Drug Enforcement Administration, Justice

Line No.	Number of pack- ages ordered	Size of packages	Name of product	Packages distrib- uted	Date distributed
1					
3					

FOOTNOTE: Line numbers may be continued according to needs of the vendor.

Number of lines completed Name of vessel
Vessel's official number
Vessel's country of registry
Owner or operator of the vessel
Name and title of vessel's officer who pre-
sented the requisition
Signature of vessel's officer who presented
the requisition

- (e) Any medical officer described in paragraph (b) of this section shall, in addition to complying with all requirements and duties prescribed for registrants generally, prepare an annual report as of the date on which his/her registration expires, which shall give in detail an accounting for each vessel, aircraft, or other entity, and a summary accounting for all vessels, aircraft, or other entities under his/her supervision for all controlled substances purchased, dispensed or disposed of during the year. The medical officer shall maintain this report with other records required to be kept under the Act and, upon request, deliver a copy of the report to the Administration. The medical officer need not be present when controlled substances are dispensed, if the person who actually dispensed the controlled substances is responsible to the medical officer to justify his/her actions.
- (f) Any registered pharmacy that wishes to distribute controlled substances pursuant to this section shall be authorized to do so, provided:
- (1) The registered pharmacy notifies the nearest Division Office of the Administration of its intention to so distribute controlled substances prior to the initiation of such activity. This notification shall be by registered mail and shall contain the name, address, and registration number of the pharmacy as well as the date upon which such activity will commence; and
- (2) Such activity is authorized by state law; and
- (3) The total number of dosage units of all controlled substances distributed by the pharmacy during any calendar

- year in which the pharmacy is registered to dispense does not exceed the limitations imposed upon such distribution by $\S1307.11(a)(1)(iv)$ and (b) of this chapter.
- (g) Owners or operators of vessels, aircraft, or other entities described in this section shall not be deemed to possess or dispense any controlled substance acquired, stored and dispensed in accordance with this section. Additionally, owners or operators of vessels, aircraft, or other entities described in this section or in Article 32 of the Single Convention on Narcotic Drugs, 1961, or in Article 14 of the Convention on Psychotropic Substances, 1971, shall not be deemed to import or export any controlled substances purchased and stored in accordance with that section or applicable article.
- (h) The Master of a vessel shall prepare a report for each calendar year which shall give in detail an accounting for all controlled substances purchased, dispensed, or disposed of during the year. The Master shall file this report with the medical officer employed by the owner or operator of his/her vessel, if any, or, if not, he/she shall maintain this report with other records required to be kept under the Act and, upon request, deliver a copy of the report to the Administration.
- (i) Controlled substances acquired and possessed in accordance with this section shall be distributed only to persons under the general supervision of the medical officer employed by the owner or operator of the vessel, aircraft, or other entity, except in accordance with part 1317 of this chapter.

[62 FR 13951, Mar. 24, 1997, as amended at 79 FR 53561, Sept. 9, 2014; 84 FR 68342, Dec. 16, 2019]

§ 1301.26 Exemptions from import or export requirements for personal medical use.

Any individual who has in his/her possession a controlled substance listed

§ 1301.27

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