V. Transcripts

A transcript will be made of the proceedings of each meeting. You may request a copy of a meeting transcript in writing from FDA's Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 30 working days after the public meetings at a cost of 10 cents per page. The transcript of each public meeting will be available for public examination at the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Information about the public meetings, contact information, and the provisions of the Bioterrorism Act under FDA's jurisdiction can be accessed at *http://www.fda.gov/oc/bioterrorism/bioact.html* and *http://www.cfsan.fda.gov/dms/fsbtact.html*.

Dated: May 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9536 Filed 5–10–05; 4:13 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, and 1307

[Docket No. DEA–240F]

RIN 1117–AA75

Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is amending its regulations to allow, where State laws permit, for retail pharmacy installation of automated dispensing systems at long term care facilities. Automated dispensing systems would allow dispensing of single dosage units and mitigate the problem of excess stocks and disposal.

DATES: *Effective Date:* This final rule is effective June 13, 2005.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

I. Background

Legal Authority

DEA enforces the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*), as amended. DEA regulations implementing this statute are published in Title 21 of the Code of Federal Regulations (CFR), part 1300 to 1399. These regulations are designed to establish a framework for the legal distribution of controlled substances to deter their diversion to illegal purposes and to ensure that there is a sufficient supply of these drugs for legitimate medical purposes. Controlled substances are those substances listed in the schedules of the CSA and 21 CFR 1308.11–1308.15, and generally include narcotics, stimulants, depressants, hallucinogens, and anabolic steroids that have a high potential for abuse and dependency. DEA's regulations require that persons involved in the manufacture, distribution, research, dispensing, import, and export of controlled substances register with DEA, keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or otherwise disposed of.

Controlled Substances at Long Term Care Facilities (LTCFs)

DEA defines a long term care facility as ''a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients'' (21 CFR 1300.01(b)(25)). Patients at LTCFs take numerous medications, including controlled substances. Unlike hospitals, LTCFs are rarely DEA registrants, (although DEA regulations do allow an LTCF to register if licensed by its State to handle controlled substances). Patients at these facilities are usually seen by their personal physicians, who prescribe any necessary medication. These prescriptions are filled by retail pharmacies and delivered to the LTCFs for patients' use. Because LTCFs usually are not registrants and generally do not have physicians or pharmacists on staff, they may not order and maintain stocks of controlled substances to be dispensed under the order of a practitioner as occurs in hospitals. Instead, the controlled substance medications are dispensed under a prescription to the specific patients by a provider pharmacy; the LTCF holds the drugs in a custodial manner for administration to the patient. DEA permits pharmacies to dispense a Schedule II prescription for a LTCF patient on a daily or dosage unit basis rather than dispense the entire quantity prescribed. Reimbursement rules under Medicare and Medicaid and other third party payers, however, make daily dispensing financially unattractive for pharmacies; pharmacies are allowed a limited number of dispensing fees plus the calculated cost of the medication per month. Consequently, pharmacies routinely dispense the entire prescription to the patient at once; the LTCF maintains the drugs and ensures that they are taken as prescribed.

A result of this dispensing practice is that when patients leave the facility or their medications change, the LTCF may be left with excess controlled substances, which must be disposed of to avoid diversion. Because they are not registrants, the LTCFs may not transfer the substances to either the pharmacy that supplied them or to a reverse distributor for disposal. The LTCF must dispose of the excess controlled substances directly.

DEA's Proposal

To address the issue of excess controlled substances in LTCFs, DEA issued a Notice of Proposed Rulemaking (NPRM) (68 FR 62255; November 3, 2003) proposing to allow a provider pharmacy to register at the site of the LTCF and store controlled substances in an automated dispensing system (ADS). An ADS is conceptually similar to a vending machine. A pharmacy stores bulk drugs in the machine in separate bins or containers and programs and controls the ADS remotely. Only authorized staff at the LTCF would have access to its contents, which are dispensed on a single-dose basis at the time of administration under a prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the drugs are not considered dispensed until the system provides them, drugs in the ADS are counted as pharmacy stock. If patients do not take all of the drugs prescribed, the excess can be dispensed to other patients.

