical performance. A supervisor must be physically present on-site and available to intervene when a student midwife performs any clinical care task at births and prenatal and postpartum care exams.

[Statutory Authority: RCW 18.50.010, 18.50.040, 18.50.050, 18.50.135, and 2014 c 187. WSR 17-15-024, § 246-834-010, filed 7/7/17, effective 8/7/17. Statutory Authority: RCW 18.50.135 and 18.50.045. WSR 92-02-018 (Order 224), § 246-834-010, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-834-010, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 18.50.135. WSR 85-23-044 (Order PL 566), § 308-115-050, filed 11/18/85; WSR 82-19-079 (Order PL 406), § 308-115-050, filed 9/21/82.]

AMENDATORY SECTION (Amending WSR 17-15-024, filed 7/7/17, effective 8/7/17)

WAC 246-834-062 Initial or reinstating application for individuals who have not been in the active practice of midwifery.

This section applies to applicants for an initial license as a

licensed midwife, or reinstatement of a midwifery license, who have not been in the active practice of midwifery prior to initial or reinstatement license application.

- (1) Any applicant who has not been engaged in the active practice of midwifery for more than three years but less than five years prior to the date of application shall, in addition to the requirements for licensure as specified in WAC 246-834-030 and 246-834-060 (($\frac{246-834-060}{246-834-060}$) 834-140)):
- (a) Provide documentation of a minimum of ((ten)) 10 births while acting as a birth assistant under the supervision of a preceptor within the last ((twelve)) 12 months; and
- (b) Provide documentation of completion of continuing education for the three years prior to application that meets the requirements of WAC 246-834-355.
- (2) Any initial or reinstating applicant who has not been engaged in the active practice of midwifery for five or more years prior to the date of application shall, in addition to the requirements for licensure as specified in WAC 246-834-030 and 246-834-060 ((and 246-834-060) 834-140)):

- (a) Provide documentation of a minimum of ((fifteen)) 15 births while acting as a birth assistant under the supervision of a preceptor within the last ((twelve)) 12 months;
- (b) Provide documentation of completion of continuing education for the three years prior that meets the requirements of WAC 246-834-355; and
- (c) If applying for reinstatement, retake and pass the current Washington state midwifery licensure examination.
- (3) This section does not apply to any applicant who has been enrolled in a recognized educational program under WAC ((246-834-135))246-834-020 or 246-834-065.

[Statutory Authority: RCW 18.50.010, 18.50.040, 18.50.050, 18.50.135, and 2014 c 187. WSR 17-15-024, \$ 246-834-062, filed 7/7/17, effective 8/7/17.1

AMENDATORY SECTION (Amending WSR 17-15-024, filed 7/7/17, effective 8/7/17)

WAC 246-834-065 Application for examination—Foreign trained.

An applicant for a midwife license who graduated from a foreign educational institution on midwifery outside of any U.S. jurisdiction may sit for the licensing examination provided the applicant completes all requirements in this section:

- (1) Complete application requirements for licensure in WAC 246-834-060;
- (2) Provide proof of a certificate or diploma from a foreign institution on midwifery of equal requirements conferring the full right to practice midwifery in the country in which it was issued. The diploma must bear the seal of the institution from which the applicant graduated. If applicable, the candidates must, at ((her or his)) the individual's own expense, present with the application a certified translation of the foreign certificate or diploma ((made by and under the seal of the consulate of the country in which the certificate or diploma was issued));
- (3) Submit proof of completing at least three years of midwifery training including the study of basic nursing that meets the requirements under WAC ((246-834-140)) 246-834-030(1);
- (4) Submit proof of meeting minimum educational requirements under WAC ((246-834-140)) 246-834-030 (2)(a) and (b);
- (5) Submit to the department documentation of attendance at ((one hundred)) 100 births that meets the requirements of WAC ((246-834- $\frac{140}{1}$) 246-834-030 (3)(a);

- (6) Submit to the department documentation of prenatal care examinations of ((fifty women)) 50 individuals and early postpartum care examinations of ((fifty women)) 50 individuals that meets the requirements of WAC ((246-834-140)) 246-834-030 (3)(b); and
- (7) Demonstrate competency in the use and administration of legend drugs and devices described in RCW 18.50.115 and WAC 246-834-250. The applicant shall submit documentation of competency to the department on a department supplied form. A licensed health care professional who, within ((his or her)) the individual's scope of practice, is qualified in the use and administration of legend drugs and devices described in RCW 18.50.115 and WAC 246-834-250 must sign the form.

[Statutory Authority: RCW 18.50.010, 18.50.040, 18.50.050, 18.50.135, and 2014 c 187. WSR 17-15-024, \$ 246-834-065, filed 7/7/17, effective 8/7/17. Statutory Authority: RCW 43.70.280. WSR 98-05-060, § 246-834-065, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-834-065, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 18.50.135. WSR 89-16-037 (Order PM 856), § 308-115-065, filed 7/25/89, effective 8/25/89.1

AMENDATORY SECTION (Amending WSR 15-20-049, filed 9/30/15, effective 10/31/15)

WAC 246-834-066 Certified professional midwife (CPM) licensure requirements. An applicant who holds a current North American Registry of Midwives (NARM) certified professional midwife (CPM) certification may apply for a Washington state midwife license by completing all requirements in this section.

- (1) To be eligible for a midwife license an applicant holding a CPM shall:
- (a) Complete all application requirements for licensure in WAC 246-834-060.
- (b) Ensure that proof of the CPM certification is sent to the department directly from NARM.
- (c) Submit to the department documentation of attendance at ((one hundred)) 100 births of which:
- (i) At least ((thirty)) 30 births where the applicant was the primary attendant under supervision of a qualified attendant;
- (ii) At least ((twenty)) 20 births where the applicant directly assisted;

- (iii) At least ((fifty)) 50 births that the applicant observed in addition to births counted in (c)(i) and (ii) of this subsection; and
- (iv) Documentation for (c)(i) through (iii) of this subsection must include at least the date, client identifier, the applicant's role at each birth, and the signature or initials of the qualified attendant at the birth of either: A licensed midwife, a CPM preceptor, a certified nurse midwife, or a practitioner licensed by their state or jurisdiction to provide maternity care. The applicant shall submit to the department the name and contact information of each signatory, if available. The department may approve exceptions to the required documentation in this subsection.
- (d) Submit to the department documentation of prenatal care examinations of ((fifty women)) 50 individuals and early postpartum care examinations of ((fifty women)) 50 individuals. The same ((women)) individuals need not be seen for both examinations. Documentation must include at least the date, client identifier, and the signature or initials of the qualified attendant at the care examination of either: A licensed midwife, a CPM preceptor, a certified nurse midwife, or a practitioner licensed by their state or jurisdiction to provide maternity care. The applicant must submit to the department the name and contact information of each signatory, if

available. The department may approve exceptions to the required documentation in this subsection.

- (e) Demonstrate competency in the use and administration of legend drugs and devices described in RCW 18.50.115 and WAC 246-834-250. The applicant shall submit documentation of competency to the department on a department supplied form. A licensed health care professional who, within ((his or her)) the individual's scope of practice, is qualified to use and administer legend drugs and devices described in RCW 18.50.115 and WAC 246-834-250 must sign the form.
- (f) Successfully complete courses on epidemiology and obstetric pharmacology from:
- (i) An institution that is accredited by an agency recognized by the Council for Higher Education Accreditation (CHEA) and included in their database of institutions on programs accredited by recognized United States accrediting organizations;
- (ii) An institution that is accredited by an agency recognized by the United States Department of Education (USDOE) and included in their database of accredited postsecondary institutions and programs; or
 - (iii) A curriculum or program approved by the department.

(2) Applicants applying under this section who have a current CPM but do not meet all of the requirements listed in subsection (1)(c) through (f) of this section may apply to the department for a trainee permit under WAC 246-834-068. The trainee permit authorizes the applicant to complete subsection (1)(c) through (e) of this section, under the supervision of a preceptor as described in WAC 246-834-067. [Statutory Authority: RCW 18.50.065, 18.50.135, and 18.50.040. WSR 15-20-049, § 246-834-066, filed 9/30/15, effective 10/31/15.]

AMENDATORY SECTION (Amending WSR 15-20-049, filed 9/30/15, effective 10/31/15)

WAC 246-834-067 Preceptor for certified professional midwife (CPM) licensure program. This section defines the role of a preceptor as used in WAC 246-834-066. A certified professional midwife (CPM) applicant for licensure as a midwife may use more than one preceptor to meet the requirements for licensure under WAC 246-834-066.

(1) A preceptor for clinical requirements including observed, managed, and assisted births, and prenatal and postpartum examinations must:

- (a) Have a current Washington state license as a midwife under chapter 18.50 RCW, physician under chapter 18.71 RCW, osteopathic physician under chapter 18.57 RCW, or certified nurse midwife under chapter 18.79 RCW; and
- (b) Have actively practiced obstetrics for at least three consecutive years or attended at least ((one hundred fifty)) 150 births.
- (2) A preceptor for legend drugs and devices must have a current Washington state credential and be, within ((his or her)) the individual's scope of practice, qualified to use and administer legend drugs and devices described in RCW 18.50.115 and WAC 246-834-250. [Statutory Authority: RCW 18.50.065, 18.50.135, and 18.50.040. WSR 15-20-049, § 246-834-067, filed 9/30/15, effective 10/31/15.]

