

(c) of this section), he/she shall submit three copies of a supplemental protocol in accordance with paragraph (a) of this section describing the new research and omitting information in the supplemental protocol which has been stated in the original protocol. Supplemental protocols shall be processed and approved or denied in the same manner as original research protocols.

[62 FR 13949, Mar. 24, 1997, as amended at 75 FR 10676, Mar. 9, 2010]

**§ 1301.19 Special requirements for online pharmacies.**

(a) A pharmacy that has been issued a registration under §1301.13 may request that the Administrator modify its registration to authorize the pharmacy to dispense controlled substances by means of the Internet as an online pharmacy. The Administrator may deny an application for a modification of registration if the Administrator determines that the issuance of a modification would be inconsistent with the public interest. In determining the public interest, the Administrator will consider the factors listed in section 303(f) of the Act (21 U.S.C. 823(f)).

(b) Each online pharmacy shall comply with the requirements of State law concerning licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses, or offers to deliver, distribute, or dispense controlled substances by means of the Internet.

(c) Application for a modified registration authorizing the dispensing of controlled substances by means of the Internet will be made by an online application process as specified in §1301.13 of this part. Subsequent online pharmacy registration renewals will be accomplished by an online process.

(d) A pharmacy that seeks to discontinue its modification of registration authorizing it to dispense controlled substances by means of the Internet as an online pharmacy (but continue its business activity as a non-online pharmacy) shall so notify the Administrator by requesting to modify its registration to reflect the appropriate business activity. Once the registration has been so changed, the pharmacy may no longer dispense controlled substances by means of the

Internet. A pharmacy that has so changed its registration status back to that of a non-online pharmacy remains responsible for submitting reports in accordance with §1304.55 of this chapter with respect to any controlled substances that it dispensed while it was registered with a modification authorizing it to operate as an online pharmacy.

(e) Registrants applying for modified registrations under this section must comply with notification and reporting requirements set forth in §§1304.40, 1304.45, 1304.50, and 1304.55 of this chapter.

(f) No person (including a registrant) required to obtain a modification of a registration under §§1301.11(b) and 1301.13 of this part authorizing it to operate as an online pharmacy may engage in any activity for which such modification of registration is required until the application for such modified registration is granted and an active Certificate of Registration indicating the modification of the registration has been issued by the Administrator to such person.

[74 FR 15622, Apr. 6, 2009]

**EXCEPTIONS TO REGISTRATION AND FEES**

**§ 1301.21 Exemption from fees.**

(a) The Administrator shall exempt from payment of an application fee for registration or reregistration:

(1) Any hospital or other institution which is operated by an agency of the United States (including the U.S. Army, Navy, Marine Corps., Air Force, and Coast Guard), of any State, or any political subdivision or agency thereof.

(2) Any individual practitioner who is required to obtain an individual registration in order to carry out his or her duties as an official of an agency of the United States (including the U.S. Army, Navy, Marine Corps, Air Force, and Coast Guard), of any State, or any political subdivision or agency thereof.

(b) In order to claim exemption from payment of a registration or reregistration application fee, the registrant shall have completed the certification on the appropriate application form, wherein the registrant's superior (if

## § 1301.22

## 21 CFR Ch. II (4–1–10 Edition)

the registrant is an individual) or officer (if the registrant is an agency) certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess, or handle controlled substances.

(c) Exemption from payment of a registration or reregistration application fee does not relieve the registrant of any other requirements or duties prescribed by law.

[62 FR 13950, Mar. 24, 1997]

### § 1301.22 Exemption of agents and employees; affiliated practitioners.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment.

(b) An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.

(c) An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:

(1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;

(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing;

(3) The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, ad-

minister, or prescribe drugs within the jurisdiction;

(4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution;

(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12); and

(6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

[62 FR 13950, Mar. 24, 1997]

### § 1301.23 Exemption of certain military and other personnel.

(a) The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his/her official duties. Such officials shall follow procedures set forth in part 1306 of this chapter regarding prescriptions, but shall state the branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his/her Social Security identification number.

(b) The requirement of registration is waived for any official or agency of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, or Public Health Service who or which is authorized to import or export controlled substances in the course of his/her official duties.