DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA–215N]

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

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice; solicitation of information.

SUMMARY: DEA is soliciting information from the affected industry, Medicare/Medicaid agencies, insurance providers, state regulatory agencies and other interested parties regarding preventing accumulation of controlled substances at long term care facilities (LTCFs). Because of current prescription reimbursement practices by Medicaid and Medicare, excess controlled substances often accumulate at LTCFs as patient medication requirements change. DEA is soliciting comments on proposed alternative solutions, as well as seeking other alternatives to prevent the accumulation of excess controlled substances at LTCFs.

DATES: Written comments must be submitted on or before June 25, 2001.

ADDRESSES: Comments should be submitted in triplicate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: Federal Register Representative/CCR.

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:

What Is the Purpose of This Notice?

The disposal of excess controlled substances that accumulate at LTCFs is a continuing problem. DEA has frequently been asked to assist in resolving the matter. The principal concern is to suggest a means to prevent the accumulation of controlled substances that are dispensed but not administered to the patient. The current delivery system requires use of prescriptions written for a specific patient that may only be filled by a pharmacist rather than maintenance of stock at the LTCF for dispensing on an as-needed basis pursuant to a practitioner's order. This is because most LTCFs are not DEA registrants. Therefore, they may not order and maintain institutional stocks of controlled substances for general dispensing pursuant to practitioner medication orders. Instead, the practitioners must issue prescriptions that are dispensed to the specific patients by a provider pharmacy and held by the LTCF in a custodial manner for administration to the patient. Any medications that are not administered are waste that must be disposed of. The purpose of this notice is to solicit comments from state regulatory agencies, affected industries, Medicare/Medicaid, insurance providers, and other interested parties to be used in resolving this problem.

What Has DEA Done To Address This Issue?

DEA addressed this circumstance through the establishment of partial dispensing provisions for Schedule II–V prescriptions (including unit-dose dispensing, if desired), to limit the number of controlled substances dispensed at one time and avoid waste if the treatment was changed or discontinued. According to the pharmacy industry, however, dispensing fees, reimbursement practices, and difficulties in educating practitioners regarding the need to prescribe controlled substances in anticipation of a patient's actual need for the controlled substance have effectively precluded using that approach.

What Do Current DEA Regulations Permit?

Although most LTCFs are not presently registered with DEA, DEA regulations currently allow a LTCF to register with DEA, if licensed by its state to handle controlled substances. DEA issues a registration in one of the following categories based upon the type of license/permit issued by a state and the authorized activities associated with the license/permit:

- Retail pharmacy-A pharmacy located on-site at the LTCF maintains stocks of controlled substances and a pharmacist dispenses patient specific controlled substances to residents of the LTCF pursuant to prescriptions.
- Hospital/clinic—The LTCF maintains institutional stocks of controlled substances for dispensing/administering to residents pursuant to medication orders.
- Mid-Level Practitioner-Controlled substance activities are limited to those authorized by the individual state.
- Practitioner-A practitioner, such as the Medical Director of the LTCF, registers at the site of the LTCF and is responsible for the handling of controlled substances utilized at the LTCF.

What Two Additional Options Is DEA Considering To Address the Continued Problem of Excess Controlled Substances at LTCFs?

To further address the issue of excess controlled substances in LTCFs, DEA is considering two additional options.

- Allow a provider pharmacy to register at the site of the LTCF and store controlled substances in an automated dispensing system. A pharmacist would remotely control access to the controlled substances and dispense at the time of administration pursuant to medication orders.
- Allow a provider pharmacy to register at the site of the LTCF and store controlled substances in an automated dispensing system. A pharmacist would receive a prescription prior to the medication being dispensed to a patient. Medications would be dispensed by LTCF personnel as needed pursuant to an existing prescription.

How Would the Use of an Automated Dispensing System Address This Circumstance?