AMENDATORY SECTION (Amending WSR 17-15-024, filed 7/7/17, effective 8/7/17)

WAC 246-834-080 Examination failures. (1) An applicant who has failed the NARM examination or the Washington state licensing examination, or both, shall retake and pass the examination(s) which he or she failed.

- (2) The applicant who fails the Washington state licensing examination may sit for the reexamination if ((he or she)) the individual:
- (a) Applies to the department at least ((fourteen)) 14 days prior to the next scheduled examination; and
 - (b) Pays the required fee as specified in WAC 246-834-990.
- (3) An applicant who fails the NARM or Washington licensing examination three consecutive times shall submit evidence to the secretary of completion of an individualized program of study approved by the department prior to retaking the examination.

[Statutory Authority: RCW 18.50.010, 18.50.040, 18.50.050, 18.50.135, and 2014 c 187. WSR 17-15-024, \$ 246-834-080, filed 7/7/17, effective 8/7/17. Statutory Authority: RCW 18.50.060. WSR 99-03-064, § 246-834-080, filed 1/18/99, effective 2/18/99. Statutory Authority: RCW 18.50.135 and 18.50.045. WSR 92-02-018 (Order 224), § 246-834-080, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-834-080, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 18.50.135. WSR 82-19-079 (Order PL 406), § 308-115-080, filed 9/21/82.]

AMENDATORY SECTION (Amending WSR 17-15-024, filed 7/7/17, effective 8/7/17)

WAC 246-834-140 Eligibility for state licensing examination.

Candidates for the state licensing examination shall meet the following conditions, unless applying under WAC 246-834-066 Certified professional midwife (CPM) licensure requirements:

- (1) Midwifery training shall be at least three academic years, and shall consist of both didactic and clinical instruction sufficient to meet the educational standards of the school and this section. However, the length of required training may be shortened, but not to less than two academic years, after consideration of the student's documented education and experience in the required subjects, if the applicant is a registered nurse or practical nurse licensed under chapter 18.79 RCW, or has had previous nursing education or practical midwifery experience.
- (2) The applicant must receive instruction in the following educational areas:
- (a) Midwifery, basic sciences (including biology, physiology, microbiology, anatomy with emphasis on female reproductive anatomy, genetics and embryology), normal and abnormal obstetrics and

gynecology, family planning techniques, childbirth education, nutrition both during pregnancy and lactation, ((breast)) chest feeding, neonatology, epidemiology, community care, and medicolegal aspects of midwifery; and

- (b) Basic nursing skills and clinical skills including, but not limited to, vital signs, perineal prep, catheterization, aseptic techniques, administration of medications both orally and by injection, local infiltration for anesthesia, venipuncture, administration of intravenous fluids, infant and adult resuscitation, and charting.
- (3) The applicant must undertake the care of not less than ((one hundred women)) 100 individuals in the intrapartum period. No less than ((fifteen)) 15 of the ((one hundred women)) 100 individuals must be cared for in the intrapartum period while the applicant was enrolled in the school from which the student graduates.
- (a) The applicant shall submit to the department documentation of attendance at ((one hundred)) 100 births of which:
- (i) At least ((thirty)) 30 births where the applicant was the primary attendant under supervision of a qualified attendant;
- (ii) At least ((twenty)) 20 births where the applicant directly assisted;

- (iii) At least (($\frac{\text{fifty}}{}$)) $\underline{50}$ births that the applicant observed in addition to births counted in (d)(i) and (ii) of this subsection; and
- (iv) Documentation for (a)(i) through (iii) of this subsection must include at least the date, client identifier, the applicants role at each birth, and the signature or initials of the qualified attendant at the birth of either: A licensed midwife, a CPM preceptor, a certified nurse midwife, or a practitioner licensed by their state or jurisdiction to provide maternity care. The applicant shall submit to the department the name and contact information of each signatory, if available. The department may approve exceptions to the required documentation in this subsection.
- (b) The applicant shall submit to the department documentation of prenatal care examinations of ((fifty women)) 50 individuals and early postpartum care examinations of ((fifty women)) 50 individuals. The same ((women)) individuals need not be seen for both examinations.
- (i) No less than ((fifteen women)) 15 individuals must be cared for in the prenatal and postpartum periods while enrolled in the school from which the student graduates.
- (ii) Documentation must include at least the date, client identifier, and the signature or initials of the qualified attendant at the care examination of either: A licensed midwife, a CPM

preceptor, a certified nurse midwife, or a practitioner licensed by their state or jurisdiction to provide maternity care. The applicant must submit to the department the name and contact information of each signatory, if available. The department may approve exceptions to the required documentation in this subsection.

(4) The applicant shall demonstrate competency in the use and administration of legend drugs and devices described in WAC 246-834-250. The applicant shall submit documentation of competency to the department on a department supplied form. A licensed health care professional who, within his or her scope of practice, is qualified in the use and administration of legend drugs and devices described in RCW 18.50.115 and WAC 246-834-250 must sign the form. [Statutory Authority: RCW 18.50.010, 18.50.040, 18.50.050, 18.50.135, and 2014 c 187. WSR 17-15-024, \$ 246-834-140, filed 7/7/17, effective 8/7/17. Statutory Authority: RCW 18.50.135 and 18.50.045. WSR 92-02-018 (Order 224), § 246-834-140, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-834-140, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 18.50.135. WSR 87-21-011 (Order PM 686), § 308-115-140, filed 10/9/87; WSR 85-23-044 (Order PL 566), § 308-115140, filed 11/18/85; WSR 82-19-079 (Order PL 406), § 308-115-140, filed 9/21/82.1

AMENDATORY SECTION (Amending WSR 22-13-079, filed 6/10/22, effective 7/11/22)

WAC 246-834-160 Student midwife permit. (1) A student midwife permit may be issued to any individual who has:

- (a) Successfully completed an accredited midwifery program as specified in WAC ((246-834-135)) 246-834-020, or is foreign trained as specified in WAC 246-834-065(1);
- (b) Obtained a minimum period of midwifery training of at least three academic years as required by WAC ((246-834-140)) 246-834-030;
- (c) Met the minimum education requirements required in WAC ((246-834-140)) 246-834-030 (2)(a) and (b);
- (d) Documentation of undertaking the care of not less than 50 ((women)) individuals in each of the prenatal, intrapartum and early postpartum periods as required by RCW 18.50.040 (2)(c);
- (e) Satisfactorily completed the NARM examination required by WAC 246-834-050; and

- (f) Filed a completed application for student midwife permit under WAC 246-834-060 and accompanied by a nonrefundable fee as specified in WAC 246-834-990.
- (2) The student midwife permit authorizes the ((individuals)) student to practice and observe ((women)) individuals in the intrapartum period under the supervision of a licensed midwife under 18.50 RCW, an allopathic physician under chapter 18.71 RCW, an osteopathic physician under chapter 18.57 RCW or certified nurse midwife under chapter 18.79 RCW.
- (3) Once all application requirements including clinical components are completed the applicant may be eligible to sit for the Washington state licensure examination as required in WAC 246-834-050. [Statutory Authority: RCW 18.50.135, 18.50.115, 18.50.060, and 2020 c 76. WSR 22-13-079, § 246-834-160, filed 6/10/22, effective 7/11/22. Statutory Authority: RCW 18.50.010, 18.50.040, 18.50.050, 18.50.135, and 2014 c 187. WSR 17-15-024, \$246-834-160, filed 7/7/17, effective 8/7/17. Statutory Authority: RCW 18.50.135 and 18.50.045. WSR 92-02-018 (Order 224), § 246-834-160, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-834-160, filed 12/27/90, effective 1/31/91.

Statutory Authority: RCW 18.50.135. WSR 82-19-079 (Order PL 406), § 308-115-160, filed 9/21/82.]

NEW SECTION

WAC 246-834-165 Application requirements for a licensed midwife seeking a limited prescriptive license extension, a license extension for medical devices, or a license extension for implants. (1) A licensed midwife seeking a limited prescriptive license extension shall:

- (a) Submit evidence of completion of 15 additional obstetrical pharmacology didactic training hours. The additional hours must include the prescription classifications listed in WAC 246-834-250(4) and provide skills and knowledge beyond entry-level skills or knowledge in antibiotics and contraceptives; and
- (b) Submit evidence of completion of additional training on family planning and treating common, low risk prenatal and postpartum conditions. Such training must be either:
- (i) A clinical experience of at least 20 cases reviewed in consultation with a licensed health care professional who, within their scope of practice, is qualified to use and administer legend

drugs and devices described in RCW 18.50.115 and WAC 246-834-250. The licensed health care professional must attest to the applicant's knowledge and skills by signing a form provided by the department; or

- (ii) A clinical training course or courses approved by the department.
- (2) A licensed midwife seeking the license extension for medical devices or the license extension for implants shall:
- (a) Submit completion of the requirements in subsection (1) of this section:
- (b) Submit evidence of completion of training as required by the medical device manufacturers, or an equivalent. The training must include at least three simulated medical device insertions under direct supervision;
- (c) Submit evidence of completion of training as required by the implant device manufacturers, or an equivalent. The training must include at least three simulated removals under direct supervision; and
- (d) Submit evidence of completion of additional training on medical devices or implants, or both that includes:
- (i) A clinical experience of four inserted medical devices and one medical device removal under direct supervision;

- (ii) A clinical experience of one inserted implant and three implant removals under direct supervision;
- (e) The clinical experience in (d) of this subsection must be supervised by a licensed health care professional who, within their scope of practice, is qualified to administer medical devices and implants and has at least two years of experience. The health care professional must attest to the applicant's knowledge and skills by signing a form provided by the department.
- (f) A licensed midwife may pursue all three license extensions. The training on prescriptive, medical devices, and implants in subsections (1) and (2) must be completed within five years from the date of application.
- (3) The license extensions referenced in this section do not apply to newborn care.

