for the dispensing of controlled substances at the long term care facility, the applicant must include with his/her application for registration (DEA Form 224) an affidavit as to the existence of the State authorization. Exact language for this affidavit may be found at the DEA Diversion Control Program Web site. The affidavit must include the following information:

(1) The name and title of the corporate officer or official signing the affidavit;
(2) The name of the corporation, partnership or sole proprietorship operating the retail pharmacy;
(3) The name and complete address (including city, state, and Zip code) of the retail pharmacy;
(4) The name and complete address (including city, state, and Zip code) of the long term care facility at which DEA registration is sought;
(5) Certification that the named retail pharmacy has been authorized by the state Board of Pharmacy or licensing agency to install and operate an automated dispensing system for the dispensing of controlled substances at the named long term care facility at which DEA registration is sought;
(6) The date on which the authorization was issued;
(7) Statements attesting to the following:
   (i) The affidavit is submitted to obtain a Drug Enforcement Administration registration number;
   (ii) If any material information is false, the Administrator may commence proceedings to deny the application under section 304 of the Act (21 U.S.C. 824(a)(1)) and suspend the registration immediately by pending revocation on the basis of section 304(d) of the Act (21 U.S.C. 824(d)). At the same time, the Administrator may seize and place under seal all controlled substances possessed by the applicant under section 304(f) of the Act (21 U.S.C. 824(f)). Intentional misuse of the affidavit procedure may subject the applicant to prosecution for fraud under section 403(a)(4) of the Act (21 U.S.C. 843(a)(4)), and obtaining controlled substances through registration by fraudulent means may subject the applicant to prosecution under section 403(a)(3) of the Act (21 U.S.C. 843(a)(3)). The penalties for conviction of either offense include imprisonment for up to 4 years, a fine not exceeding $30,000 or both.

§ 1301.18 Research protocols.

(a) A protocol to conduct research with controlled substances listed in Schedule I shall be in the following form and contain the following information where applicable:

(1) Investigator:
   (i) Name, address, and DEA registration number; if any.
   (ii) Institutional affiliation.
   (iii) Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications).

(2) Research project:
   (i) Title of project.
   (ii) Statement of the purpose.
   (iii) Name of the controlled substances or substances involved and the amount of each needed.
   (iv) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.
   (v) Location where the research will be conducted.
   (vi) Statement of the security provisions for storing the controlled substances (in accordance with §1301.75) and for dispensing the controlled substances in order to prevent diversion.

§ 1301.18 Research protocols.

(a) A protocol to conduct research with controlled substances listed in Schedule I shall be in the following form and contain the following information where applicable:

(1) Investigator:
   (i) Name, address, and DEA registration number; if any.
   (ii) Institutional affiliation.
   (iii) Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications).

(2) Research project:
   (i) Title of project.
   (ii) Statement of the purpose.
   (iii) Name of the controlled substances or substances involved and the amount of each needed.
   (iv) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.
   (v) Location where the research will be conducted.
   (vi) Statement of the security provisions for storing the controlled substances (in accordance with §1301.75) and for dispensing the controlled substances in order to prevent diversion.
§ 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 submit a request to the Registration Unit, Drug Enforcement Administration, by registered mail, return receipt requested. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. The request shall contain the following information: DEA registration number; name of the controlled substance or substances and the quantity of each authorized in the approved protocol; and the additional quantity of each desired. Upon return of the receipt, the registrant shall be authorized to purchase the additional quantity of the controlled substance or substances specified in the request. The Administration shall review the letter and forward it to the Food and Drug Administration together with the Administration comments. The Food and Drug Administration shall approve or deny the request as an amendment to the protocol and so notify the registrant. Approval of the letter by the Food and Drug Administration shall authorize the registrant to use the additional quantity of the controlled substance in the research project.

(d) In the event the registrant desires to conduct research beyond the variations provided in the registrant’s approved protocol (excluding any increase in the quantity of the controlled substance requested for his/her research project as outlined in paragraph (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.