



Department of Justice

STATEMENT OF

**JOSEPH RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
DRUG ENFORCEMENT ADMINISTRATION**

BEFORE THE

**SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE**

ENTITLED

**“THE WAR ON DRUGS MEETS THE WAR ON PAIN: NURSING HOME
PATIENTS CAUGHT IN THE CROSSFIRE”**

PRESENTED

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**Statement of
Joseph Rannazzisi
Deputy Assistant Administrator
Drug Enforcement Administration
Before the U.S. Senate Special Committee on Aging
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INTRODUCTION

Chairman Kohl, Ranking Member Corker, and distinguished members of the Committee, I thank you for holding this hearing regarding the issue of prescribing controlled substances to patients at Long-Term Care Facilities (LTCFs). Let me assure you that both the Department of Justice and the Drug Enforcement Administration (DEA) share your concern over the health and welfare of patients that are cared for in these facilities.

LONG-TERM CARE FACILITIES

Federal 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.” 21 C.F.R. § 1300.01(25). LTCFs serve an important role in the nation’s health care system by providing both non-medical and medical care for patients suffering from chronic health problems and/or disabilities.

There are important differences and distinctions that set LTCFs apart from other health care facilities such as hospitals. First and foremost, LTCFs are the patient’s “home.” Patients 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. Conversely, patients in hospitals are typically there for short periods of time and are regularly monitored by their attending physician or hospital staff physicians. Another important distinction is that states authorize hospitals to have independent controlled substance authority and accordingly hospitals can register with the 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 or federal controlled substance authority and accordingly are not eligible to become DEA registrants. This means they may not maintain common stocks of controlled substances. Therefore, any prescribed medication in a LTCF setting belongs to the patient and not the facility. Further, LTCFs are not subject to DEA oversight, recordkeeping requirements, inspection, administrative or civil sanctions. Though they lack controlled substance authority, LTCFs are, however, subject to other types of state and federal regulatory oversight. Federally, the Department of Health and Human Services regulates LTCFs that are certified for participation in the Medicare and Medicaid programs, and most – if not all – states regulate these facilities as well. Other important distinctions between hospitals and LTCFs are reflected in the CSA and its implementing regulations.

THE CONTROLLED SUBSTANCES ACT GENERALLY

Since the enactment of the Controlled Substances Act (CSA) 40 years ago, federal law has mandated that a controlled substance may only be prescribed or dispensed by a DEA-registered practitioner. Furthermore, prior to the issuance of any such prescription, the practitioner, acting in the usual course of professional practice, must determine, each and every time, that there is a legitimate medical purpose for the patient to receive the drug being dispensed.

The CSA established this closed system of distribution (CSD) to provide security and accountability for the nations' controlled substance supply. Specifically, the CSD is a system of registration, accountability requirements, and security measures that protect the integrity of the controlled substance supply chain from the procurement of raw materials to the dispensing of controlled substances to ultimate users. The system ensures that there is an adequate supply of controlled substances for legitimate medical, research and industrial needs, while at the same time protects the public from the diversion of controlled substances into the illicit market. Most importantly, the requirements are designed to facilitate appropriate medical care and thereby ensure the safety of patients.

One of the most important principles underlying the CSA and its implementing regulations is that every prescription for a controlled substance must be predicated on a determination of legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. The usual course of professional practice is described as those actions that are in accordance with the standards of medical practice generally accepted in the United States. The following key regulations pertain to a valid prescription as part of the CSA's closed system of distribution:

- Prescriptions must be dated as of the date signed, and are required to contain specific information including: name and address of the patient; drug name and strength; dosage form; quantity prescribed; directions for use; and name, address, and DEA number of the issuing practitioner. 21 C.F.R. § 1306.05(a).
- A valid prescription for a controlled substance must be issued by a DEA-registered practitioner for a legitimate medical purpose in the usual course of professional practice. 21 C.F.R. § 1306.04(a); *U.S. v Moore*, 423 US 122 (1975); and 21 U.S.C. §829(e)(2)(A). A practitioner who issues a prescription for a controlled substance that fails to satisfy this requirement is subject to criminal prosecution under the CSA. *See Moore*, 423 U.S. at 131 (“only the lawful acts of registrants” under the CSA are exempted from prosecution under 21 USC §841(a)(1)). Only a DEA registered practitioner may make the determination if a controlled substance is medically necessary.
- In the case of an oral prescription (limited to medications in schedules III-V), the prescription may be communicated to a pharmacist by an employee or agent of the practitioner, but the practitioner remains responsible for ensuring that the prescription

conforms in all essential respects to the law and regulations. Even in these instances the pharmacist must reduce the oral prescription to writing. This requires the practitioner to decide – on a prescription by prescription basis – whether there is a legitimate medical purpose for each prescription and that all the essential elements of the prescription are met.