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AMENDATORY SECTION (Amending WSR 22-13-079, filed 6/10/22, effective 7/11/22)

WAC 246-834-250 Legend drugs and devices. A licensed midwife shall have a procedure, policy or guideline for the use of each legend drug and device. A midwife may not administer or prescribe a legend drug or use a legend device for which they are not qualified by education, training, and experience.

- (1) A licensed midwife may purchase and use legend drugs and devices as follows:
- (a) Dopplers, syringes, needles, phlebotomy equipment, sutures, urinary catheters, intravenous equipment, amnihooks, airway suction devices, electronic fetal monitors, jada system, tocodynamometer monitors, oxygen and associated equipment, glucose monitoring systems and testing strips, neonatal pulse oximetry equipment, hearing screening equipment, centrifuges, and nasopharyngeal or nasal swabs for appropriate testing;
- (b) Nitrous oxide as an analgesic, self-administered inhalant in a 50 percent blend with oxygen, and associated equipment, including a scavenging system;
- (c) Ultrasound machine used in the real time ultrasound of pregnant uterus for the confirmation of viability, first trimester dating, third trimester presentation, placental location, and amniotic fluid assessment; and
- (d) Neonatal and adult resuscitation equipment and medication, including airway devices and epinephrine for neonates.

- (2) Pharmacies may issue ((breast)) the following as ordered by a licensed midwife: Lactation pumps, compression stockings and belts, maternity belts, diaphragms and cervical caps, glucometers and testing strips, iron supplements, prenatal vitamins, and recommended vaccines as specified in subsection (3)(e) through (j) of this section ((ordered by licensed midwives)).
- (3) In addition to prophylactic ophthalmic medication, postpartum oxytocic, vitamin K, Rho (D) immune globulin, and local anesthetic medications as listed in RCW 18.50.115, licensed midwives may obtain and administer the following medications:
- (a) Intravenous fluids limited to Lactated Ringers, ((5%)) five percent Dextrose with Lactated Ringers, and 0.9% sodium chloride;
 - (b) Sterile water for intradermal injections for pain relief;
- (c) Magnesium sulfate for prevention or treatment of ((maternal)) peripartum seizures pending transport;
- (d) Epinephrine for use in ((maternal)) peripartum anaphylaxis and resuscitation and neonatal resuscitation, pending transport;
- (e) Measles, Mumps, and Rubella (MMR) vaccine to nonimmune postpartum ((women)) individuals;
- (f) Tetanus, diphtheria, acellular pertussis (Tdap) vaccine for use in pregnancy;

- (q) Hepatitis B (HBV) birth dose for any newborn administration;
- (h) HBIG and HBV for any neonates born to a hepatitis ((B+mothers)) B positive gestational parent;
 - (i) Influenza vaccine ((for use in pregnancy));
- (j) Any vaccines recommended by the Centers for Disease Control and Prevention (CDC) advisory committee on immunization practices for ((pregnant or postpartum people or)) infants in the first two weeks after birth((, as it existed on the effective date of this section)) or pregnant or postpartum people;
- (k) Terbutaline to temporarily decrease contractions pending emergent ((intrapartal)) intrapartum transport;
- (1) Antibiotics for intrapartum prophylaxis of Group B ((beta hemolytic)) Streptococcus (GBS) per current CDC guidelines; ((and))
- (m) Antihemorrhagic drugs to ((control)) treat postpartum hemorrhage including, but not limited to, intravenous tranexamic acid, oxytocins, misoprostol, methylergonovine maleate (oral or intramuscular), and prostaglandin F2 alpha; and
 - (n) Nifedipine for indication of preterm labor pending transport.
- (4) A licensed midwife with a limited prescriptive license extension may prescribe, obtain, and administer the items in subsections (1) through (3) of this section, and the following

medications and therapies for the prevention and treatment of outpatient conditions that do not constitute a significant deviation from normal per RCW 18.50.010 during pregnancy or postpartum based on current evidence and practice:

- (a) Antibiotics;
- (b) Antiemetics;
- (c) Antivirals;
- (d) Antifungals;
- (e) Low-potency topical steroids;
- (f) Antipruritic medications and therapies;
- (g) Other medications and therapies including, but not limited

to:

- (i) Galactagogues;
- (ii) Topical analgesia for anal, vulvar, and perineal pain;
- (iii) Preterm labor preventatives;
- (iv) Stool softeners;
- (v) Vitamins and minerals for preventing and treating deficiencies;
 - (vi) Over-the-counter medications as needed;
 - (vii) Nonopioid medication for therapeutic rest;
 - (viii) Medications for SAB miscarriage prevention and completion;

- (ix) Smoking cessation;
- (x) Prescription referrals for IV iron infusions; and
- (h) Hormonal and nonhormonal family planning methods.
- (5) Pursuant to RCW 18.50.010, a licensed midwife with a license extension that includes medical devices or implants, or both may prescribe, obtain, and administer hormonal and nonhormonal family planning method devices including, but not limited to, copper or other nonhormonal intrauterine devices (IUD), IUDs with levonorgestrel or other progestin, implants or as consistent with current evidence and practice so long as they have a license extension to perform the task.
- (6) The client's records must contain documentation of all medications and devices prescribed, ordered, and administered. [Statutory Authority: RCW 18.50.135, 18.50.115, 18.50.060, and 2020 c 76. WSR 22-13-079, § 246-834-250, filed 6/10/22, effective 7/11/22. Statutory Authority: RCW 18.50.135 and 18.50.115. WSR 19-15-005, § 246-834-250, filed 7/5/19, effective 8/5/19. Statutory Authority: RCW 18.50.115. WSR 05-06-118, \$246-834-250, filed 3/2/05, effective 4/2/05. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-834-250, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 18.50.040(3) and 18.50.115. WSR 88-12-040 (Order PM 732), § 308-115-250, filed 5/27/88.]

AMENDATORY SECTION (Amending WSR 17-15-024, filed 7/7/17, effective 8/7/17)

WAC 246-834-255 Elements of care for the newborn. The customary scope of care of a newborn up to two weeks of age by a licensed midwife includes, but is not limited to, clinical assessment, treatment, education, support and referral as described in this section. Newborn care shall not go beyond the scope of the midwife's education, training and experience.

- (1) Immediate newborn care includes, but is not limited to:
- (a) Appearance, pulse, grimace, activity and respiration (APGAR) assessment;
- (b) Stabilization and monitoring of the newborn for a minimum of two hours postpartum;
- (c) Early initiation and facilitation of ((breast or bottle)) infant feeding;
 - (d) Complete physical examination;
- (e) Education for parents regarding care and monitoring of the normal newborn; and
- (f) Physician consultation, referral and/or transfer of care in the event of significant deviations from normal.

- (2) Other support may include:
- (a) Neonatal resuscitation; and
- (b) Legend drugs and devices allowed in RCW 18.50.115 and WAC 246-834-250.
 - (3) Subsequent care may include, but is not limited to:
- (a) Evaluating the newborn for well-being such as jaundice, weight loss, and adequate feeding and elimination patterns;
 - (b) Newborn metabolic screening per RCW 70.83.020;
- (c) Critical congenital heart disease screening per RCW 70.83.090;
 - (d) Lactation care and services; and
- (e) Consultation ((and/or)) and possible referral to pediatric care for any significant deviation from normal.

[Statutory Authority: RCW 18.50.010, 18.50.040, 18.50.050, 18.50.135, and 2014 c 187. WSR 17-15-024, \$ 246-834-255, filed 7/7/17, effective 8/7/17.]

AMENDATORY SECTION (Amending WSR 15-24-092, filed 11/30/15, effective 12/31/15)

WAC 246-834-345 License renewal. A licensed midwife must renew their license every year on ((his or her)) the individual's birthday. To renew a license, a licensed midwife shall comply with the requirements in:

- (1) RCW 18.50.102 License renewal;
- (2) RCW 18.50.108 Written plan for consultation, emergency transfer, and transport;
 - (3) WAC 246-12-030 How to renew a credential;
 - (4) WAC 246-834-355 Continuing education;
 - (5) WAC 246-834-360 Quality improvement program;
 - (6) WAC 246-834-370 Data submission; and
- (7) WAC 246-834-990 Midwifery fees and renewal cycle. [Statutory Authority: RCW 18.50.102 and 18.50.135. WSR 15-24-092, § 246-834-345, filed 11/30/15, effective 12/31/15.]

