FOR FURTHER INFORMATION CONTACT: John Maounis, Captain John Smith Chesapeake National Historic Trail, National Park Service, 410 Severn Avenue, Suite 314, Annapolis, MD 21403, 410–260–2473.

Dated: May 13, 2010.

John Maounis,

Superintendent, Captain John Smith Chesapeake National Historic Trail.

[FR Doc. 2010–15725 Filed 6–28–10; 8:45 am]

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DEPARTMENT OF THE INTERIOR

National Park Service

Official Trail Marker for the Star-Spangled Banner National Historic Trail

AGENCY: National Parks Service, Interior.

ACTION: Official Insignia, Designation.

Authority: National Trails System Act, 16 U.S.C. 124(a) and 1246(c) and Protection of Official Badges, insignia, etc. in 18 U.S.C. 701.

SUMMARY: This notice issues the official trail marker insignia of the Star-Spangled Banner National Historic Trail. The insignia for this trail was completed in August 2008 after the Trail was designated. It first came into public use in 2008. The National Park Service uses this insignia to mark the Trail's route. This publication accomplishes the official designation of the insignia in use by the National Park Service.

SUPPLEMENTARY INFORMATION: The primary author of this document is John Maounis, Superintendent, Star-Spangled Banner National Historic Trail. The insignia depicted below is prescribed as the official trail marker for the Star-Spangled Banner National Historic Trail, administered by the National Park Service, Chesapeake Bay Office, Annapolis, Maryland. Authorization for use of this trail marker is controlled by the administrator of the Trail.

In making this prescription, notice is hereby given that whoever manufactures, sells or possesses these insignia or any colorable imitation thereof, or photographs or prints or in any other manner makes or executes any engraving, photograph or print, or impression in the likeness of this insignia, or any colorable imitation thereof, without written authorization from the United States Department of the Interior is subject to the penalty provisions of section 701 of Title 18 of the United States Code.

FOR FURTHER INFORMATION CONTACT: John Maounis, Star-Spangled Banner National Historic Trail, National Park Service, 410 Severn Avenue, Suite 314, Annapolis, MD 21403, 410–260–2473.

Dated: May 13, 2010.

John Maounis,

Superintendent, Star-Spangled Banner National Historic Trail.

[FR Doc. 2010–15727 Filed 6–28–10; 8:45 am]

BILLING CODE P

INTERNATIONAL TRADE COMMISSION

[USITC SE–10–023]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: July 1, 2010 at 10 a.m.

PLACE: Room 101, 500 E Street, SW., Washington, DC 20436, *Telephone:* (202) 205–2000.

STATUS: Open to the public.

Matters To Be Considered

1. Agenda for future meetings: None.
2. Minutes.
3. Ratification List.
4. Inv. Nos. 701–TA–466 and 731–TA–1162 (Final)(Wire Decking from China)—briefing and vote. (The Commission is currently scheduled to transmit its determinations and Commissioners' opinions to the Secretary of Commerce on or before July 26, 2010.)
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission:

Issued: June 24, 2010.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. 2010–15804 Filed 6–25–10; 11:15 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–337N]

Dispensing of Controlled Substances to Residents at Long Term Care Facilities

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice; solicitation of information.

SUMMARY: To analyze ongoing issues related to the dispensing of controlled substances to residents residing at long term care facilities (LTCFs), DEA is soliciting information on this subject from practitioners, pharmacists, LTCFs, nurses, residents and family of residents in long term care facilities, State regulatory agencies, and other interested members of the public. Specifically, DEA is exploring whether—while adhering to the framework of the Controlled Substances Act—any further revisions to the DEA regulations are feasible and warranted toward the goal of making it easier for residents of LTCFs to receive controlled substance medications. This notice recites the pertinent statutory considerations and contains a series of questions designed to elicit public comment that will assist DEA in making this evaluation.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before August 30, 2010. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–337" on all written and electronic correspondence. Written comments being sent via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be sent to DEA by sending an electronic message to *dea.diversion.policy@usdoj.gov.* DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern Time on the day the comment period closes because *http://www.regulations.gov* terminates the public's ability to submit comments at midnight Eastern Time on the day the comment period closes. Commenters in time zones other than Eastern Time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; telephone: (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, *etc.*) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, *etc.*) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please *see* the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

In enacting the Controlled Substances Act (CSA) in 1970, Congress recognized at the outset of the Act that while "[m]any of the drugs included with [the Act] have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people, * * * [t]he illegal * * * distribution, and possession and improper use of controlled substances have a substantial and detrimental impact on the health and general welfare of the American people." 21 U.S.C. 801. To minimize the likelihood that pharmaceutical controlled substances would be diverted into illicit channels, Congress established under the CSA a "closed system of drug distribution" for legitimate handlers of controlled substances. This system is comprised of a series of statutory provisions designed to ensure that all persons in the legitimate distribution chain are registered and keep records with respect to all transfers of controlled substances. Another key element of the CSA regulatory scheme is the requirement (first established under Federal law in 1914) that controlled substances only be dispensed for a legitimate medical purpose by DEA-registered practitioners acting in the usual course of their professional practice.