- While the practitioner has a responsibility to ensure that each prescription is issued for a legitimate medical purpose in the usual course of professional practice, a corresponding responsibility rests upon the pharmacist who fills the prescription. 21 C.F.R. § 1306.04(a).
- Additionally, the CSA has always required that a practitioner seeking a DEA registration be authorized to dispense controlled substances by the appropriate licensing body within the state in which he or she practices, or, for Federal practitioners, in the state in which he or she is licensed.

The Controlled Substances Act was enacted, in part, to guard against the illegal distribution and improper use of controlled substances, which can have a substantial and detrimental effect on the health and welfare of the American people. These detrimental effects can be amplified when the people at issue are residents of LTCFs, who have chronic health problems and disabilities that make them a very fragile patient population.

The requirements of the CSA help ensure that a controlled substance is prescribed to a patient only after a DEA registered practitioner has made a determination that the drug is needed to treat a legitimate medical condition. The prescription is then delivered to a pharmacy where the pharmacist is obligated under the CSA to determine if the prescription is valid before dispensing the medication to the patient. This system of checks and balances helps combat diversion, but also protects the patient. If such substances are illegally dispensed to the patient without the proper medical determination by a qualified practitioner, the health of the patient could be jeopardized. This is particularly true for Schedule II and III opioids, which can have dangerous side effects that could harm rather than help the patient's condition.

THE CONTROLLED SUBSTANCES ACT AS APPLIED TO LTCFs

There are numerous ways for residents of LTCFs to obtain prescription medications within the confines of the Controlled Substances Act. The most traditional approach would be for the resident's physician, or other DEA-registered practitioner, upon an in-person visit, to write a prescription for the needed controlled substances. That prescription would then be provided in written form to a pharmacy, which would fill the prescription. In the case of prescriptions for Schedule III –V controlled substances, in lieu of a written prescription, the practitioner or his agent could call in an oral prescription to the pharmacy.

While every prescription for a controlled substance must be predicated on a proper medical evaluation by the practitioner, an in-person visit is not always feasible in the LTCF setting. In particular, because the resident's physician, or other DEA-registered practitioner, is

often not located on the LTCF premises, he or she may not be able to visit the resident as frequently or as quickly as the resident may require, and may not be present when pain presents. Recognizing the unique nature of the LTCF setting, DEA has implemented numerous regulations over the years to make it easier to dispense controlled substances to patients in LTCFs, while at the same time ensuring that the administration of those substances is always pursuant to a valid prescription of a DEA-registered practitioner, and that the health of the patient is never compromised. Currently, short of an in-person visit from the resident's physician or other DEA-registered practitioner and delivery of a written prescription to the pharmacy, the following regulatory options and exemptions help ensure that patients' medical needs at LTCFs are met:

- 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. This accommodation obviates the need to physically deliver a Schedule II written prescription to the pharmacy, and results in time and resource savings for LTCFs. This can be particularly helpful to LTCFs, because in many circumstances a resident's physician (or the covering physician, or other DEA-registered practitioner) may not always be available on-site; this option allows a nurse at an LTCF to call the practitioner to relay information about the patient's state, and the practitioner can then fax a prescription directly to the pharmacy from his remote location. It should be noted that in ordinary, non-LTCF circumstances, schedule II controlled substances may only be dispensed pursuant to an original, written prescription of a practitioner, as they have a particularly high abuse potential. 21 U.S.C. § 829(a).
- In LTCFs, just as in outpatient settings, there are instances when an emergency arises (i.e., breakthrough pain) and controlled substances are needed expeditiously. DEA has worked to accommodate the special circumstances of LTCFs for these instances as well. For example, practitioners may issue emergency oral prescriptions to a pharmacy, followed by a written prescription to the dispensing pharmacy within seven days. To further facilitate the receipt of controlled substances under these circumstances, DEA has allowed pharmacies to establish "emergency kits" in the LTCFs that are routinely stocked with commonly dispensed controlled substances. These kits are extensions of the pharmacy and are controlled under the pharmacy's DEA registration. In the case that a practitioner himself is not available on site, a nurse at a LTCF can access the medications in the emergency kit after a practitioner has called in the emergency oral prescription to the pharmacy or faxed a written prescription to the pharmacy.
- Another regulation specifically designed to accommodate LTCFs provides for the dispensing of controlled substances on the premises of a LTCF through the use of an automated dispensing machine. Such dispensing must still be accomplished via a legitimate prescription, but these machines can alleviate much of the burden on LTCFs by placing the supply of controlled substances directly on-site for convenient dispensing to a patient. 21 C.F.R. § 1301.27. Once a pharmacy receives a valid prescription issued