AMENDATORY SECTION (Amending WSR 15-24-092, filed 11/30/15, effective 12/31/15)

WAC 246-834-355 Continuing education. (1) A licensed midwife shall complete ((thirty)) 30 hours of continuing education (CE) every three years and must comply with ((chapter 246-12 WAC, Part 7)) WAC

- 246-12-170 through 246-12-240. CE course work must contribute to the professional knowledge and development of the licensed midwife.
- (a) A minimum of ((twenty-five)) 25 hours must be directly related to the clinical practice of midwifery. A licensed midwife who has a license extension shall complete a minimum of three hours of CE relevant to the license extension or extensions they hold as part of the 25-hour requirement.
- (b) In addition to the 25 hours of clinical practice CE in (a) of this subsection, a licensed midwife shall complete two hours of health equity CE every four years per chapter 43.70 RCW and in compliance with WAC 246-12-800 through 246-12-830.
- (c) Any remaining hours may be in professional development activities that enhance the practice of the licensed midwife.
- (2) A licensed midwife shall obtain CE hours through one or more of the categories listed below. Documentation for all activities must include licensee's name, date of activity, and number of hours. Additional specific documentation is defined below:
- (a) Acceptable CE course work. A minimum of ((ten)) 10 hours is required per reporting period in acceptable CE course work. For the purposes of this section, acceptable CE course work means courses offered or authorized by industry recognized local, state, private,

national and international organizations, agencies or institutions of higher learning. The department will not authorize or approve specific CE courses. The required documentation for this category is a certificate or documentation of attendance.

- (b) Course work or classes offered by an accredited college or university. The course work must provide skills and knowledge beyond entry-level skills. The required documentation for this category is a transcript or documentation of attendance. A maximum of ((ten)) 10 hours is allowed per reporting period for this category.
- (c) Research, writing, or teaching. The required documentation for this category is a two-page synopsis for each activity written by the licensee. A maximum of ((fifteen)) 15 hours is allowed per reporting period for this category.
- (d) Documented self-study or life experience. The required documentation for this category is a two-page synopsis of each activity written by the licensee. A maximum of five hours is allowed per reporting period for this category.
- (e) Serving on a professional board, committee, disciplinary panel, or association. The required documentation for this category is a letter or other documentation from the organization. A maximum of five hours is allowed per reporting period for this category.

- (f) Professional manuscript review. The required documentation for this category is a letter from the publishing organization verifying review of the manuscript. A maximum of ((ten)) 10 hours is allowed per reporting period for this category.
- (g) Professional conference or workshop. The required documentation for this category is a certificate or documentation of attendance. A maximum of ((ten)) 10 hours is allowed per reporting period for this category.
- (3) Continuing education credit will not be given for the following:
 - (a) A cardiopulmonary resuscitation course;
 - (b) A neonatal resuscitation course; or
 - (c) Participation in data submission on perinatal outcomes.
- (4) ((Verification of)) The department may verify completion of continuing competency hours ((will begin on January 1, 2019)). [Statutory Authority: RCW 18.50.102 and 18.50.135. WSR 15-24-092, § 246-834-355, filed 11/30/15, effective 12/31/15.]

AMENDATORY SECTION (Amending WSR 15-24-092, filed 11/30/15, effective 12/31/15)

WAC 246-834-360 Quality improvement program. (1) As a condition of renewing a license, a licensed midwife shall:

- (a) Participate in a Washington state coordinated quality improvement program peer review process that complies with the requirements in RCW 43.70.510.
- (b) Attest every two years that the midwife has completed peer review for a minimum of five of the midwife's clinical cases over the course of those two years.
- (2) A midwife may be excused from or granted an extension of participation in a peer review process due to illness or other extenuating circumstances. The department, upon request, will determine if the requirements may be waived or if an extension may be granted.
- (3) For auditing purposes, written confirmation of participation in a peer review process from the approved coordinated quality improvement program shall suffice. The midwife must keep ((her/his)) their participation records; records must not be sent to the department.
- (4) Verification of completion of participation in a peer review process will begin on January 1, 2018.

[Statutory Authority: RCW 18.50.102 and 18.50.135. WSR 15-24-092, § 246-834-360, filed 11/30/15, effective 12/31/15.]

AMENDATORY SECTION (Amending WSR 22-13-079, filed 6/10/22, effective 7/11/22)

WAC 246-834-370 Data submission. (1) As a condition of renewing a license, a licensed midwife shall report data on all courses of care for every ((mother)) gestational parent and newborn under the midwife's care to a national or state research organization approved by the department. If the ((mother)) gestational parent declines to participate in the collection of data, the midwife shall follow the protocol of the approved national or state research organization.

- (2) The licensed midwife shall verify compliance by submitting an attestation to the department annually with the license renewal. For good cause, the secretary may waive reporting requirements.
- (3) For auditing purposes, written confirmation of full participation in data collection from the approved state or national research organization shall suffice.

(4) The midwife must keep ((her/his)) their data and participation records; data and participation records will not be submitted directly to the department.

[Statutory Authority: RCW 18.50.135, 18.50.115, 18.50.060, and 2020 c 76. WSR 22-13-079, § 246-834-370, filed 6/10/22, effective 7/11/22. Statutory Authority: RCW 18.50.102 and 18.50.135. WSR 15-24-092, § 246-834-370, filed 11/30/15, effective 12/31/15.]

AMENDATORY SECTION (Amending WSR 19-15-005, filed 7/5/19, effective 8/5/19)

WAC 246-834-400 Expired license. A midwife licensed under this chapter may reinstate an expired license or license extension.

- (1) If a midwife's license ((under this chapter)) has been expired for less than three years, ((to reinstate the license)) the practitioner shall meet the requirements of ((chapter 246-12 WAC, Part $\frac{2}{2}$)) WAC 246-12-040.
- (2) If a midwife's license ((under this chapter)) has expired and the practitioner has been engaged in the active practice of midwifery in another United States jurisdiction or territory, or other location

approved by the department, ((to reinstate the license)) the practitioner shall:

- (a) Submit verification of active practice; and
- (b) Meet the requirements of ((chapter 246-12 WAC, Part 2)) WAC 246-12-040.
- (3) If a midwife's license ((under this chapter)) has been expired for three years or more but less than five years at time of application, and the practitioner has not been actively engaged in midwifery, the practitioner shall:
- (a) Work as a birth assistant under the supervision of a department-approved preceptor for a minimum of ((ten)) 10 births; and
- (b) Meet the requirements of ((chapter 246-12 WAC, Part 2)) WAC 246-12-040.
- (4) If a midwife's license ((under this chapter)) has been expired for more than five years at time of application, and the practitioner has not been actively engaged in midwifery, the practitioner shall:
- (a) Work as a birth assistant under the supervision of a department-approved preceptor for a minimum of ((fifteen)) 15 births;
- (b) Retake and successfully pass the Washington state licensing examination; and

- (c) Meet the requirements of ((chapter 246-12 WAC, Part 2)) WAC 246-12-040.
 - (5) A proposed preceptor shall:
- (a) Hold an active license without restriction, current discipline, or conditions as a midwife under chapter 18.50 RCW, a certified nurse midwife under chapter 18.79 RCW, an allopathic physician under chapter 18.71 RCW, or an osteopathic physician under chapter 18.57 RCW;
- (b) Have actively practiced at least three consecutive years or attended at least ((one hundred fifty)) 150 births; and
- (c) Have demonstrated ability and skill to provide safe, quality care.
- (6) If a midwife's license extension has expired and the practitioner has been engaged in the active practice of midwifery prescriptive or medical devices and implant practice in another United States jurisdiction or territory, or other location approved by the department, the practitioner shall:
- (a) Submit verification of active practice of prescriptive, devices, or implant practices; and
 - (b) Meet the requirements of WAC 246-12-040.

- (7) A licensed midwife with an expired license extension for less than five years at the time of reactivation and has not been actively practicing in midwifery prescriptive, medical devices, and implants practice, the individual may submit their records for their initial training as required in WAC 246-834-165 and meet the requirements in WAC 246-12-040.
- (8) A licensed midwife with an expired license extension for five years or more at the time of reactivation, and has not been actively engaged in midwifery prescriptive or medical devices and implant practice, the practitioner shall retake the required training in WAC 246-834-165.

[Statutory Authority: RCW 18.50.135 and 18.50.115. WSR 19-15-005, § 246-834-400, filed 7/5/19, effective 8/5/19. Statutory Authority: RCW 18.50.010, 18.50.040, 18.50.050, 18.50.135, and 2014 c 187. WSR 17-15-024, § 246-834-400, filed 7/7/17, effective 8/7/17. Statutory Authority: RCW 43.70.280. WSR 98-05-060, § 246-834-400, filed 2/13/98, effective 3/16/98.]

AMENDATORY SECTION (Amending WSR 19-15-005, filed 7/5/19, effective 8/5/19)

WAC 246-834-450 Inactive license. (1) A licensed midwife may obtain an inactive license by meeting the requirements of ((chapter 246-12 WAC, Part 4)) WAC 246-12-090.

