Interpretive Statement

Title:	Physician Assistants' Use of DEA Waiver for Buprenorphine INS2018-01
References:	RCW 18.71A.030; WAC 246-918-055; 21 U.S.C. § 823(g)
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Effective Date:	March 2, 2018
Approved By:	Warren Howe, MD, Chair (signature on file)

The Medical Quality Assurance Commission (Commission) interprets RCW 18.71A.030, WAC 246-918-055, and 21 U.S.C. § 823(g) to permit an allopathic physician assistant who has received a waiver from the federal Drug Enforcement Administration (DEA) to provide buprenorphine for the treatment of opioid addiction even if the supervising physician has not received a waiver, provided that the physician assistant is supervised by a qualifying physician and the delegation agreement between the physician and the physician assistant complies with Washington law. Under 21 U.S.C. § 823(g), a qualifying physician is a physician who is an addiction specialist or who has taken the appropriate training, as defined in the federal statute.

In 2000, the United States Congress passed the Drug Addiction Treatment Act of 2000 to allow qualified physicians to apply for waivers to enable them to dispense or prescribe narcotic drugs approved by the FDA, including buprenorphine, to individuals for maintenance treatment or detoxification treatment for opioid use disorder (formerly known in the DSM-IV as opioid dependence) in settings other than approved opioid treatment programs. In 2016, the United States Congress passed the Comprehensive Addiction and Recovery Act (CARA), amending the prior law to permit physician assistants and nurse practitioners to apply for waivers to enable them to dispense or prescribe narcotic drugs, including buprenorphine, to individuals for maintenance or detoxification treatment if certain conditions are met. CARA provides that this exception expires in 2021.

In Washington, the scope of practice of a physician assistant is limited only by the education, training and experience of the physician assistant, the expertise and scope of practice of the supervising physician, and the Commission-approved delegation agreement between the physician assistant and their sponsoring or supervising physician. The Commission generally approves delegation agreements in which the physician assistant and the supervising physician have expertise in the area of practice proposed in the delegation agreement. The Commission

does not require the physician assistant's practice to be the same as the supervising physician, but it cannot exceed the supervising physician's expertise and practice.

RCW 18.71A.030 provides:

Limitations on practice—Scope of practice.

- (1) A physician assistant may practice medicine in this state only with the approval of the delegation agreement by the commission and only to the extent permitted by the commission. A physician assistant who has received a license but who has not received commission approval of the delegation agreement under RCW 18.71A.040 may not practice. A physician assistant shall be subject to discipline under Chapter 18.130 RCW.
- (2) Physician assistants may provide services that they are competent to perform based on their education, training, and experience and that are consistent with their commission-approved delegation agreement. The supervising physician and the physician assistant shall determine which procedures may be performed and the degree of supervision under which the procedure is performed. Physician assistants may practice in any area of medicine or surgery as long as the practice is not beyond the supervising physician's own scope of expertise and practice.

WAC 246-918-055 provides in part:

Delegation agreements.

- (1) The physician assistant and sponsoring physician must submit a joint delegation agreement on forms provided by the commission. A physician assistant may not begin practicing without written commission approval of a delegation agreement.
- (2) The delegation agreement must specify:

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- (b) A detailed description of the scope of practice of the physician assistant;
- (c) A description of the supervision process for the practice; and

...

- (3) The sponsoring physician and the physician assistant shall determine which services may be performed and the degree of supervision under which the physician assistant performs the services.
- (4) The physician assistant's scope of practice may not exceed the scope of practice of the supervising physician.

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21 U.S.C. § 823(g) provides in part:

- (g) PRACTITIONERS DISPENSING NARCOTIC DRUGS FOR NARCOTIC TREATMENT; ANNUAL REGISTRATION; SEPARATE REGISTRATION; QUALIFICATIONS; WAIVER
 - (1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose.

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(2)

- (A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).
- (B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:
 - (i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).
 - (ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary—
 - (I) all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and
 - (II) appropriate counseling and other appropriate ancillary services.

(iii)

(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

- (II) The applicable number is 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients.
- (III) The Secretary may by regulation change such applicable number.
- (IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.

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(G) For purposes of this paragraph:

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- (ii) The term "qualifying physician" means a physician who is licensed under State law and who meets one or more of the following conditions:
 - (I) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.
 - (II) The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.
 - (III) The physician holds a board certification in addiction medicine from the American Osteopathic Association.
 - (IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include—
 - (aa) opioid maintenance and detoxification;
 - **(bb)** appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;

- (cc) initial and periodic patient assessments (including substance use monitoring);
- **(dd)** individualized treatment planning, overdose reversal, and relapse prevention;
- (ee) counseling and recovery support services;
- (ff) staffing roles and considerations;
- (gg) diversion control; and
- (hh) other best practices, as identified by the Secretary.
- **(V)** The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate- dependent patients.
- (VI) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.
- (iii) The term "qualifying practitioner" means—

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- (II) during the period beginning on July 22, 2016, and ending on October 1, 2021, a qualifying other practitioner, as defined in clause (iv).
- (iv) The term "qualifying other practitioner" means a nurse practitioner or physician assistant who satisfies each of the following:
 - (I) The nurse practitioner or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.
 - (II) The nurse practitioner or physician assistant has—
 - (aa) completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations,

seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or

(bb) has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner or physician assistant to treat and manage opiate-dependent patients.

(III) The nurse practitioner or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

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The federal Substance Abuse and Mental Health Services Administration (SAMHSA) has informed the Washington State Department of Health that the supervising physician is not required to obtain a waiver before a physician assistant may obtain a waiver,¹ so long as the supervising physician and the physician assistant otherwise meet the requirements as set forth above. SAMHSA explained that each state may impose such a requirement, or impose any other restriction or limitation on the scope of a physician assistant's practice.

RCW 18.71A.040 and WAC 246-918-055 require a supervising physician and physician assistant to submit a delegation agreement detailing the physician assistant's scope of practice and the degree of supervision. Physician assistants may provide services that they are competent to perform based on their education, training, and experience and that are consistent with their commission-approved delegation agreement. A physician assistant's scope of practice may not exceed the scope of practice of the supervising physician.

The Commission interprets RCW 18.71A.030, WAC 246-918-055, and 21 U.S.C. § 823(g) to permit an allopathic physician assistant who has received a waiver from the DEA to provide buprenorphine for the treatment of opioid addiction even if the supervising physician has not received a waiver, provided that the physician assistant is supervised by a qualifying physician and the delegation agreement between the physician and the physician assistant complies with Washington law. The Commission interprets the term "scope of practice of the supervising

¹ Email from Ivette M. Ruiz, Compliance Officer for Health and Human Services, Regions 4 and 7, to Maura Craig, Policy Analyst, Washington State Department of Health, dated November 17, 2017.

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physician" to describe the actual practice of the supervising physician. Since a qualifying physician is an addiction specialist or has taken training in treating and managing opiate-dependent patients, the qualifying physician does not need a DEA waiver to supervise a physician assistant who provides buprenorphine to opiate-dependent patients through a DEA waiver.

Meeting the challenges of the ongoing opioid epidemic will require increased access to addiction treatment, and recognizing a physician assistant's ability to obtain a DEA waiver is one method to attempt to meet the needs of Washington citizens suffering from opioid use disorder. When applying for a waiver, practitioners are strongly encouraged to let their practice address be publically listed to facilitate access to treatment of opioid use disorder.



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NOTICE OF ADOPTION OF AN INTERPRETIVE STATEMENT

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