DEA's proposal allowed the use of automated dispensing systems as an option, not a requirement. DEA recognizes that there are reasons why ADSs may not work in many circumstances, but believes that some LTCFs will find ADSs a viable solution for preventing accumulation of excess controlled substances.

Current Federal law does not prohibit the use of ADSs for storage and dispensing of controlled substances at LTCFs where the LTCF itself is a DEA registrant. However, to allow the use of

an ADS when the LTCF is not a registrant, several regulatory revisions are required. In the NPRM, DEA proposed the following:

- Addition of a definition of automated dispensing system to § 1300.01.
- Modification of § 1301.17 to incorporate an additional ''special procedure'' for the type of registrations that are the subject of this notice. Specifically, pharmacies applying for a separate registration to operate an ADS at a LTCF will need to provide as part of their registration application an affidavit attesting to the existence of a State license, permit, or other authorization for activities at the LTCF.

In general, States currently do not authorize (by license, permit, or other authorization) a provider pharmacy to function at the location of the LTCF using an ADS. States generally have not established policies and procedures regarding system security, access, and the like. States will need to amend their laws and regulations to fully implement this change in DEA regulations within their jurisdictions.

- Addition of a new § 1301.27 to provide that only registered pharmacies may operate automated dispensing systems at long term care facilities. The section would further indicate that a pharmacy must maintain a separate registration at each long term care facility location at which automated dispensing systems are installed and operated, and that if more than one pharmacy operates an automated dispensing system at a long term care facility, each pharmacy must maintain its own separate registration at that facility. Finally, this section indicates that pharmacies applying for separate registrations to install and operate automated dispensing systems at long term care facilities would be exempt from application fees for those separate registrations.
- Modification of § 1304.04 to permit a registered pharmacy with one or more associated registrations at LTCFs to keep all records for those LTCF locations at the pharmacy site or other approved central location.
- Since the provider pharmacy would likely be ordering controlled substances for multiple LTCFs that it services, modification of § 1307.11(b), which limits total distribution by a practitioner to 5 percent of all controlled substances dispensed in the course of a year to provide an exemption for this activity.

II. Comments Received in Response to the NPRM Published November 3, 2003

DEA received seven comments in response to the NPRM. The comments were all supportive of DEA efforts to address the issues associated with surplus controlled substances at LTCFs.

One commenter cited benefits of the proposed approach in addition to those noted by DEA in the NPRM. This commenter also suggested that DEA and other Federal entities should do more than simply allow the use of ADSs, but rather ''encourage and enable'' LTCFs to use them. These additional benefits included the following:

- Private pay nursing home consumers will benefit from more efficient dispensing of controlled substance medications through the use of ADSs.
- The benefits of using ADSs are even greater if they are used to dispense both controlled and noncontrolled substances.
- Evidence from a pilot study in one State indicates that ADSs not only saved money, but also reduced opportunities for errors and abuse and added a level of security to the existing system.
- Dispensing machines may reduce the incidents of hospitalization for acute and psychiatric care because of the ability to order and dispense medications more quickly.

Several commenters also noted, as DEA had noted in its NPRM, that a complete solution to this problem involves policies and requirements outside the jurisdiction of DEA, particularly in the area of reimbursements. In addition, one commenter reiterated a number of practical limitations to what DEA proposed, including the substantial regulatory barriers that exist at the State level, the inability to anticipate (and store) all of the controlled substances that might be needed at an LTCF, and nurse staffing shortages at LTCFs and the impact that might have on security and safety with ADSs. Nevertheless, these commenters supported the efforts of DEA to deal with the issue of surplus controlled substances at LTCFs.

At the same time, several commenters offered suggestions or asked questions regarding the DEA proposal. These comments are addressed below.

Two commenters pointed to DEA's use of the term ''retail pharmacy'' as being too narrow, and noted that most States allow other types of pharmacies to service LTCFs. DEA does not intend to limit the types of retail pharmacies that are eligible under this rule. As part of their licensing process, States may have a more limited definition of ''retail pharmacy'' or multiple categories of pharmacy licenses. These regulations apply to those retail pharmacies registered with DEA, regardless of the type of State license the pharmacy holds. Therefore, DEA is clarifying the fact that only retail pharmacies are permitted to operate ADSs at LTCFs. DEA wishes to note that pharmacies registered with DEA solely as central fill pharmacies are not permitted to operate ADSs at LTCFs.