- (2) An inactive license must be renewed every year on the midwife's birthday according to WAC 246-12-100 and by paying the fee required under WAC 246-834-990.
- (3) A midwife with an inactive license may return to active status.
- (a) A midwife with an inactive license for three years or less who wishes to return to active status must meet the requirements of ((chapter 246-12 WAC, Part 4)) WAC 246-12-110.
- (b) A midwife with an inactive license for more than three years, who has been in active practice in another United States jurisdiction or territory or other location approved by the department and wishes to return to active status ((must)) shall:
 - (i) Submit verification of active practice; and
- (ii) Meet the requirements of ((chapter 246-12 WAC, Part 4)) WAC 246-12-110.
- (c) A midwife with an inactive license for more than three years but less than five, who has not been in active practice and wishes to return to active status must:

- (i) Work as a birth assistant under the supervision of a department-approved preceptor for a minimum of ((ten)) 10 births; and
- (ii) Meet the requirements of ((chapter 246-12 WAC, Part 4)) WAC 246-12-110.
- (d) A midwife with an inactive license for more than five years who has not been in active practice and wishes to return to active status ((must)) shall:
- (i) Work as a birth assistant under the supervision of a department-approved preceptor for a minimum of ((fifteen)) 15 births;
- (ii) Retake and successfully pass the Washington state licensing examination; and
- (iii) Meet the requirements of ((chapter 246-12 WAC, Part 4)) WAC 246-12-110.
 - (4) A proposed preceptor shall:
- (a) Hold an active license without restriction, current discipline, or conditions as a midwife under chapter 18.50 RCW, a certified nurse midwife under chapter 18.79 RCW, an allopathic physician under chapter 18.71 RCW, or an osteopathic physician under chapter 18.57 RCW;
- (b) Have actively practiced at least three consecutive years or attended at least ((one hundred fifty)) 150 births; and

- (c) Have demonstrated ability and skill to provide safe, quality care.
- (5) A licensed midwife with an inactive license extension who has been engaged in the active practice of midwifery prescriptive or medical devices and implant practice in another United States jurisdiction or territory, or other location approved by the department, and wishes to return to active practice shall:
- (a) Submit verification of active practice of prescriptive, devices, or implant practices; and
 - (b) Meet the requirements of WAC 246-12-110.
- (6) A licensed midwife with an inactive license extension for less than five years at the time of reactivation, and has not been actively practicing in midwifery prescriptive, medical devices, and implants practice, the individual may submit their records for their initial training as required in WAC 246-834-165 and meet the requirements in WAC 246-12-040.
- (7) A licensed midwife with an inactive license extension for five years or more at the time of reactivation, and who has not been actively engaged in midwifery prescriptive or medical devices and implant practice, shall retake the required training in WAC 246-834-165.

[Statutory Authority: RCW 18.50.135 and 18.50.115. WSR 19-15-005, \S 246-834-450, filed 7/5/19, effective 8/5/19. Statutory Authority: RCW 18.50.010, 18.50.040, 18.50.050, 18.50.135, and 2014 c 187. WSR 17-15-024, \$246-834-450, filed 7/7/17, effective 8/7/17.]

NEW SECTION

The following sections of the Washington Administrative Code are decodified and recodified as follows:

Old WAC Number	New WAC Number
246-834-080	246-834-055
246-834-135	246-834-020
246-834-140	246-834-030



December 6, 2023

Amelia Boyd Program Manager Washington Medical Commission

Dear Amelia,

On behalf of the Washington State Medical Association (WSMA), we wanted to share information specific to the midwives' legend drugs and devices item on the December 8 interested parties policy meeting agenda. WSMA began work on this issue when it was under sunrise review by the Department of Health (Department), as well as when SSB 5765 was in front of the legislature. Throughout the subsequent rulemaking, WSMA has worked with relevant stakeholders to improve patient safety, remove inconsistencies, and maintain legislative intent.

For the commission's reference, I've included WSMA's and the Washington Chapter of the American College of Obstetrics and Gynecologists' (WA-ACOG) most recent correspondence with the Midwifery Advisory Committee (MAC) recommending edits to a draft of the rule we received on September 13. We would direct the commission's attention to the section specific to nifedipine which is included in the updated draft of WAC-246-834-250:

We are also deeply concerned about the inclusion of nifedipine in WAC 246-834-250. Nifedipine is used to treat preterm labor or hypertension – both of which are outside of the "...the prevention and treatment of common prenatal and postpartum conditions" this rulemaking is specific to. If the prescription of nifedipine delays referral to a physician, potential complications may include significant hypotension, pre-eclampsia, organ damage, or failure to get steroids necessary for fetal lung maturity. It is critical to both the patient and the fetus that this provision be removed from the draft. When a patient presents with preterm labor or hypertension, immediate patient referral is the appropriate and responsible next step.

The recommendation to remove this specific drug comes directly from WSMA and WA-ACOG member physicians. We request the WMC to share this and any other concerns with the MAC.

With regards to the training on medical devices and implants in WAC 246-834-165, DOH staff has shared that the concerns outlined in our September 13 letter have been at least partially resolved. This area of draft WAC has improved immensely since initial iterations were shared in the late Spring.

Thank you for the opportunity to share our concerns specific to this rulemaking. Should you have any follow-up questions, please contact WSMA Associate Policy Director Billie Dickinson.

Sincerely,

Nariman Heshmati, MD, MBA, FACOG President

> John Bramhall, MD, PhD President-Elect

Katina Rue, DO, FAAFP, FACOFP Past President

> Bridget Bush, MD, FASA Vice President

Matt Hollon, MD, MPH, MACP Secretary-Treasurer

> Jennifer Hanscom Chief Executive Officer

Billie Dickinson

Billie Dickinson Associate Policy Director Washington State Medical Association



October 4, 2023

Nariman Heshmati, MD, MBA, FACOG

President

Kathy Weed Program Manager Department of Health

John Bramhall, MD, PhD President-Elect

RE: Midwives limited prescriptive authority rulemaking

Katina Rue, DO, FAAFP, FACOFP

Dear Ms. Weed,

Bridget Bush, MD, FASA Vice President Dear Ms. Weed,

Matt Hollon, MD, MPH, MACP Secretary-Treasurer

Secretary-Treasurer

Jennifer Hanscom Chief Executive Officer On behalf of the Washington State Medical Association (WSMA) and the Washington Chapter of the American College of Obstetrics and Gynecologists (WA-ACOG), thank you for the opportunity to provide comment on the rulemaking implementing SSB 5765 regarding limited prescriptive authority for licensed midwives. Both WSMA and WA-ACOG are grateful for our continued partnership with licensed midwives and their contributions to the care team. We also appreciate the Midwifery Advisory Committee (MAC) considering our recommendations on the previous draft of this WAC. While the draft received on September 13 is much improved, additional changes will improve patient safety, remove inconsistencies, and maintain legislative intent.

As written, draft WAC 246-834-165 is inconsistent with regards to the manufacturer's training – requiring it for implants, but not for medical devices. The training provided by the manufacturer is critical to understanding the nuances of any medical device or implant, as well as its successful insertion and/or removal. The draft WAC also requires simulated medical device insertions to be done under direct supervision, but no such requirement exists for simulated implant removals. Expert opinion agrees that the removal of an implant is the most technical procedure contemplated in this draft – supervision, guidance, and feedback is imperative to ensuring patient comfort and safety. As such, we recommend the following changes to draft WAC 246-834-165:

- (1) Licensed midwives seeking an additional license extension that includes medical devices or implants, or both shall:
 - (a) Submit completion of the requirements in subsection (1) above;
 - (b) Submit evidence of completion of <u>training as required by the medical device</u> <u>manufacturers, or an equivalent. The training must include</u> at least three simulated medical device insertions under direct supervision;
 - (c) Submit evidence of completion of training as required by the implant device manufacturers, or an equivalent. The training must include at least 3 simulated removals under direct supervision; and

We are also deeply concerned about the inclusion of nifedipine in WAC 246-834-250. Nifedipine is used to treat preterm labor or hypertension – both of which are outside of the "...the prevention and treatment of common prenatal and postpartum conditions" this rulemaking is specific to. If the prescription of nifedipine delays referral to a physician, potential complications may include significant hypotension,

pre-eclampsia, organ damage, or failure to get steroids necessary for fetal lung maturity. <u>It is critical to both the patient and the fetus that this provision be removed from the draft. When a patient presents with preterm labor or hypertension, immediate patient referral is the appropriate and responsible next step.</u>

Our organizations have appreciated the opportunity to provide comment on this rulemaking throughout the process. We look forward to offering our support for this rulemaking once the issues noted above have been resolved. Should you have any follow-up questions, please contact <u>WSMA Associate Policy</u> <u>Director Billie Dickinson</u>.

Sincerely,

Washington State Medical Association Washington Chapter of the American College of Obstetrics and Gynecologists

Guidance Document



Medical Records: Documentation, Access, Retention, Storage, Disposal, and Closing a Practice

Observe, record, tabulate, communicate.

-Sir William Osler (1849-1919)

Introduction

The Washington Medical Commission provides this guidance document to physicians and physician assistants (practitioners) on the appropriate documentation of a medical record; special considerations for maintaining an electronic health record; providing access to medical records; the retention, storage and disposal of medical records; and handling records when closing a practice. The Commission recognizes that in some practice settings, practitioners may not have control over the records and may not be able to fully implement the recommendations made below. The Commission appreciates the variety of medical practices and urges practitioners to exercise reasonable judgment which may vary by specialty in the application of the guidance document. An appendix contains a history of the medical record, illustrative examples of complaints regarding medical records made to the Commission, and additional information on the implementation of electronic health records.

Guidance

I. Documentation

A. Purpose of the Medical Record

As part of delivering high-quality, safe, and integrated medical care, it is critically important that each practitioner maintains accurate, clinically useful, timely, and consistent medical records. A practitioner should maintain a medical record for each patient for whom he or she provides care. Notes, either handwritten, typed or dictated, must be legible. Dictation must be transcribed, reviewed, and signed within a reasonable time. The practitioner must ensure that the transcription of notes is accurate, particularly when using dictation or voice-recognition software.

The medical record is a chronological document that:

- 1. Records pertinent facts about an individual's health and wellness;
- 2. Enables the treating care provider to plan and evaluate treatments or interventions, making clear the rationale for diagnoses, plans and interventions;
- 3. Enhances communication between professionals, assuring the patient optimum continuity of care;

- 4. Assists both patient and practitioner in communication with third party participants;
- 5. Facilitates the practitioner's development of an ongoing quality assurance program;
- 6. Provides a legal document for verification and/or audit of the delivery of care; and
- 7. Is available as a source of clinical data for research and education.