As the agency responsible for enforcing the CSA and administering the regulatory provisions of the Act, DEA has continually sought to reevaluate the regulations within the statutory framework. That is, any DEA regulation must maintain the statutory requirements of the CSA. Also, whenever DEA is evaluating whether to revise the regulations, the agency must take into account the dual aims of facilitating the delivery of controlled substance medications to patients for legitimate medical purposes and safeguarding against the diversion of these drugs into illicit channels.

Controlled Substances

DEA regulates controlled substances which account for between 10 percent and 11 percent of all prescriptions written in the United States. Controlled substances are drugs and other substances that have a potential for abuse and psychological and physical dependence; these include opioids, stimulants, depressants, hallucinogens, anabolic steroids, and drugs that are immediate precursors of these classes of substances. The CSA and implementing regulations at 21 CFR 1308 list controlled substances and place them in five schedules based on whether they have an accepted medical use in the United States and their relative abuse potential and likelihood of causing dependence when abused. The degree of restriction under the CSA depends upon the schedule of a given controlled substance. The intent of the statute and regulations is to protect the public health and safety by ensuring that there is a sufficient supply of controlled

substances for medical, scientific, and other legitimate purposes while preventing and deterring the diversion of controlled substances to illegal purposes.

Schedule I substances have a high potential for abuse and have no accepted medical use in treatment in the United States. 21 U.S.C. 812(b)(1). These substances may only be used for research, chemical analysis, or manufacture of other drugs. Schedule II controlled substances have accepted medical use in treatment in the United States while having a high potential for abuse and having the greatest potential for physical and psychological dependence of the FDA-approved pharmaceutical controlled substances. 21 U.S.C. 812(b)(2). For this reason, Schedule II controlled substances are subject to the highest levels of controls among FDA-approved controlled substances. Examples of schedule II narcotics include morphine, codeine, and opium. Some common brand names include hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®), and fentanyl (Sublimaze® or Duragesic®). Schedule II narcotics are commonly prescribed for the treatment of moderate to severe pain.

Controlled substances in Schedules III–V have an accepted medical use in the United States and have a lower dependence and abuse potential than Schedule II substances. 21 U.S.C. 812(b)(3), (4), (5). Thus, the statutory and regulatory restrictions on Schedule III–V substances, while significant, are not as extensive as those for Schedule II substances. Examples of schedule III narcotics include combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®, Lorcet®, and Lortab®) and products containing not more than 90 milligrams of codeine per dosage unit (i.e., Tylenol with codeine®). Schedule III narcotics are commonly prescribed for moderate pain. Substances in this schedule have a lower potential for abuse relative to substances in Schedule II.

Examples of Schedule IV substances include propoxyphene (Darvon® and Darvocet-N 100®), alprazolam (Xanax®), clonazepam (Klonopin®), and triazolam (Halcion®). Examples of Schedule V substances are cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, and Phenergan with Codeine®).

Long Term Care Facilities

With specific regard to nursing homes and other Long Term Care Facilities (LTCFs), DEA has made a number of revisions to the regulations over the years to make it easier for residents of these facilities to receive controlled substance medications, including the following:

- For schedule II controlled substances, a practitioner or a practitioner's agent may fax to a pharmacy a prescription written by the practitioner for a LTCF resident. 21 CFR 1306.11(f). This accommodation obviates the need to physically deliver a hard copy of the original written prescription to the pharmacy. It should be noted that allowance for faxing prescriptions for schedule II controlled substances is not permissible as a general rule in non-LTCF settings.
- Pharmacies may install at a LTCF (but in no other setting) an automated dispensing system (ADS). 21 CFR 1301.27. As with all dispensing of controlled substances by pharmacies, such dispensing must still be pursuant to valid prescription, but these machines can alleviate certain burdens in the LTCF setting by placing the supply of controlled substances directly on site for convenient dispensing to a resident. Once a pharmacy receives a valid prescription issued by the practitioner, the pharmacy initiates the release of the prescribed drugs from the automated dispensing system at the LTCF by remotely entering a code. Thereafter, a practitioner or authorized nurse at the LTCF enters another code that completes release of the drugs from the machine. In this manner, pharmacies may, in their discretion, dispense small amounts of the drugs (*e.g.,* daily doses) rather than the entire amount indicated on the prescription at one time. The automated dispensing systems may be used in both emergency and nonemergency situations. The automated dispensing systems thereby provide at least two benefits: (1) They allow for immediate dispensing of controlled substances in emergency situations and (2) they help to prevent accumulation of unused medications at the LTCF.
- The regulations make a special allowance in the LTCF setting for partial filling by pharmacists of prescriptions for schedule II controlled substances. 21 CFR 1306.13(b). Under this provision, where the patient is a resident of a LTCF (or is terminally ill), such partial filling may occur as long as the amount dispensed does not exceed the total prescribed and occurs within 60 days of the date that the prescription was written. This lessens the extent to which LTCFs accumulate unused controlled substances.
- Although the CSA prohibits the refilling of prescriptions for schedule II controlled substances (21 U.S.C. 829(a)), DEA has issued a regulation that allows practitioners to issue multiple sequential prescriptions authorizing a patient to receive up to a 90-day supply for these substances. 21 CFR 1306.12. This accommodation applies to all practitioners, not just those with patients in LTCFs, but it can be particularly useful in the LTCF setting where physicians sometimes visit the residents only once every 30 or 60 days.
- To facilitate the dispensing of controlled substances in emergencies, DEA has allowed pharmacies to place in LTCFs "emergency kits" that are routinely stocked with commonly dispensed controlled substances (45 FR 24128, April 9, 1980). These kits are considered extensions of the pharmacy and are controlled under the pharmacy's DEA registration. Again, the same requirement of a valid prescription delivered to the pharmacy prior to dispensing applies with respect to these kits; however, they provide an immediate supply of the drugs in emergencies and eliminate the need to wait for a delivery from the pharmacy in such circumstances.

DEA is continuing to evaluate whether further regulatory changes are warranted for the LTCF setting and is seeking public comment on this topic. As indicated, the dispensing of controlled substances to residents of LTCFs—as with the dispensing of controlled substances to patients in any other setting—must take place in accordance with the CSA. Thus, in order to consider what types of controlled substance dispensing practices might be permissible in a LTCF setting, and whether any revisions to the DEA regulations might be warranted to accommodate such practices, the provisions of the CSA governing the dispensing of controlled substances must be considered. The following is a brief summary of these provisions, which have remained consistent since the enactment of the CSA in 1970.

The registration requirement—As set forth in 21 U.S.C. 822(a), every person who dispenses any controlled substance must obtain a DEA registration issued in accordance with the agency regulations. The regulations governing registration are set forth in 21 CFR Part 1301. Persons registered with DEA are authorized to dispense controlled substances only to the extent authorized by their registration and in conformity with the CSA. 21 U.S.C. 822(b). In addition, to be eligible under the CSA to obtain a registration to dispense controlled substances, a practitioner—which could be an individual (such as

a physician), an institution (such as a hospital), or a pharmacy—must be licensed or otherwise authorized to dispense controlled substances under the laws of the State in which the practitioner practices. 21 U.S.C. 802(21), 823(f), 824(a)(3).

The recordkeeping requirement—As set forth in 21 U.S.C. 827(a), every registrant authorized to dispense controlled substances must maintain, on a current basis, a complete and accurate record of each such substance dispensed.

The prescription requirement—The requirement of a prescription is set forth in 21 U.S.C. 829. For schedule II controlled substances, this provision states, in pertinent part:

> Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug * * *, may be dispensed without the written prescription of a practitioner, except that in emergency situations * * *, such drug may be dispensed upon oral prescription in accordance with [21 U.S.C. 353(b)].

21 U.S.C. 829(a).

For schedule III and IV controlled substances, the pertinent part of the statute states:

> Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug * * * may be dispensed without a written or oral prescription in conformity with [21 U.S.C. 353(b)].

21 U.S.C. 829(b).

Prescriptions are required to contain specific information including: patient name and address; drug name, strength, dosage form, quantity prescribed, directions for use; and name, address, and DEA number of the issuing practitioner. 21 CFR 1306.05(a). All prescriptions for controlled substances must be dated as of, and signed on, the day when issued.

Two aspects of these statutory provisions bear emphasis here. First, in those situations in which a controlled substance is *not* dispensed directly by a practitioner (*e.g.,* it is dispensed by a pharmacy), the dispensing must be pursuant to a prescription issued by a practitioner. Second, the prescription must be issued in writing by the practitioner if the drug is a schedule II controlled substance (except in an emergency, in which an oral prescription issued by the practitioner is permitted); whereas the prescription may be issued in writing or orally by the practitioner if the drug is a schedule III or IV controlled substance.