One commenter asked whether the proposed rule prohibited access by a nurse to emergency supply controlled substances from an ADS prior to communication of a prescription to the pharmacy by a physician. Some State programs currently allow access to controlled substances from emergency kits that are kept at LTCFs. It will be up to each State to decide whether they will allow the access described by the commenter to occur at an LTCF where an ADS has been installed. DEA can foresee that permitting emergency access to an ADS prior to communication from the physician to the pharmacy would likely entail some special programming of the machine to ensure, among other things, proper control of its inventory. States will need to establish appropriate requirements/procedures to ensure that emergency use of controlled substances in ADSs does not create new opportunities for diversion of those substances.

Another commenter questioned the need for a separate pharmacy registration at the LTCF where its ADS is located. The commenter noted that there would be (superfluous) recordkeeping requirements that would flow between these two registered sites of the same pharmacy when controlled substances are stocked in the ADS. The commenter further suggested that they believed an ADS at an LTCF could be considered a secondary place of business under the statute or that another exception (to separate registration requirements) could be added to § 1301.12. DEA disagrees. Because this is a separate physical location and controlled substances are being stored and dispensed at this separate physical location, DEA believes it is consistent with the law to require a separate registration. Also, the exception suggested by the commenter is unlike the other exceptions now included in the regulations, which focus on settings where controlled substances are not distributed or dispensed and (except for a warehouse) where controlled substances are not stored.

There will be additional recordkeeping requirements as a result of having a separate registration, but this is simply an essential requirement of DEA's diversion control program. DEA has attempted to minimize the burden associated with a separate registration

by exempting the additional registrations from application fees.

Another commenter expressed a related concern, suggesting that by requiring registration at each site, a pharmacy was now accountable to DEA for diversion that might result because of LTCF personnel. DEA does not currently hold pharmacies supplying LTCFs accountable for diversion of dispensed medications by LTCF staff and does not believe it is imposing a different or greater burden on pharmacies that choose to register and place an ADS at an LTCF.

DEA does believe that the use of ADSs can reduce certain types of diversion opportunities present at LTCFs and improve overall security regarding controlled substances. In addition, DEA can foresee that, with an ADS, a pharmacy may be able to more readily assist an LTCF in investigating diversion because of the automatic tracking and information collection that will occur in routine use of its on-site system.

Two commenters expressed concern that rental payments for an ADS paid by an LTCF to a pharmacy might run afoul of Federal anti-kickback statutes if they are not ''fair market'' rental payments. Although this is not an issue within DEA's purview, DEA would suggest that each State currently has a policy/approach for handling equipment rental/purchase issues within their jurisdiction and that is where an LTCF should look for guidance. States also may address this issue when establishing policies and protocols for use of ADSs. Presumably, in at least some cases rental payments may be required. If any required payments are greater than the financial and other benefits an LTCF receives by using an ADS, then the situation is probably not one where use of an ADS is appropriate. As DEA stated in its proposal, the use of ADSs is an option, not a requirement, and there are reasons why ADSs may not work in many circumstances.

One commenter expressed concern that use of an ADS would require changes to third-party and Medicaid billing practices, noting that most payment systems currently bill when the medication leaves the pharmacy, not after actual use by the LTCF resident or at the end of the month. Again, this is not an issue within DEA's control. However, DEA notes that the controlled substances still belong to the pharmacy until they are actually dispensed from the machine. Regarding billing practices, DEA urges all parties involved to think creatively about this and look at options for altering existing billing systems where ADSs are used. There may be potential financial and security benefits to using these systems and DEA urges other changes be made, where possible, to promote their use.