One way to eliminate the accumulation of unneeded medications is to alter the process so that drugs are not dispensed until they are to be administered. This could be done if the drugs were stored and dispensed by a DEA registrant at the LTCF site. Most definitions of ''dispense'' under state and federal regulations require or imply that a pharmacist orchestrate the dispensing at the request of the licensed (and, in the case of controlled substances, DEA-registered) practitioner. The most appropriate application of this type of registration would be for the provider pharmacy to use an automated dispensing system (ADS), programmed by a pharmacist according to specific patient prescription orders, that would serve as the LTCF pharmacy. The provider pharmacy would purchase the controlled substances from its primary location for subsequent transfer to the LTCF system. The controlled substances would be stored at the LTCF in the ADS. The pharmacist would ''dispense'' the controlled substances from a remote location via the ADS. The appropriate staff at the LTCF would then provide the controlled substances to the patient. The controlled substances stored in the ADS are pharmacy stock, have not been dispensed, and would not become waste.

Generally, residents of LTCFs are visited infrequently by their physicians. Consequently, if a nurse determines that

a patient's medications need to be changed, the nurse contacts the physician who authorizes the change. The nurse subsequently calls the pharmacist to relay the change in the treatment. DEA is often advised that physicians consider contacts from provider pharmacies burdensome when they have already communicated the patient's medical needs to nursing staff at the LTCF. However, a pharmacist may only fill an order issued by a physician and communicated by the physician or the physician's agent. Since no legal agency relationship exists between the LTCF nurse and the physician, this widely-used system is not in compliance with legal requirements. If the pharmacist contacts the physician after speaking with the nurse, all requirements will be satisfied, and the physician will receive only one communication. Although it is common practice for the nurse to communicate a patient's needs to the physician, it is suggested the nurse contact the provider pharmacy, and the pharmacist then contact the physician. This procedural change would assist the pharmacist in fulfilling the requirement to communicate with the prescriber prior to filling the prescription. If an ADS were located at the LTCF, the nurse could telephone the pharmacist, who would communicate with the doctor prior to remotely dispensing the new prescription. Schedule III–V controlled substances would be treated as oral prescriptions. Orders for Schedule II controlled substances would have to be provided to the pharmacist by the practitioner in the form of a written, signed prescription or facsimile thereof. This requirement will be mitigated by a pending electronic prescription process. In order to implement this solution, states would need to grant approval for the provider pharmacy to function at the location of the LTCF, allow use of an ADS, and certify the location to DEA for purposes of controlled substance registration. States could define such an operation so as to avoid the many peripheral requirements of traditional pharmacies such as sinks, reference books, etc. Since the provider pharmacy would likely be ordering controlled substances for all of the LTCFs it serviced, current regulations (limiting total distribution to 5% of all controlled substances dispensed in the course of a year) would be amended to provide an exemption to accommodate this activity. Utilization of official order forms (DEA Form-222) for transfer of Schedule II controlled substances would remain necessary due to federal statutory requirements. The future implementation of electronic transmission of order forms would make this transfer easier. Transfers of stock for Schedules III–V controlled substances to the LTCF would have to be documented. Parameters for secure storage of the controlled substances in the absence of a registered pharmacist would also need to be defined. Most can be addressed through security measures of the ADS. When preparing comments, please include the feasibility of applying these parameters in the absence of an ADS.

Why Is DEA in Favor of This Option?

DEA recommends allowing for the use of an automated dispensing system located at the LTCF. Sufficient flexibility exists to accommodate such a system within the existing law and regulations. The key elements of an automated dispensing system would be:

- Issuing DEA registrations to the provider pharmacy at the LTCF as an extension of the current DEA registration;
- Locating pharmacy stock in the automated dispensing units at the LTCF; and
- Establishing the appropriate protocols with respect to access to pharmacy stock by LTCF nursing personnel, secure storage of the controlled substances, transfer of the controlled substances from the primary pharmacy location to the LTCF site, etc.

How Would Registration of LTCFs Address the Waste and Disposal Issues?

Another possible solution to the accumulation of waste controlled substances at LTCFs is to register LTCFs with DEA as institutional practitioners. Registration would address the waste issue, as well as ancillary issues that have been raised regarding the problems associated with prescriptions as opposed to medical orders. As DEA registrants, the LTCFs could order and maintain institutional stocks of controlled substances that could be administered to patients pursuant to medical orders issued by the practitioners. Unlike the present system that relies on prescriptions and patient-specific stock (which becomes excess if not administered), any unadministered medications would remain institutional stock and be available for administration to other patients.