B. The Essential Elements of a Medical Record

The practitioner should include the following elements in all medical records:

- 1. The purpose of each patient encounter and appropriate information about the patient's history and examination, the patient's perspective and preferences, plan for any treatment, and the care and treatment provided;
- 2. The patient's pertinent medical history including serious accidents, operations, significant illnesses, and other appropriate information;
- 3. Prominent notation of medication and other significant allergies, or a statement of their absence;
- 4. Known or suspected reactions including allergy warnings;
- 5. Clearly documented informed consent obtained from the patient or from a person authorized to consent on behalf of the patient. In some emergency situations, the reason for a lack of informed consent should be clearly documented; and
- 6. The date of each entry, and the time as appropriate.

C. Additional Elements of a Medical Record

The following additional elements reflect commonly accepted standards for medical record documentation:

- 1. Each page in the medical record contains the patient's name or ID number.
- 2. Personal biographical information such as home address, employer, marital status, emergency contact information and all telephone numbers, including home, work, and mobile phone numbers.
- 3. Each entry in the medical record contains the author's identification. Author identification may be a handwritten signature, initials, or a unique electronic identifier.
- 4. All drug therapies are listed, including dosage instructions and, when appropriate, indication of refill limits. Prescription refills should be recorded.
- 5. Encounter notes should include appropriate arrangements and specified times for follow-up care.
- 6. All consultation, laboratory, and imaging reports should be entered into the patient's record, reviewed, and the review documented by the practitioner who ordered them. Abnormal reports should be noted in the record, along with corresponding follow-up plans and actions taken.
- 7. An appropriate immunization record is kept up to date by the primary care provider and, ideally, readily accessible by all clinicians caring for the patient, as technology permits.
- 8. Documentation of appropriate preventive screening and services being offered in accordance with accepted practice guidelines, as relevant to the visit and/or the specific provider's role in caring for the patient.
- 9. Documentation of other persons present during the encounter.

Where possible, the practitioner should avoid judgmental language in the medical record. The practitioner should consider that patients increasingly have access to and will read their own medical record. The practitioner should also be aware that a patient has a statutory right to submit a concise statement describing a correction or amendment for inclusion in the medical record. RCW 70.02.110. For a history of the medical record, see Appendix, Part I.

D. Special Considerations When Using an Electronic Health Record

An electronic health record (EHR), a digital version of the traditional paper-based medical record, documents health care that took place within a practitioner's office, single health care facility or health care system as well as all other communications (records of phone calls, emails, etc.) between the health care team and the patient. [1] The ideal EHR is designed to contain and share information among all involved providers, patients, and their designated caretakers.

The EHR offers a number of potential benefits over the paper medical record. However, as with any innovation, there are challenges and potential hazards in its meaningful use. The Commission recognizes several problematic documentation practices while using an EHR that in some instances interfere with delivery of high-quality, safe, and integrated medical care; impede medico-legal or regulatory investigation; or are fraudulent.

1. Recommendations for Practitioners

The following recommendations, which are not necessarily exhaustive, are intended to inform practitioners of the appropriate use of an EHR, and to indicate how the Commission will evaluate a medical record, including records that are the product of an electronic system.

The patient record in an EHR should reflect the same or improved content and functionality as that produced in traditional formats, and will be held to essentially the same standard.

- a. A practitioner using an EHR must ensure:
 - i. authorized use and compliance with state and federal privacy and security legal requirements, law, and with institutional privacy and security policies;
 - ii. a timely, accurate, succinct, and readable entry;
 - iii. consistency and accuracy between various aspects of a record; and
 - iv. assumption of ultimate responsibility for trainees' and scribes' documentation.
- b. Retention or re-entry of inaccurate, inconsistent, or outdated information in the EHR from historic entries should be avoided. Original information needs to be retrievable from a separate location in the EHR via a secure and permanent audit trail.
- c. A practitioner's actions and decision-making should be accurately reflected in the documentation. The record will include a description of any shared decision-making process, when appropriate.¹

¹ EHRs have the potential to support shared decision-making. Studies show that EHRs that have incorporated shared decision-making tools result in improved clinical outcomes. *The Promise of Electronic Health Records to Promote Shared Decision Making: A Narrative Review and a Look Ahead*, Medical Decision Making, Vol. 38(8) 1040-1045 (2018). For more information on shared decision making, see the Washington State Health Care Authority web site on shared decision making, and the Bree Collaborative web site describing its work on this topic.

- d. Documenting aspects of a practitioner-patient interaction that did not transpire, such as indicating that components of a physical examination were performed when they were not, even when it occurs inadvertently because of EHR design or function, may be considered fraud. Similarly, when documentation about a significant aspect of the practitioner-patient interaction is not present, the assumption is that it did not occur.
- e. It is important to distinguish those portions of the history that were obtained by the note writer from those that were copied or carried forward from another practitioner's note. [2] The practitioner must recognize that "carry forward" or "cut-and-paste" functions, even when done automatically by the EHR software, represent significant risks to patient safety. Concerns about "clinical plagiarism" or fraudulent billing may arise when appropriate and accurate attribution of copy-paste or carry-forward information is missing from an EHR note. Practitioners should carefully review and edit any EHR-generated note to assure its accuracy prior to authenticating it.
- f. Laboratory and imaging data should only be brought into the practitioner's note when pertinent to the decision making process for the patient. Wholesale importation of laboratory data and imaging data that is already documented elsewhere in the chart is to be avoided as such practice can make interpretation of medical records by subsequent caregivers extremely difficult.
- g. The practitioner should assure that problem lists and medication lists are kept current, and that they are not cluttered with outdated information.

Examples of complaints received by the Commission relating to EHRs can be found in Appendix, Part II.

2. Suggestions for EHR Software Developers and Healthcare Institutions

The fruitful evolution of the EHR will require collaboration between entities that develop and purchase EHR systems and practitioners who use the EHR. The primary goal of the EHR is to promote high-quality, safe, and integrated health care. Other roles, such as documentation to support coding and billing, are secondary. It is unfortunate that, in general, these roles seem reversed in current EHR systems. With this in mind, the Commission offers suggestions about potential EHR improvements for software developers and health care institutions, and believes that practitioners should be involved in collaborative efforts with those entities to improve the EHR.

- a. Practitioners and clinical information specialists have an important role to play in development, decision-making, evaluation and improvement of EHR systems.
- b. EHR systems should result in a patient record that is organized, concise, and easily-readable. Lengthy and redundant information in the EHR, a source of common practitioner complaint, makes it difficult for other practitioners to identify data within the EHR that is relevant to actual patient care.[3]
- c. EHR systems should also include tools to support the clinician to use best practices when available as well as shared decision-making.
- d. An ultimate goal of the EHR universe should be widely compatible systems allowing seamless transfer and sharing of electronic medical information within and among practitioners, medical offices and clinics, hospitals and other health care institutions, as well as patients and their caregivers.
- e. It is essential to have capacity within EHR systems to correct errors as soon as they come to light, and thereby prevent their perpetuation. The original documentation must be retrievable in the EHR via secure and permanent audit trail.

- f. As patients increasingly have access to their EHR, they will undoubtedly find information within the medical record that is erroneous or with which they disagree. There should be a mechanism in place within healthcare institutions to respond to patients' questions and concerns that arise from review of their EHR, and to allow patients to submit a correction or amendment for inclusion in the medical records. RCW 70.02.110.
- g. Software supporting EHR clinical documentation should be designed and constructed for the type of provider who will use it (e.g., specialty, training) and the context in which it will be employed (e.g., admitting, consulting, ambulatory). It should automatically attribute information to each author.[4]
- h. The medical record serves many audiences who need to be considered in the design and implementation of EHR systems. To meet their potential, EHRs should incorporate comprehensive decision support that:
 - i. leads to improved patient outcomes;
 - ii. ensures safe transitions of patients from one practitioner, facility, or office to another;
 - iii. allows easy tracking and reporting of patient care metrics and outcomes; and
 - iv. promotes patient-centered communication between patients and the health care system.[3]
- i. Health care institutions should consider having mechanisms in place to monitor documentation quality and practitioner satisfaction with the EHR, and to identify changes to support improved usability, validation, integrity, and quality of data within the EHR.[4]
- j. The EHR should be designed for maximum portability and interoperability of information to benefit the patient and the public health. Full integration into the Washington State Health Information Exchange provides benefit to the patient requiring treatment when away from their medical home and provides meaningful data to assess population health. Technology vendors should design their systems with these functions as standards and institutions should mandate these functionalities as standard requirements for their implemented systems.
- k. The EHR should support rapid, minimally complicated integration with the state's prescription monitoring program to facilitate inquiry in those systems.

For additional information on the implementation of an EHR, see the Appendix, Part III.

II. Access to Medical Records

A practitioner's practices relating to medical records under his or her control should be designed to benefit the health and welfare of patients, whether current or past, and should facilitate the transfer of clear and reliable information about a patient's care. The Commission recognizes that electronic health records systems may not be compatible, making it challenging to send records to a practitioner in another electronic health record system. Practitioners should do the best they can to get medical records to patients and subsequent providers in a usable format.

A. Per <u>RCW 70.02.080</u>, a practitioner is legally obligated to make medical records available to a patient to examine or copy within 15 days of the request. A practitioner may deny the request under circumstances specified in <u>RCW 70.02.090</u>.