The requirement of a legitimate medical purpose in the usual course of professional practice—As the United States Supreme Court explained in *United States* v. *Moore,* 423 U.S. 122, 136–138 (1975), implicit in the CSA is the requirement that every prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. As the Supreme Court stated in *Moore, id.,* this implicit requirement of the CSA is made explicit in a provision of the DEA regulations, 21 CFR 1306.04(a), which states:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

The *Moore* decision also makes clear that, under the CSA, the requirement of a legitimate medical purpose in the usual course of professional practice is tied to the concept of registration. The Supreme Court stated, with respect to the prescribing and dispensing of controlled substances, "only the lawful acts of *registrants* are exempted" from the CSA's general prohibition on dispensing controlled substances. *Id.* at 131 (emphasis added). Further, the Court stated that the CSA was intended "to limit a registered physician's dispensing authority to the course of his 'professional practice' " and that the registration of a practitioner "is limited to the dispensing and use of drugs 'in the course of professional practice * * *.' " *Id.* at 140–141.

The foregoing aspects of the CSA, viewed collectively, can be reiterated as setting forth the following principles:

- To lawfully dispense a controlled substance to a patient, the dispenser must be in one of the following two categories: (1) A practitioner authorized to dispense controlled substances directly to patients (such as a physician or a hospital) or (2) a pharmacy or other entity authorized to dispense controlled substances pursuant to a prescription issued by a practitioner.
- For either of the foregoing two categories of dispensers, the dispenser must be licensed or otherwise authorized under State law to engage in such activity and also have a DEA registration authorizing such activity.
- Because controlled substances may only be dispensed for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, and only a DEA-registered practitioner may make the determination there is such a legitimate medical purpose for a given instance of dispensing, a DEA registrant may *not* delegate to a subordinate the medical decision making that must underlie each instance of dispensing.

Accordingly, to be consistent with the CSA, any type of arrangement under which controlled substances would be dispensed to patients who reside in LTCFs must adhere to the foregoing principles.

Note Regarding Electronic Prescribing of Controlled Substances

DEA revised its regulations effective June 1, 2010 to provide practitioners with the option of writing prescriptions for controlled substances electronically. 75 FR 16236, March 31, 2010. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. This rule provides another tool for practitioners to use when prescribing a controlled substance for their patients, including those who reside in a LTCF. This rule allows a practitioner to use a computer, laptop or personal digital assistant (PDA) to send a prescription to a pharmacy from a remote location instantaneously. The basic framework of the CSA outlined above remains in effect with respect to the issuance of electronic prescriptions.

Note Regarding Authority of Agents of Individual Practitioners

While a prescription for a controlled substance must always be issued by a DEA-registered practitioner (rather than the agent of a practitioner), an agent may, under certain circumstances, be involved in the transmission of the prescription to the pharmacy. The general statutory requirements, as implemented through regulations, are described below.

The CSA provides that—except in emergency situations—a controlled substance in schedule II may only be dispensed by a pharmacy pursuant to a written prescription signed by a practitioner. 21 U.S.C. 829(a). The written prescription generally must be directly, physically provided to the pharmacist.[1] Where the patient is a

[1] As stated above, DEA has recently issued regulations allowing for the electronic prescribing

resident of a LTCF, and the drug being dispensed is a schedule II controlled substance, the DEA regulations permit an individual practitioner, or his agent where a valid agency relationship exists, to transmit by facsimile to the pharmacy a written prescription that has been issued and signed by the practitioner. 21 CFR 1306.11(f).

As indicated, the CSA contains an exception that allows practitioners to issue oral prescriptions for schedule II controlled substances in an emergency. 21 U.S.C. 829(a). In this context, Congress assigned to the Secretary of HHS, in consultation with the Attorney General, responsibility for defining the term "emergency" by regulation. The Secretary delegated this responsibility to the Food and Drug Administration, which set forth the definition of "emergency" in 21 CFR 290.10. Assuming the situation constitutes a bona fide emergency within the meaning of the FDA regulation, and a practitioner determines that such emergency warrants the dispensing of a schedule II controlled substance, a pharmacy may dispense the medication upon receiving oral authorization from the practitioner in accordance with 21 CFR 1306.11(d). That regulation requires, among other things, that the quantity prescribed and dispensed be limited to the amount adequate to treat the patient during the emergency period, and that the practitioner follow up within 7 days with a written prescription to the dispensing pharmacy. 21 CFR 1306.11(d). The regulation further requires the pharmacy to make a reasonable effort to determine that the oral authorization came from the practitioner, which may include a callback to the practitioner using his phone number as listed in the telephone directory.

For controlled substances in schedules III–V, the CSA provides that a pharmacy may dispense pursuant to a "written or oral prescription." 21 U.S.C. 829(b). Where an oral prescription is permitted by the CSA, the DEA regulations also provide that a practitioner may transmit to the pharmacy a facsimile of a written, manually signed prescription in lieu of an oral prescription. 21 CFR 1306.21(a). As a result, a prescription issued by a practitioner for substance in schedules III–V may be transmitted to a pharmacy in the following ways: (1) By delivery to the pharmacy of the original, written prescription signed by the practitioner; (2) by the practitioner or his agent (where a valid agency relationship exists) faxing the written prescription signed by the practitioner; or (3) by the practitioner or his agent (where a valid agency relationship exists) orally transmitting the prescription to a pharmacy, where it is promptly reduced to writing by the pharmacist prior to dispensing. 21 CFR 1306.21(a) and 1306.03(b).