The use of institutional registrations would allow medications to be dispensed pursuant to medication orders rather than prescriptions. With prescriptions, the medications are dispensed when they are delivered by the pharmacy to the LTCF for the patient. The LTCF must maintain the drugs as patient-specific stock and any portion that is not used cannot be re-dispensed. With medication orders, the drugs are not dispensed until they are administered to the patient. Any unused drugs remain institutional stock and are available for dispensing to other patients. The institutional practitioner would be able to dispose of any remaining waste as a registrant. It is conceivable that the use of the automated dispensing system, as described previously, would suffice in this instance as well.

Why Does DEA Believe the Institutional Practitioner Alternative Is Less Likely To Succeed?

DEA believes this option is less likely to succeed and raises a number of problematic issues. If a LTCF is registered as an institutional practitioner, it may need staff pharmacists to dispense medications. In reality, this option tries to compare a LTCF to a hospital—and most hospitals have pharmacists dispense medications. Hospitals operate as one entity with the doctors and pharmacists all working, either as staff members or through contract, for the liable party. In a LTCF, the doctors and pharmacists have no responsibility to the facility or each other, and necessary communication and legal responsibilities are more difficult to define.

Will Medication Delivery Systems Currently Utilized by LTCFs Still Be Allowed?

Yes. DEA is not suggesting that unit dose delivery systems or other medication delivery systems currently utilized by most LTCFs be replaced. DEA recognizes that the cost of an automated dispensing system as well as other requirements associated with its use at a LTCF may not be warranted by every provider pharmacy. Therefore, the utilization of an automated dispensing system for storage and dispensing of controlled substances to residents of LTCFs would be an option available to the provider pharmacy. Any changes to the regulations DEA proposes based upon this solicitation for comment would be in addition to, not a replacement of, the existing regulations, and would be subject to notice and comment.

What Information Is DEA Soliciting?

DEA has identified possible approaches to prevent the accumulation of controlled substances at LTCFs. However, any solution to this problem must fit within state as well as federal regulations. The alternatives suggested in this notice are not meant to exclude

any other possible solutions to this problem. Therefore, DEA is soliciting comments from the affected industries, Medicare/Medicaid agencies, insurance providers, state regulatory agencies, and other interested parties regarding the feasibility of these options, alternative options, and suggestions to resolve the problem of excess controlled substances at LTCFs. DEA is requesting comments in support of allowing controlled substances to be stored at the LTCF and dispensed at the time of administration utilizing an automated dispensing system as well as comments in opposition to this proposed allowance. DEA is specifically seeking information on the following:

1. Do state regulations currently allow for nonpatient-specific medications to be stored and dispensed at a LTCF other than in emergency kits?

2. Do state regulations currently allow, or are states considering allowing, the use of automated dispensing systems at LTCFs? If states allow the use of automated dispensing systems at LTCFs, who is responsible and accountable for the controlled substances stored in those systems?

3. In states that currently allow the use of an automated dispensing system at the LTCF, please comment on any problems associated with utilization of an automated dispensing system for controlled substances and provide any data regarding the amount of excess generated and/or diversion of controlled substances.

4. What are the roles of dispensing pharmacists and consultant pharmacists in LTCFs?

Please submit written comments no later than June 25, 2001 to Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Attention: Federal Register Representative/CCR.

Dated: April 12, 2001.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 01–10256 Filed 4–24–01; 8:45 am]

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DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Comment Request

ACTION: Notice of information collection under review; screening requirements of carriers.

The Department of Justice, Immigration and Naturalization Service has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until June 25, 2001.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Screening Requirements of Carriers.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* No Agency Form Number (File No. OMB–16). Inspections Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. This information is used by the Immigration and Naturalization Service to determine whether sufficient steps are taken by a carrier demonstrating improvement in the screening of its passengers in order for the carrier to be eligible for automatic fines mitigation.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 65 responses at 100 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 6,500 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 4034, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, National Place Building, 1331 Pennsylvania Avenue, NW., Suite 1220, Washington, DC 20530.

Dated: April 19, 2001.

Richard A. Sloan,

Department Clearance Officer, Immigration and Naturalization Service, Department of Justice.

[FR Doc. 01–10167 Filed 4–24–01; 8:45 am]

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DEPARTMENT OF LABOR

Employment and Training Administration

Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration (ETA) is soliciting comments concerning the proposed