- B. Except for patients appealing the denial of social security benefits, the practitioner may charge a reasonable fee for making records available to a patient, another provider, or a third party and is not required to honor the request until the fee is paid. RCW 70.02.030(2). What constitutes a reasonable fee is defined in WAC 246-08-400. The practitioner cannot, however, withhold the records because an account is overdue or a bill is owed.
- <u>C.</u> To prevent misunderstandings, the practitioner's policies about providing copies or summaries of medical records and about completing forms should comply with appropriate laws and should be made available in writing to patients when the practitioner-patient relationship begins.
- A patient has a statutory right to submit a concise statement describing a correction or amendment for inclusion in the medical record. RCW 70.02.110.
- D.E. The failure to provide medical records to patients in violation of RCW 70.02 can result in disciplinary action by the Commission.

III. Retention of Medical Records

- A. There is no general law in Washington requiring a practitioner to retain a patient's medical record for a specific period of time.² The Commission appreciates the variety of medical practices and urges practitioners to exercise reasonable judgment which may vary by specialty for the retention of medical records. When appropriate, the Commission concurs with the Washington State Medical Association recommendation that practitioners should retain medical records and x-rays for at least:
 - 1. ten years from the date of a patient's last visit, prescription refill, telephone contact, test or other patient contact;
 - 2. 21 years from the date of a minor patient's birth;
 - 3. six years from the date of a patient's death; or
 - 4. indefinitely, if the practitioner has reason to believe:
 - a. the patient is incompetent;
 - b. there are any problems with a patient's care, or
 - c. the patient may be involved in litigation.
- B. A practitioner should consider whether it is feasible to retain patients' medical records indefinitely.
- C. A practitioner should verify the retention time required by their medical malpractice insurer.
- D. A practitioner should inform patients how long the practitioner will retain medical records.

IV. Storage of Records

A. A practitioner is responsible for safeguarding and protecting the medical record, whether in electronic or paper format, and for providing adequate security measures.

² RCW 70.02.160 requires a health care provider to maintain a record of existing health care information for at least one year following receipt of an authorization to disclose that health care information and during the pendency of a patient's request either to examine or copy the record or to correct or amend the record. For hospital medical record retention requirements, see RCW 70.41.190.

B. A practitioner may contract with a third party to act as custodian of the medical records. The responsible person, corporation, or legal entity acting as custodian of the records must comply with federal and or state confidentiality laws and regulations.

V. Disposing of Records

- A. When retention is no longer required, records should be destroyed by secure means. The Privacy Rule in the Health Insurance Portability and Accountability Act (HIPAA) prohibits digital and paper records containing confidential information from being thrown away in a public dumpster or recycling bin until they have been rendered unreadable or indecipherable by shredding, burning or other destruction.
- B. A practitioner should give patients an opportunity to claim records or have them sent to another provider before records are destroyed. For some practitioners, the nature of their specialty will make notifying patients impractical.

VI. Handling Medical Records When Closing a Medical Practice

- A. The obligation to make medical records available to patients and other providers continues even after a practitioner closes a medical practice.
- B. The recommendations in this section do not apply to:
 - 1. A practitioner who leaves a multi-practitioner practice. In that instance, the remaining practitioners in the practice typically assume care of the patients and retain the medical records.
 - 2. A specialist or other practitioner who does not have ongoing relationships with patients. These practitioners typically provide patient records to the referring practitioner, the patient's primary care provider, or directly to the patient.
- C. Prior to closing a practice, a practitioner should notify active patients and patients seen within the previous three years.
- D. The notice should be given at least 30 days in advance, with 90 days being the best practice.
- E. The notice should be given by:
 - 1. individual letter to the last known patient address;
 - 2. electronically, if this is a normal method of clinical communication with the patient; or
 - 3. placing a notice on the practitioner's web site, if the practitioner has a web site.
- F. The notice should include:
 - 1. the name, telephone number and mailing address of the responsible entity or agent to contact to obtain records or request transfer of records;
 - 2. how the records can be obtained or transferred;
 - 3. the format of the records, whether hard copy or electronic;
 - 4. how long the records will be maintained before they are destroyed; and
 - 5. the cost of recovering records or transferring records as defined in Chapter 70.02 RCW.
- G. The practitioner is encouraged to provide notice to the local medical society, whether the practitioner is a member or not.

- H. If the practitioner practices as part of an institution, the institution may provide the notice of the closing of the practice.
- I. If the practice closes due to the practitioner's death, the practitioner's estate becomes the owner of the medical records and is encouraged to provide this notification to patients.
- J. Disciplinary action by the Commission, including suspension, surrender or revocation of the practitioner's license, does not diminish or eliminate the obligation to provide medical records to patients.

There is no more difficult art to acquire than the art of observation, and for some it is quite as difficult to record an observation in brief and plain language.

-Sir William Osler (1849-1919)

Number: GUI2020-01

Date of Adoption: January 17, 2020

Reaffirmed: N/A

Supersedes: Retention of Medical Records GUI2017-02; and Physician and Physician Assistants' Use of the Electronic

Medical Record MD2015-09

Appendix

I. History of the Medical Record

The medical record, as an entity documenting an encounter between a patient and a practitioner, is a relatively new concept. Prior to the turn of the 20th century, patient case reports were written retrospectively, primarily for the purpose of teaching [5], with less emphasis on continuity of care. In the early 1900's, real-time documentation describing patient history and treatment was an emerging format, but patient care data were scattered and disorganized. A first step towards improving the quality and utility of medical documentation occurred in 1907 when assigning a unique number to each patient and consolidating all data for that patient into a single record was introduced. [5]

As medical education and the medical profession progressed following the Flexner Report in 1910 [2], it became necessary to document a patient's history for continuity of care and to accommodate growing involvement of medical and surgical specialists. In 1918, the American College of Surgery initiated a requirement that hospitals maintain records on all patients so that their content could be used for quality improvement. [5]

Throughout the 20th century, standards for formatting of the medical record continued to evolve. The Problem Oriented Medical Record (POMR) was introduced by Dr. Lawrence Weed in 1968. [5] The initial intent of the POMR was as an educational tool to help trainees organize their decision-making and treatment plan around each of a patient's separate medical problems. [6] [7] However, the POMR gained widespread acceptance among practitioners at all levels as did the SOAP (Subjective-Objective-Assessment-Plan) note format, which was derived from the POMR. [8] Additionally, within health care institutions and specialties, standards have emerged for documenting various types of encounters between practitioners and patients (e.g., History and Physical, Operative Note, Ambulatory New and Return Patient Notes, Interim and Discharge Summaries).

Requirements for clinical documentation were dramatically altered by release of the Evaluation and Management (E&M) guidelines by the Centers for Medicare & Medicaid Services (CMS) in 1995 and 1997. [8] Intended as a measure of cognitive (as opposed to procedural) services, the E&M guidelines specified the format and necessary components to be included in the medical record to support specific CPT codes for billing. The complexity of these requirements led many practitioners to rely on medical record templates, which were designed to promote compliance with E&M guidelines.

Until the late 20th century, the medical record was largely recorded on paper, either written longhand, or dictated and then subsequently transcribed. In part driven by approximately \$30 billion of federal incentive payments over the last five years, the rate of EHR adoption has since risen quickly, [9] such that practitioners and health care institutions not currently using EHR are now outliers. The EHR has specific goals (Table 1) and serves the needs of a variety of audiences (Table 2).

Table 1: Goals of the Medical Record³ (as informed largely by Shoolin, et al [4])

- Tell the patient's unique story as it relates to the patient's concerns ("the patient voice")
- Demonstrate diagnostic thinking and decision-making process undertaken by the practitioner.
- Provide clinical information to allow covering or consulting colleagues to maintain care and make informed decisions regarding further care
- Support coordinated longitudinal plans of care and care transitions within and across organizations
- Provide a clear and easily understood summary of the encounter, including findings and recommendations, to the patient or the patient's designated representative
- Provide clinical information to drive accurate Clinical Decision Support
- Support and identify the quality of care provided to patients
- Satisfy reasonable documentation requirements from payers
- Create the legal business record of the patient care facility
- Support population data collection and research
- Create the legal record of a patient's medical and surgical care
- Meet legal, accreditation, and regulatory criteria

-

³ These goals are similar to the intentions of "Meaningful Use." For additional background, refer to: http://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives

Table 2: Medical Record Audiences

- Patients and their designated representatives.⁴
- > Fellow practitioners
- > Other members of the health care team
- Researchers
- Public health systems
- Payers
- Legal counsel
- Courts, juries and medical review/regulatory bodies

II. Examples of Complaints Received by the Commission Relating to EHRs

After reviewing many complaints about EHRs, the Commission is concerned about problematic features of EHR implementation and use and offers the following examples of EHR-related problems, which are based on cases reviewed by the Commission:

- A patient complains a practitioner documented a complete physical examination in the EHR when only a focused examination of a patient's rash had been performed.
- Under the physical examination section of a patient's EHR, "tympanic membranes within normal limits" is explicitly stated, but in the assessment, the patient is described as having a "right acute otitis media."
- An error in a CT report about a mass in the right kidney is subsequently corrected to indicate that the mass is in the left kidney. The original diagnosis of right kidney mass is carried forward in the EHR problem list, leading to a wrong-site surgery.
- A primary care practitioner forgets to include a patient's bleeding disorder in the EHR problem list following his first appointment with the patient. The incomplete problem list is carried forward without review or update for inclusion in numerous other documents. During major surgery two months later, the patient suffers a massive hemorrhage. The surgeon was unaware the patient had a bleeding disorder.
- A practitioner complains that her colleague copies and pastes the assessment portion of patients' EHR, including detailed medical decision-making, from other practitioners' notes and then bills at a higher level than his actual work would support.
- A patient files a medical malpractice claim after delay in diagnosis of a brain tumor. The
 practitioner says that she performed a complete neurologic examination, which was normal,
 but the EHR documentation for the neurologic portion of the examination only states
 "Patellar reflexes 2+ bilaterally."