As previously discussed, the CSA does not permit the prescribing practitioner to delegate to an agent or any other person the practitioner's authority to issue a prescription for a controlled substance. Thus, the determination of a legitimate medical purpose must be made by the practitioner acting in the usual course of their professional practice; the determination may not be made by the agent. Likewise, the required elements of the prescription (set forth in 21 CFR Part 1306) must be specified by the prescribing practitioner—not the agent. The pharmacist who fills a prescription for a controlled substance has a corresponding responsibility to ensure that these requirements have been met. 21 CFR 1306.04(a), 1306.05(a).

Other Considerations Regarding State Licensure

As indicated, to be eligible for a DEA registration, a practitioner must be licensed or otherwise authorized by the State in which he practices to carry out the specific activity for which he seeks a registration. This typically entails a determination by the applicable State regulatory body that the practitioner meets certain qualifications. For example, to practice medicine, States generally require that a physician obtain a medical license issued by the State medical board, which typically requires the physician to demonstrate the completion of certain education and training, to pass an examination demonstrating competency to practice medicine, and to undergo a background check to verify professional competence, ethics, and character. To operate a hospital, States generally require, at a minimum, that the facility obtain a license from the State public health department, which typically requires the facility to demonstrate that it has appropriate levels of qualified healthcare professional staff (physicians, nurses, *etc.*) and facilities to provide a proper standard of hospital service to the community. As part of the licensure process, States may also require that the hospital demonstrate specific qualifications to provide particular types of services. In addition, some States may require hospitals to obtain accreditation and/or certification from public and private agencies. To operate a pharmacy, States generally require the pharmacy to obtain a license from the State board of pharmacy, which also typically requires a showing of properly qualified staff and facilities.

Thus, by requiring practitioners to obtain a State license or other State authorization as a prerequisite to obtaining a DEA registration, the CSA ensures that controlled substances are only dispensed by those persons who have appropriate professional qualifications and who follow professional standards.

Accordingly, to remain consistent with the CSA, if a LTCF were to be eligible to obtain a DEA registration, it would need to have the requisite State license or other State authorization that is commensurate with the extent of the qualifications of its staff and with its ability to adhere to applicable professional standards for dispensing controlled substances to patients.

Distinctions Between LTCFs and Hospitals

An important distinction between LTCFs and hospitals is that States authorize hospitals to have independent controlled substances authority and accordingly hospitals may register with DEA. This means, among other things, that hospitals are authorized to maintain common stocks of controlled substances for immediate dispensing or administration pursuant to a practitioner's medication order and are subject to DEA regulatory oversight and inspection. LTCFs, on the other hand, typically have no independent State controlled substances authority and accordingly are not eligible to become DEA registrants, as explained above. This means they may not maintain common stocks of controlled substances. Therefore, any prescribed controlled substance medication in a LTCF is deemed, for CSA purposes, to be possessed by the resident and not the facility. A further consequence of their lack of DEA registration is that LTCFs are not subject to direct DEA regulatory oversight and inspection, security and recordkeeping requirements, or administrative action (suspension or revocation of registration).

There are a variety of reasons that States may currently treat LTCFs differently than hospitals. For example, although LTCFs provide care for residents, the nature of their practice is not the same as that of a hospital. LTCF

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of controlled substances. Where a practitioner issues an electronic prescription in accordance with these regulations, such a prescription constitutes a written prescription within the meaning of the CSA. When such an electronic prescription is used, the prescription information is conveyed electronically from the practitioner to the pharmacy, rather than through the delivery to the pharmacy of a hard copy of the prescription that was signed by the practitioner.

residents typically reside in these facilities for long periods of time and have health issues and disorders that require long-term medical attention. Generally, they do not receive daily care from an on-site physician; and, indeed, many facilities do not employ a physician as part of their staff 24 hours a day. Likewise, the extent to which registered nurses (rather than licensed practical nurses or nursing assistants) are involved in resident care is generally less in LTCFs than in hospitals. Also, in contrast to the length of stays of residents of LTCFs, patients in hospitals are typically there for short periods of time and are regularly monitored by their attending physician or hospital staff physicians.

