in schedules II, III, IV, or V, which he/she has lawfully obtained for his/her personal medical use, or for administration to an animal accompanying him/her, may enter or depart the United States with such substance notwithstanding sections 1002–1005 of the Act (21 U.S.C. 952–955), provided the following conditions are met:

(a) The controlled substance is in the original container in which it was dispensed to the individual; and

(b) The individual makes a declaration to an appropriate customs officer stating:

(1) That the controlled substance is possessed for his/her personal use, or for an animal accompanying him/her; and

(2) The trade or chemical name and the symbol designating the schedule of the controlled substance if it appears on the container label, or, if such name does not appear on the label, the name and address of the pharmacy or practitioner who dispensed the substance and the prescription number.

(c) In addition to (and not in lieu of) the foregoing requirements of this section, a United States resident may import into the United States no more than 50 dosage units combined of all such controlled substances in the individual's possession that were obtained abroad for personal medical use. (For purposes of this section, a United States resident is a person whose residence (*i.e.*, place of general abode—meaning one's principal, actual dwelling place in fact, without regard to intent) is in the United States.) This 50 dosage unit limitation does not apply to controlled substances lawfully obtained in the United States pursuant to a prescription issued by a DEA registrant.

[69 FR 55347, Sept. 14, 2004, as amended at 81 FR 97019, Dec. 30, 2016]

### § 1301.27 Separate registration by retail pharmacies for installation and operation of automated dispensing systems at long term care facilities.

(a) A retail pharmacy may install and operate automated dispensing systems, as defined in § 1300.01 of this chapter, at long term care facilities, under the requirements of § 1301.17. No person other than a registered retail pharmacy may install and operate an automated dispensing system at a long term care facility.

(b) Retail pharmacies installing and operating automated dispensing systems at long term care facilities must maintain a separate registration at the location of each long term care facility at which automated dispensing systems are located. If more than one registered retail pharmacy operates automated dispensing systems at the same long term care facility, each retail pharmacy must maintain a registration at the long term care facility.

(c) A registered retail pharmacy applying for a separate registration to operate an automated dispensing system for the dispensing of controlled substances at a long term care facility is exempt from application fees for any such additional registrations.

[70 FR 25465, May 13, 2005]

### § 1301.28 Exemption from separate registration for practitioners dispensing or prescribing Schedule III, IV, or V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

(a) An individual practitioner may dispense or prescribe Schedule III, IV, or V narcotic controlled drugs or combinations of narcotic controlled drugs which have been approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment without obtaining the separate registration required by § 1301.13(e) if all of the following conditions are met:

(1) The individual practitioner meets the conditions specified in paragraph (b) of this section.

(2) The narcotic drugs or combination of narcotic drugs meet the conditions specified in paragraph (c) of this section.

(3) The individual practitioner is in compliance with either paragraph (d) or paragraph (e) of this section.

(b)(1) The individual practitioner must submit notification to the Secretary of Health and Human Services stating the individual practitioner's intent to dispense or prescribe narcotic

drugs under paragraph (a) of this section. The notice must contain all of the following certifications:

(i) The individual practitioner is registered under §1301.13 as an individual practitioner and is a ''qualifying physician'' as defined in section 303(g)(2)(G)(ii) of the Act (21 U.S.C. 823(g)(2)(G)(ii)); a ''qualifying other practitioner'' as defined in section 303(g)(2)(G)(iv) of the Act (21 U.S.C. 823(g)(2)(G)(iv)) who is a nurse practitioner or physician assistant; or during the period beginning on October 1, 2018 and ending on October 1, 2023, a ''qualifying other practitioner'' as defined in section 303(g)(2)(G)(iv) of the Act (21 U.S.C. 823(g)(2)(G)(iv)) who is clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife. The Secretary of Health and Human Services may, by regulation, revise the requirements for being a qualifying other practitioner.

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the individual practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary of Health and Human Services:

(A) 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

(B) Appropriate counseling and other appropriate ancillary services.

(iii)(A) The total number of patients to whom the individual practitioner will provide narcotic drugs or combinations of narcotic drugs under this section at any one time will not exceed the applicable number. Except as provided in paragraphs (b)(1)(iii)(B) and (C) of this section, the applicable number is 30.

(B) The applicable number is—

(*1*) 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 Health and Human Services of the need and intent of the practitioner to treat up to 100 patients;

(*2*) 100 if the practitioner holds additional credentialing, as defined in 42 CFR 8.2;

(*3*) 100 if the practitioner provides medication-assisted treatment using covered medications (as such terms are defined in 42 CFR 8.615) in a qualified practice setting (as described in 42 CFR 8.615); and

(*4*) 275 if the practitioner meets the requirements specified in 42 CFR 8.610 through 8.655.