⁴ With implementation and expansion of the EHR and EHR, patients either already have or soon will have greater access to their own health information.

• A judge in a medical malpractice case found the EHR inadmissible because it contained so much redundant and irrelevant information.

III. Current EHR Implementation

Potential benefits and advantages of the EHR. There are potential benefits of the EHR, particularly as compared to paper medical records. Certain capabilities of the EHR may present both the potential for improving and for interfering with optimal documentation and patient care, which reinforces the importance of thoughtful and careful EHR planning, implementation, and use.

- Legibility: Handwritten notes could be illegible.
- Potentially greater efficiency for practitioners who, under increasing time pressures and facing large volumes of data, need ways to streamline their record keeping.
- Reviewing and documenting in the EHR can be done remotely.
- Within an EHR, there is the capability to transfer important information about a patient from one note to another, reducing the need to rewrite information that has not changed.
- EHR templates save time by displaying information in a standard format and relieving the practitioner of reestablishing a format each time a similar note is needed.
- More efficient computer entry, "real-time," i.e., during a patient encounter, could save time and
 reduce the need to recall details about the patient visit at a later time, potentially leading to greater
 accuracy.
- Better system efficiency including data retrieval, remote access, and transfer of information.
 Electronic access eliminates the cost and time needed to request and locate the hard chart. It also diminishes the chance of lost records, physical space required to store charts, and the need for personnel to assemble, store, and retrieve paper records.
- EHR systems allow multiple providers to simultaneously enter data during a patient encounter. This saves time tracking down and waiting to document in the hard chart.
- The EHR is more readily searched than the hard chart, which often existed in multiple volumes. The EHR is typically indexed by type of record, author, and date.
- EHRs integrate different types of information that at one time were maintained in separate paper
 files in the inpatient setting (e.g., practitioner orders, nurses and other ancillary staff documentation,
 prescription and medication administration records, allergies, vital signs, laboratory and radiographic
 studies, problem lists, and demographic information), into a single system and allow such
 information to be imported into electronic clinical notes.
- Real-time reminders and alerts can be incorporated into an EHR system including:
 - o reminders about health care maintenance (e.g., immunization timing),
 - o education (e.g., link to evidence-based guidelines), and
 - error checks (e.g., alerts about allergies or potential drug interaction or incorrect medication dosing).
- Improved regulatory and security monitoring the EHR includes "meta-data" (such as date and time stamps) and audit trail information that didn't exist in the legal paper record.

• Ease of quality improvement and research studies electronic data are more readily accessible for quality improvement, public health, and research studies.

Potential challenges with current EHR implementation. The EHR theoretically promises to improve efficiency and communication, reduce errors, and improve quality of care. Yet, every advance brings with it the potential for new problems, and the EHR is no exception. There are serious negative implications to poorly designed EHR systems, suboptimal EHR implementation, or careless EHR use by practitioners. A poor quality medical record, which could be inaccurate, inconsistent, incomplete, or obscure important information among unneeded or redundant detail, may adversely impact current or future care, transfers of care, and/or medico-legal investigations. Problematic aspects of current EHRs include:

- Increased work load: Data entry into the EHR can be time-consuming, particularly for practitioners who do not type well.⁵
- **Copy-paste:** Electronically carrying forward or copying portions of previously written notes and pasting them into a currently drafted note is problematic when it is either:
 - Copying the work of others without attribution ("clinical plagiarism") or without independent confirmation.⁶
 - o Introducing unnecessary redundancy (see next point—"note-bloat.").
- "Note-bloat": Note bloat refers to unnecessary and redundant expansion of a note's length and complexity. With electronic documentation, it is easy to incorporate large volumes of data into clinical documentation. Inappropriate copy-paste, carry-forward, and computer-aided data entry (auto-filling) increases the risk of lengthy but information-poor notes. Such redundant content detracts from readability, makes it more difficult to interpret and identify pertinent content, and jeopardizes the communication for which clinical notes are intended.
- "Boilerplate": Despite the appeal of using templates, "boilerplate" text may add unnecessary detail that detracts from more important information. Furthermore, busy practitioners may carelessly retain parts of a normal review of systems or examination from the template rather than correctly indicating abnormal reports or findings from their interaction with the patient, resulting in inconsistent and erroneous information within the medical record.
- Differences between the electronic version and paper copy of the EHR: The printed copy of the
 EHR may look very different from the electronic version. Specifically, the paper copy of the EHR may
 differ from the electronic version either by including auto-populated redundant or extraneous
 information or excluding data that could not be readily printed. Currently, however, when copies of
 records are requested for patient care, investigative, or discovery purposes; they are typically
 provided as paper copies, often at a considerable cost to the requesting party, which may be difficult
 to read or incompletely reflect patient care.

⁶ The US Department of Health and Human Services and the Office of the Attorney General have expressed concern for fraud resulting from liberal copying-pasting within the EHR and subsequent upcoding, citing "possible abuses including 'cloning' of medical records, where information about one patient is repeated in other records, to inflate reimbursement In 2012, the Obama administration warned against such practice: "There are troubling indications that some providers are using this technology to game the system, possibly to obtain payments to which they are not entitled. False documentation of care is not just bad patient care; it is fraud." (Abelson and Creswell, 2012)

⁵ Some practitioners rely on scribes or speech recognition software. Ultimately, the practitioner is responsible for ensuring that the medical record is accurate.

- "Pseudo-history" and "pseudo-examination": Some EHRs convert checked symptom boxes into sentences and paragraphs that are then imported into the EHR such that they appear to recount the verbatim report of the patient. However, the generated history is not derived from the patient's actual words; it only represents binary (YES/NO) data processed into standardized phrases. A similar process with checkbox-to-sentence physical examination findings is available. Such technology potentially undermines consideration of each patient as an individual and conceals the nuances of his/her unique history and needs.
- Errors in the EHR can be perpetuated and difficult to correct: Some of these errors have serious undesirable implications for subsequent care and patients' health. Providers and patients complain that when an error occurs in the EHR, it can be very difficult to correct. These errors in documentation can be perpetuated over time and may lead to actual medical errors and adverse patient outcomes.
- Interference with provider-patient relationship: Real-time EHR entry during a patient visit may interfere with face-to-face contact with the patient, which may reduce active listening, conceal important diagnostic clues, and damage patient-practitioner rapport.
- Overemphasis on documentation to meet billing specifications: This issue largely dates back to E&M regulatory efforts, initiated when paper medical records still predominated. However, EHR systems have also incorporated E&M elements into their electronic templates leading to concern that documentation whose major design objective is to support coding and billing may subvert the true goal of the EHR, which is to promote high-quality, safe, and integrated health care.

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Mike Farrell

Manager of Policy Committee

Washington Medical Commission

Jan. 2, 2024

Dear Mr. Farrell and the Policy Committee,

Washington Advocates for Patient Safety would like to take this opportunity to comment on the proposed update to the commission's policy on medical records.

Throughout our patient experiences of seeking medical care, many of us have encountered inaccuracies in our medical records. Some of these errors were minor, but some were serious enough to affect our care. When requesting corrections or amendment to correct records, many of us have also experienced difficulties and frustration, due to the fact that not all providers fully understood or followed the state and federal laws governing patients' right to correct or amend their medical records.

As patients and families, we understand that it is imperative to have accurate medical records for patients to receive safe and high-quality care. It is also critically important for patients to be able to amend their medical records in case of inaccuracy. Therefore, we strongly support the added language under section "Access to Medical Records" to explicitly spell out the patient's right to submit a correction or amendment for inclusion in the medical record. Meanwhile, we would like to suggest the following minor changes in the proposed policy update.

1. On page 6 of 8, **item D** under "Access to Medical Records", we suggest that the federal HIPAA Privacy Rule 45 CFR § 164.526 be added, in additional of listing the state law, RCW 70.02.110. This HIPAA law protects patients' civil right, allowing them to request an amendment to their health information. If the request is denied, the provider must provide a written denial, stating

the basis of the denial, indicating the patient's rights to review the denial, and preparing a written rebuttal that will be provided to the individual who submitted the record amendments.

- 2. On page 6 of 8, **item E** under "Access to Medical Records", we suggest that a wording be added, so that the failure to comply with the HIPAA Rule 45 CFR § 164.526 can also result in disciplinary action by the Commission.
- 3. Similarly, on page 5 of 8, item f under "D. Special Considerations When Using an Electronic Health Record" and "2. Suggestions for EHR Software Developers and Healthcare Institutions", we suggest that the HIPAA rule 45 CFR § 164.526 be added, in addition to the state law, RCW 70.02.110.
- 4. On Page 10 of 8, in *Table 1: Goals of the Medical Record* --- We suggest that the following new item be added to the list:
 - ➤ Document accurately the conversation with the patient or designated caretaker about diagnosis, treatment options, care plans, and any discussions on informed consent/shared decision-making.

Again, we appreciate the opportunity to comment on the proposed update on the medical record policy.

Sincerely,

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