Note Regarding Chart Orders

As explained above, because a DEA-registered hospital is a "practitioner" within the meaning of the CSA, it is permissible under the Act for such a hospital to dispense controlled substances directly to patients without a prescription. 21 U.S.C. 829(a), (b). Because of this, in a hospital setting, a hospital may dispense a controlled substance, for immediate administration to a patient, pursuant to an order for medication made by a physician (or other individual practitioner) who is an employee or agent of the hospital. 21 CFR 1306.11(c). This may occur, for example, through the issuance of a "chart order" by a hospital physician. In this context, the term "chart order" should be distinguished from the term "prescription." A prescription—unlike a chart order—must contain all the information specified in 21 CFR 1306.05 (including, among other things, the signature of the physician).[2]

It bears emphasis that regardless of whether the controlled substance is dispensed by a pharmacy pursuant to a prescription or hospital pursuant to a chart order, the person who issues the prescription or order must be authorized under the CSA to make the medical determination, while acting in the usual course of professional practice, that there is a legitimate medical purpose for the drugs to be dispensed to the patient. The CSA ensures this condition is satisfied by allowing only those practitioners who have obtained the requisite State licensure and DEA registration to make such medical determination and issue the corresponding prescription or chart order. Another point worth noting is that, in the hospital setting, where a physician issues a chart order for a controlled substance, the physician, as well as the nursing staff and hospital pharmacy staff who take certain steps in carrying out the order, are all acting as employees or agents of the DEA-registered hospital and thus are collectively viewed as the "practitioner" within the meaning of the CSA. The physician who issues the chart order is doing so under the hospital's DEA registration number in accordance with the requirements of 21 CFR 1301.22(c). The hospital is, therefore, responsible for ensuring that all such persons are acting in accordance with the CSA and DEA regulations, and any failure to do so may result in criminal or civil liability on the part of the hospital or loss of the hospital's DEA registration. These legal consequences are part of the fabric of the CSA that promotes compliance with the Act.

As indicated, most LTCFs are not licensed by the State as hospitals or other practitioners authorized to dispense controlled substances directly to patients, and thus they are not eligible under the CSA for registration as practitioners.

Other Federal Regulations Governing Long Term Care Facilities

For purposes of the CSA, DEA defines the term "long term care facility" (LTCF) 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). The Secretary of Health and Human Services (HHS) applies more specific definitions for purposes of defining facilities eligible to participate in Medicare and Medicaid. 42 CFR 483.5.

HHS establishes requirements deemed necessary for the health and safety of individuals to whom services are furnished in nursing facilities participating in Medicare and Medicaid. 42 CFR 483.1. For example, basic resident rights and obligations are outlined along with certain basic responsibilities of the facility. Some of these responsibilities include facility organization such as requiring a medical director (42 CFR 483.5(b)(2)(iii)) and maintaining a quality assessment and assurance committee consisting of a physician, the director of nursing services and three others. 42 CFR 483.75(o). The facility must operate and provide services in compliance with all applicable Federal, State and local laws and professional standards. 42 CFR 483.75(b).

Other HHS requirements for LTCFs establish a level of care. For example, the facility must perform periodic assessments of a resident's needs (42 CFR 483.20(b), (c)) and must establish and follow nursing services standards. 42 CFR 483.30. Among requirements for physician care are:

- The facility must have physician orders for the resident's immediate care at the time each resident is admitted. 42 CFR 483.20(a).
- Each resident must remain under the care of a physician and there must be physician supervision when their attending physician is unavailable. 42 CFR 483.40(a).
- The facility must provide or arrange for the provision of physician services 24 hours a day, in case of an emergency. 42 CFR 483.40(d).
- The facility must provide or obtain laboratory services only when ordered by the attending physician. 42 CFR 483.75(j)(2)(i).
- A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies. 42 CFR 483.40(e)(2).

A few of the requirements with respect to medications are that:

- The facility must employ or obtain the services of a licensed pharmacist to establish a system of records of receipt and disposition of all controlled drugs and, among other responsibilities, to review the drug regimen of each resident at least monthly. 42 CFR 483.60(b), (c).
- The facility must establish minimal requirements for quality of care, including that a resident's drug regimen must be free from unnecessary drugs as defined in 42 CFR 483.25(l).
- The facility must also provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II and other drugs subject to abuse unless the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. 42 CFR 483.60(e)(2).
- Among the standards required for the provision of hospice-related inpatient care in a participating Medicare/Medicaid facility is the hospice's responsibility to provide "drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions." 42 CFR 418.112(c)(6).

As an element of certification and enforcement, HHS utilizes different

[2] If a physician wrote all the elements of a prescription specified in 21 CFR 1306.05(a) on a patient's chart, including the signature on the date when issued, this would be considered a valid "prescription" within the meaning of the CSA and DEA regulations, and such document containing all the required elements could be delivered to a pharmacy for dispensing in accordance with 21 U.S.C. 829.

"surveys" of a given facility. These various surveys gather periodic, resident-centered information about the quality of service furnished in a facility to determine compliance with the requirements for participation in Medicare and Medicaid. 42 CFR 488.301.