(2) If an individual practitioner wishes to prescribe or dispense narcotic drugs pursuant to paragraph (e) of this section, the individual practitioner must provide the Secretary of Health and Human Services the following:

(i) Notification as required under paragraph (b)(1) of this section in writing, stating the individual practitioner's name and DEA registration number issued under §1301.13.

(ii) If the individual practitioner is a member of a group practice, the names of the other individual practitioners in the group and the DEA registration numbers issued to the other individual practitioners under §1301.13.

(c) The narcotic drugs or combination of narcotic drugs to be dispensed or prescribed under this section must meet all of the following conditions:

(1) The drugs or combination of drugs have been approved for use in ''maintenance treatment'' or ''detoxification treatment'' under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

(2) The drugs or combination of drugs have not been the subject of an adverse determination by the Secretary of Health and Human Services, after consultation with the Attorney General, that the use of the drugs or combination of drugs requires additional standards respecting the qualifications of practitioners or the quantities of the drugs that may be provided for unsupervised use.

(d)(1) After receiving the notification submitted under paragraph (b) of this section, the Secretary of Health and Human Services will forward a copy of the notification to the Administrator. The Secretary of Health and Human Services will have 45 days from the date of receipt of the notification to make a determination of whether the

individual practitioner involved meets all requirements for a waiver under section 303(g)(2)(B) of the Act (21 U.S.C. 823(g)(2)(B)). Health and Human Services will notify DEA of its determination regarding the individual practitioner. If the individual practitioner has the appropriate registration under § 1301.13, then the Administrator will issue the practitioner an identification number as soon as one of the following conditions occurs:

(i) The Administrator receives a positive determination from the Secretary of Health and Human Services before the conclusion of the 45-day review period, or

(ii) The 45-day review period has concluded and no determination by the Secretary of Health and Human Services has been made.

(2) If the Secretary denies certification to an individual practitioner or withdraws such certification once it is issued, then DEA will not issue the individual practitioner an identification number, or will withdraw the identification number if one has been issued.

(3) The individual practitioner must include the identification number on all records when dispensing and on all prescriptions when prescribing narcotic drugs under this section.

(e) An individual practitioner may begin to prescribe or dispense narcotic drugs to a specific individual patient under this section before receiving an identification number from the Administrator if the following conditions are met:

(1) The individual practitioner has submitted a written notification under paragraph (b) of this section in good faith to the Secretary of Health and Human Services.

(2) The individual practitioner reasonably believes that the conditions specified in paragraphs (b) and (c) of this section have been met.

(3) The individual practitioner reasonably believes that the treatment of an individual patient would be facilitated if narcotic drugs are prescribed or dispensed under this section before the sooner of:

(i) Receipt of an identification number from the Administrator, or

(ii) Expiration of the 45-day period.

(4) The individual practitioner has notified both the Secretary of Health and Human Services and the Administrator of his or her intent to begin prescribing or dispensing the narcotic drugs before expiration of the 45-day period.

(5) The Secretary has not notified the registrant that he/she is not qualified under paragraph (d) of this section.

(6) The individual practitioner has the appropriate registration under § 1301.13.

(f) If an individual practitioner dispenses or prescribes Schedule III, IV, or V narcotic drugs approved by the Food and Drug Administration specifically for maintenance or detoxification treatment in violation of any of the conditions specified in paragraphs (b), (c) or (e) of this section, the Administrator may revoke the individual practitioner's registration in accordance with § 1301.36.

[70 FR 36342, June 23, 2005, as amended at 73 FR 29688, May 22, 2008; 83 FR 3074, Jan. 23, 2018; 85 FR 69166, Nov. 2, 2020]

### § 1301.29 [Reserved]

## Action on Application for Registration: Revocation or Suspension of Registration

### § 1301.31 Administrative review generally.

The Administrator may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to subpart A of part 1316 of this chapter. The Administrator shall review the application for registration and other information gathered by the Administrator regarding an applicant in order to determine whether the applicable standards of section 303 (21 U.S.C. 823) or section 1008 (21 U.S.C. 958) of the Act have been met by the applicant.

[62 FR 13953, Mar. 24, 1997]

### § 1301.32 Action on applications for research in Schedule I substances.

(a) In the case of an application for registration to conduct research with controlled substances listed in Schedule I, the Administrator shall process the application and protocol and forward a copy of each to the Secretary of