Finally, this same commenter asked whether multiple pharmacies can share an ADS at an LTCF. DEA would not object to multiple pharmacies maintaining separate ADS' at an LTCF location; however, multiple pharmacies cannot share a single ADS because of the accountability issues surrounding the controlled substances. This would be tantamount to two registered pharmacies sharing one registered location and one storage/dispensing system, which is unacceptable to DEA. The sharing of an ADS by two registered pharmacies would cause stocks of controlled substances to be commingled, making inventory, recordkeeping, reporting and accountability requirements almost impossible to administer.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small business entities. This rule provides the option of using an automated dispensing system to dispense controlled substances to patients at long term care facilities. Facilities that currently use automated dispensing systems for the dispensing of noncontrolled substances and, where permitted by DEA registration, for controlled substances report in industry literature that, while there are costs associated with the lease or purchase of an automated dispensing system, automated dispensing systems have the following benefits:

- Significantly reduce drug waste. Various studies over the past ten years have indicated that between 4 and 10 percent of medications at long term care facilities are wasted. Additional reports indicate that the use of an automated dispensing system reduces this waste by 90 percent.
- Significant cost savings for payers. As noted previously, automated dispensing systems have the potential to reduce the cost of medications dispensed because medications are dispensed in a ''just in time'' manner for administration rather than dispensing a larger quantity of medication less frequently, which can create waste.
- Reduce nursing and pharmacy labor costs. Nurses and pharmacy personnel no longer must prepare medications for dispensing to individual patients. Time is also saved by nursing staff due to the fact that medication administration records are now maintained electronically. Often, this time is then redirected to providing patient care.
- Reduce the potential for medication dispensing and administration errors. Automated dispensing systems provide greater accuracy in the dispensing and administration of medications.

Because the rule does not require the use of automated dispensing systems, DEA believes that only retail pharmacies and LTCFs that find use of these systems cost-effective will adopt this approach.

Executive Order 12866

The Deputy Assistant Administrator, Office of Diversion Control, further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). It has been determined that this is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget. This final rule permits the installation of automated dispensing systems at long term care facilities by retail provider pharmacies, so long as State regulations permit such installation. The use of automated dispensing systems by long term care facilities provides another alternative to address the problem of accumulation of surplus controlled substances at long term care facilities. DEA believes that persons choosing to utilize this method of dispensing controlled substances to patients at long term care facilities may realize cost savings. More importantly to DEA, the use of such systems should reduce the accumulation of excess controlled substances at these facilities, thereby reducing the potential for diversion of these controlled substances.

Paperwork Reduction Act

This rule requires a retail pharmacy currently registered with DEA to apply for separate registration at the location of the long term care facility at which it intends to install and operate an automated dispensing system. Application for registration is made using currently existing DEA registration forms (DEA Form 224 for registration and 224A for registration renewal). DEA estimates that approximately 100 persons per year will apply for registration to operate automated dispensing systems at long term care facilities. Therefore, DEA has revised its OMB-approved information

collection (OMB 1117–0014) to reflect this increased burden due to this program change.

Further, within this rulemaking DEA is requiring that, at the time of application for this separate registration at the long term care facility by the retail pharmacy, the applicant must include with their application for registration (DEA Form 224) an affidavit as to the existence of State authorization to operate the automated dispensing system at the long term care facility. DEA has provided a format for the affidavit as part of its regulations. This affidavit is exempt from the requirements of the Paperwork Reduction Act (5 CFR 1320.3(h)(1)).

Executive Order 12988

This final rule meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This final rule does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $115,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act

This final rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects

21 CFR Part 1300

Definitions, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1304

Drug traffic control, Prescription drugs.

21 CFR Part 1307

Drug traffic control.

■ For the reasons set out above, 21 CFR parts 1300, 1301, 1304, and 1307 are amended as follows:

PART 1300—DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

■ 2. Section 1300.01 is amended by adding a new paragraph (b)(45) to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

(45) The term automated dispensing system means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 3. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 951, 952, 953, 956, 957.

■ 4. Section 1301.17 is amended by redesignating paragraph (c) as paragraph (d) and adding new paragraph (c) to read as follows:

§ 1301.17 Special procedures for certain applications.

* * * * *

(c) If at the time of application for a separate registration at a long term care facility, the retail pharmacy has been issued a license, permit, or other form of authorization from the appropriate State agency to install and operate an automated dispensing system 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 (including the license or permit number, if applicable);

(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));

(iii) Any false or fraudulent material information contained in this affidavit may subject the person signing this affidavit and the above-named corporation/partnership/business to prosecution under section 403 of the Act (21 U.S.C. 843);

(8) Signature of the person authorized to sign the Application for Registration for the named retail pharmacy;

(9) Notarization of the affidavit.