Solicitation of Information

Within the foregoing statutory framework, DEA is hereby seeking input from interested members of the public regarding the types of lawful controlled substance dispensing practices currently taking place in the LTCF setting or which might take place if appropriate amendments to the DEA regulations were issued that comported with the CSA. Along similar lines, DEA is seeking comment on the types of controlled substance licensing authorities that States currently provide to LTCFs, or which States might be willing to provide in the future. To facilitate the gathering of relevant information, DEA has specific questions that appear below. These questions are separated into general issues. Commenters are encouraged to reference the question number enumerated below in their response.

A. Definitions

The terminology used to describe and classify facilities that DEA considers to be LTCFs varies between agencies and from State to State.

1. The definitions of facilities for Medicare reimbursement purposes are different in many respects from the terms used in DEA regulations. The DEA regulations define a LTCF as "a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients." How do State regulators/licensing authorities define facilities that DEA would consider LTCFs?

2. Are all LTCFs Medicare/Medicaid facilities? If not, what differentiates a facility that is not a Medicare/Medicaid facility from one that is?

3. What does the term "prescription" mean as used in a LTCF?

4. What does the term "chart order" mean as used in a LTCF?

5. What does the term "standing order" mean as used in a LTCF?

B. Scope

6. For how many residents does your LTCF provide care? Of those, what percentage require controlled substance medications?

7. Approximately what percentage of those residents requiring controlled substance medications receive such medications on a daily basis? Further, of those who receive controlled substances on a daily basis, what percentage receive Schedule II controlled substances?

8. When a person comes to a LTCF, does the person bring their own already-dispensed medications?

9. What, if any, State requirements impact a person's ability to bring medication into a LTCF?

10. If a person arrives at the facility without any medication information, how does the facility obtain any needed medications?

11. If a person is moving from an acute care facility to a LTCF, what factors impact the acute care practitioner's ability and willingness to provide written prescriptions to the person?

12. If a person arrives at a facility without medication and without prescriptions, what steps does the facility take to assess the person's medication needs?

13. What are the current practices for obtaining controlled substance prescriptions for residents at a LTCF? How do these practices differ between Schedule II controlled substances and Schedule III–V controlled substances? How do these practices differ between an emergency situation and a non-emergency situation?

14. What types of emergency situations arise at a LTCF that would necessitate the use of controlled substances?

15. What are the standard operating procedures to address emergencies? What are the procedures in a LTCF for obtaining controlled substance medications for residents in an emergency situation? Is the process different for Schedule II as opposed to Schedule III–V controlled substances?

16. Has your facility experienced delays in obtaining controlled substance medications for residents? If so, why have these delays occurred? At what steps in the prescribing process have these delays occurred? Please specify whether the delay was with a Schedule II controlled substance or with a substance in Schedule III through V.

17. Have any residents at your facility experienced problems caused by delays in obtaining prescriptions for controlled substances? If so, what was the reason for the delay? How often have such problems occurred? Did the delays occur with Schedule II controlled substances or with substances in Schedule III through V?

18. Does your facility send residents to the hospital to receive controlled substance medications because they were unable to receive the medications at your facility in a timely manner? If so, how many times did this occur in the last 12 months?

C. Communication

19. How often are practitioners contacted by LTCFs regarding requests for changes in residents' medications generally? How often does this occur for controlled substance prescriptions specifically?

20. How does communication currently occur among the practitioner, the LTCF and the pharmacy, *e.g.* phone, fax, other? Do you expect the new DEA regulations providing the option of electronic prescriptions will be used by practitioners and pharmacies in your LTCF setting? If so, do you anticipate that the use of electronic prescriptions will alleviate delays you may have experienced in providing controlled substances to residents?

21. Does the LTCF or practitioner communicate other information to the pharmacy, such as changes in the resident's practitioner or the change in status of a resident?

22. Would practitioners have any interest in designating certain persons at LTCFs as their agents solely for the purpose of communicating controlled substance prescription information to the pharmacy, understanding that the agent would be working under the prescriber's DEA registration and that the prescriber would be responsible for the agent's actions, which must be consistent with the CSA?

D. Pharmacy Service

23. Would your LTCF be amenable to having a pharmacy on site as an integral element of the LTCF? If so, would you seek to have the pharmacy operate under a registration granted to the LTCF or operate independently at the LTCF under its own pharmacy registration?

24. Does your State allow pharmacies to install and operate automated dispensing systems at LTCFs? If not, is your State considering allowing them to do so?

E. Chart Orders

Additional information about the current use of chart orders for other than controlled substances would be helpful.

25. In current practice, when must a practitioner acknowledge a chart order by signing it? Do State laws/regulations, HHS regulations, or other standards (*e.g.* Joint Commission) define the time period within which the practitioner must sign the chart order for any care setting (hospital, clinic, or LTCF)?