by the practitioner, the pharmacy initiates the release of the prescribed drugs from the automated dispensing machine 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 machines 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 .

- Under the CSA, practitioners may not issue refills for schedule II controlled substance prescriptions. 21 U.S.C. 829(a). However, DEA has implemented a regulation that allows practitioners to issue multiple prescriptions authorizing a patient to receive up to a 90-day supply for these substances. 21 C.F.R. § 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 a doctor sometimes visits the patient only once every 30 or 60 days.
- Pharmacists may also partially fill schedule II prescriptions for LTCF patients or individuals with terminal illnesses, 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. (21 C.F.R. § 1306.13(b)). This lessens the extent to which LTCFs accumulate unused controlled substances.
- For schedules III-V controlled substances, prescriptions may be written, but may also be orally transmitted or faxed by the practitioner or the practitioner's agent. In addition, such prescriptions may be refilled up to five times in a six-month period as directed by the practitioner. 21 C.F.R. 1306.22. Partial filling is also permissible for schedule III-V prescriptions not to exceed 6 months from date of issuance.

Finally and importantly, DEA is also pleased to announce that OMB has concluded review of an Interim Final Rule that will allow electronic prescribing of controlled substances, which will soon be published in the *Federal Register*. This rule will provide yet another tool for practitioners to use when prescribing a controlled substance for their patients, including those who reside in a LTCF. This rule will allow practitioner to use a computer, laptop or PDA device to send a prescription to a pharmacy from a remote location instantaneously.

PUBLIC HEALTH AND SAFETY ISSUES AT LONG-TERM CARE FACILITIES

As a result of its investigations of complaints received from pharmacists and others, DEA is aware that some pharmacies affiliated with LTCFs are violating the CSA and its implementing regulations by dispensing controlled substances based upon the receipt of a faxed "chart order"

from nurses of these facilities in lieu of a valid prescription issued by a practitioner. In some instances this was done completely independently of any practitioner. As examples, investigations have revealed instances of nurses calling or faxing in schedule II & III prescriptions without a practitioner's knowledge; the quantity of controlled substances prescribed being determined by the pharmacist rather than the practitioner; and large numbers of prescriptions being filled under an "emergency" exemption when no emergency existed. Further, pharmacies have "shopped" for doctors to sign prescriptions after the pharmacies received them, regardless of whether those doctors had authorized the prescriptions or if the patients were even under their care. When interviewed, doctors told investigators that they were not involved in the prescription process at all. These practices concern DEA not only because they are violations of the CSA, but because these practices – basically, the dispensing of controlled substances *without practitioner involvement in patient care* – are dangerous for patients, particularly the vulnerable populations in LTCFs.

CONCLUSION

Federal law and regulations relating to controlled substances are designed to protect the public health and safety while permitting access for legitimate medical use. On any given day there are more than 66,000 retail pharmacies that operate in the U.S. The vast majority of these pharmacies can and do operate in compliance with the CSA and its regulations. While operating in compliance, these same pharmacies are also able to provide timely access to controlled substance medications for patients in need. Existing regulations provide mechanisms for the proper care of LTCF patients by a DEA-registered practitioner, including several regulations specifically promulgated to accommodate LTCF treatment. The Drug Enforcement Administration recognizes the importance of providing safe and effective medications to patients in need. That is why DEA has and continues to implement regulations whenever possible that allow for the proper prescribing and dispensing of controlled substances commensurate with evolving technologies or other means.

Thank you for your interest in this matter. The Department of Justice and the Drug Enforcement Administration look forward to working with the Congress and are committed to ensuring that patients in LTCFs receive the appropriate standard of care they deserve.