* * * * *

■ 5. Section 1301.27 is added to read as follows:

§ 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.

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

■ 6. The authority citation for part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 871(b), 958(e), 965, unless otherwise noted.

■ 7. Section 1304.04 is amended by revising paragraph (a) to read as follows:

§ 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§ 1305.17 and 1305.27 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge. All notifications must include the following:

(i) The nature of the records to be kept centrally.

(ii) The exact location where the records will be kept.

(iii) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(iv) Whether central records will be maintained in a manual, or computer readable, form.

(2) A registered retail pharmacy that possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this part for those additional registered sites at the retail pharmacy or other approved central location.

* * * * *

PART 1307—MISCELLANEOUS

■ 8. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

■ 9. Section 1307.11 is amended by adding a new paragraph (c) to read as follows:

§ 1307.11 Distribution by dispenser to another practitioner or reverse distributor.

* * * * *

(c) The distributions that a registered retail pharmacy makes to automated dispensing systems at long term care facilities for which the retail pharmacy also holds registrations do not count toward the 5 percent limit in paragraphs (a)(1)(iv) and (b) of this section.

Dated: May 5, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 05–9538 Filed 5–12–05; 8:45 am]

BILLING CODE 4410–09–P

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 203

Registration of Agencies for Voluntary Foreign Aid; Summary of Comments

AGENCY: U.S. Agency for International Development, USAID.

ACTION: Final rule.

SUMMARY: USAID is revising Part 203 in its entirety to clarify the purposes of Registration and to emphasize that organizations must be private and voluntary in nature in order to be registered.

DATES: *Effective Date:* May 13, 2005.

FOR FURTHER INFORMATION CONTACT: Mary Q. Newton, Registrar, Office of Private Voluntary Cooperation—American Schools & Hospitals Abroad; telephone: 202–712–4747; telefax: 202–216–3041 or e-mail: *mnewton@usaid.gov*.

SUPPLEMENTARY INFORMATION: On May 7, 2002, the Agency published in the **Federal Register** a proposed revision of Part 203.

The comment period was May 8, 2003, to July 8, 2002.

The Agency received comments from eleven private voluntary organizations (PVOs) as well as comments from two cooperative development organizations (CDOs). The following summarizes the principal comments and actions taken:

1. Annual Documentation Requirements (see § 203.5). For PVOs submitting an Office of Management and Budget (OMB) Circular A–133 Audit, the due date for submitting annual documents was changed from six months to nine months following the organization's fiscal year end to take into account the time required for the registrant to prepare the OMB Circular A–133 audit.

2. Submission of Documents. A comment expressed opposition to submitting duplicate documents to various offices within USAID. The words ''the same or'' were deleted from 203.4(d). The sentence now reads: ''Other USAID officials may request similar information at a later date for purposes of determining the PVO's eligibility for a particular grant or cooperative agreement.''

3. Registration Status—Transition Provisions. PVOs currently registered will continue to be registered under the new rule. The new annual documentation requirements are in effect as of the date of the new rule. The previous rule and the new rule are available on the USAID Web site at *http://www.usaid.gov* Keyword: PVO Registration. New applicants will be required to submit their applications and documentation under the revised Conditions of Registration and new rules.

4. Registration of CDOs. Two comments were made with regard to the elimination of Registration eligibility for IRS 501(c)(4) and 501(c)(6) organizations, specifically cooperative development organizations (CDOs). The Agency's intent is not to eliminate CDOs from the U.S. PVO Registry at *http://www.usaid.gov* Keyword: Registry. Therefore, CDOs will continue to be listed in the Registry and will continue to be required to meet the annual documentation requirements in § 203.5. (see § 203.12)

5. AID Form 1550–2. A comment requested that PVOs not currently receiving funding from the U.S. Government for overseas programs not be required to submit the AID Form 1550–2. The suggested change was not adopted since AID Form 1550–2 provides current demographic information on each PVO as well as