26. Currently, are chart orders (in hospitals or in LTCFs for non-controlled substances) required to have an

"expiration" date, at which time they must be either reauthorized or closed? LTCFs differ from hospitals in that residents in LTCFs by definition stay for a longer period. Because of this, should chart orders in LTCFs "expire" at some time after issuance? If so, what time period would be appropriate?

27. If certain persons at the LTCF were designated to act as agents of individual practitioners (to the extent authorized by the CSA) to communicate controlled substance information from the individual practitioner to the pharmacy, how would this change current practices at your facility for obtaining controlled substance medications for residents? What safeguards should be required?

F. State Regulatory Authorities

28. What authority does your State currently give LTCFs for handling and managing controlled substances? Which agency is responsible for such authority?

29. What controlled substance activities, if any, are authorized, e.g. prescribing, administering, or dispensing? In what schedules? How many LTCFs apply for any such authorization and how many receive such authorization?

30. What State requirements are there pertaining to the storage of controlled substances at LTCFs?

31. Is your State considering giving/increasing LTCFs' authority to handle/dispense controlled substances? If so, is your State considering creating a new type of registration just for LTCFs or would your State consider allowing LTCFs to register as institutional practitioners like hospitals?

32. What changes in State pharmacy and LTCF laws/regulations would be necessary for pharmacies to operate in LTCFs under a registration granted to the LTCF or to operate independently at the LTCF under its own pharmacy registration?

33. Do State laws or regulations specify or limit access to emergency kits or to controlled substances in LTCFs?

34. Do State inspectors check the records and stock of emergency kits? If so, how often?

G. Certification/Accreditation

To be eligible for Medicare or Medicaid reimbursement, nursing facilities and skilled nursing facilities must be inspected by State officials for compliance with HHS requirements. HHS regulations, for instance, impose staffing requirements and requirements regarding the safekeeping of drugs.

35. How often do State regulators inspect LTCFs? What is the legal requirement in your State for frequency of inspection, and what is the actual timing?

36. Has your LTCF sought accreditation by the Joint Commission or other non-governmental accrediting organization? What do LTCFs see as the advantages and disadvantages of seeking such accreditation?

H. Staff

37. Does the Medical Director of your facility also serve as Medical Director for other locations or facilities? If so, for how many?

38. Is the Medical Director of your facility also an attending physician?

39. Is your Medical Director registered with DEA as a practitioner?

40. If your LTCF is a Medicare or Medicaid approved facility, what barriers, if any, has your facility faced in assuring the provision of physician services 24 hours a day in case of an emergency?

41. As a LTCF, does your facility have a physician on site during regular business hours?

42. How does your facility communicate with a resident's practitioner?

43. How frequently is a physician on site at your facility? Do most physicians treat multiple residents at a single facility?

44. Does your facility have a registered nurse on duty for more than 8 hours a day, 7 days a week? Less?

45. When a registered nurse is not on duty at your facility, how are procedures relating to medications different?

46. What are the State education and continuing education requirements for licensed nurses other than registered nurses (LPNs, *etc*)? Does the State require a criminal background check prior to licensing?

47. What role do nurses' aides have in helping residents get their medications?

48. What are the State education and continuing education requirements for nurses' aides? Does your State license nurses' aides?

49. What personnel/job descriptions have access to emergency kits in your facility?

50. What personnel/job descriptions have access to controlled substance storage in your facility? Are temporary employees or volunteers given access?

51. What personnel/job descriptions have authority to contact the pharmacy to relay a noncontrolled substance prescription/drug order for a resident?

I. Emergency Kits

52. Does your facility have an emergency kit that contains controlled substances? If so, what controlled substances does your emergency kit contain?

53. If your facility has an emergency kit that contains controlled substances, how are those controlled substances procured and dispensed?

54. What are the current controlled substance inventory protocols for any emergency kit and/or automated dispensing system at your LTCF?

55. What records document receipt and dispensing of controlled substances to and from this kit?

56. How often in the last two years have controlled substances been lost or stolen from an emergency kit at your facility?

Please submit written comments no later than August 30, 2010 using the address information provided at the beginning of this document.

Dated: June 24, 2010

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 2010–15757 Filed 6–28–10; 8:45 am]

BILLING CODE 4410–09–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act; Notice of Agency Meeting

TIME AND DATE: 11 a.m., Wednesday, June 30, 2010.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Closed.

Matter To Be Considered

1. Consideration of Supervisory Activities. Closed pursuant to Exemptions (8), (9)(A)(ii) and (9)(B).

FOR FURTHER INFORMATION CONTACT: Mary Rupp, Secretary of the Board, Telephone: 703–518–6304.

Board Secretary,

Mary Rupp.

[FR Doc. 2010–15957 Filed 6–25–10; 4:15 pm]

BILLING CODE P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

TIME AND DATE: 9:30 a.m., Tuesday, July 13, 2010.

PLACE: NTSB Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.

STATUS: The ONE item is open to the public.