Statement
of
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Before
The Special Committee on Aging
United States Senate

Hearing on
"The War on Drugs Meets the War on Pain:
Nursing Home Residents Caught in the Crossfire"

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Chairman Kohl, Ranking Member Corker, and members of the Committee, thank you for inviting me here today on behalf of Golden Living to discuss the process by which Skilled Nursing Facilities (SNFs) dispense controlled medications, and how, in some cases, policies that are well-intentioned inhibit the ability of SNFs to most appropriately meet the needs of their residents and patients.

I am the Vice President of Pharmacy Services at Fort Smith, AR-based Golden Living, which operates more than 300 SNFs in 21 states in the U.S. Collectively, the Golden Living family of companies employs more than 40,000 people and cares for more than 60,000 residents and patients every day in 37 states.

I am a Certified Geriatric Pharmacist (CGP) and licensed Doctor of Pharmacy. I taught Pharmacy Practice in Geriatrics at Mercer University's Southern School of Pharmacy in Atlanta. Additionally, I have been Secretary/Treasurer and a member of the Board of Directors of the American Society of Consultant Pharmacists, as well as a Past President of the Georgia Chapter.

I would like to discuss how some current Drug Enforcement Agency (DEA) regulations — as they are being interpreted and applied in SNFs — are in some cases imposing barriers to the timely and medically appropriate dispensing of controlled medications in these facilities.

This is, essentially, a collision of good intentions. The DEA works to protect the public against the diversion of harmful drugs. But the agency's regulations concerning the dispensing of Schedule II drugs can cause needless suffering for patients with legitimate medical needs for medications such as morphine, oxycodone, and dextroamphetamine — particularly after hours.

Further, I will note how some of these applications are potentially placing SNFs at risk of being noncompliant with Medicare and Medicaid regulations governing the patient care responsibilities of SNFs.

First though, I wish to state that Golden Living fully supports the DEA's role in protecting the public from drug diversion and illegal practices regarding the use of controlled substances — wherever they may occur. We commend the DEA for the work it does to protect against the distribution and use of harmful and illegal substances in our communities. We also are in full agreement with the goal of identifying and removing any healthcare worker who is impaired or diverting medications from the healthcare system and the patients in need of those drugs.

It is our shared goal that all Golden Living employees and healthcare workers are drug-free and that any identified drug diversion be addressed through local and state licensing boards and law enforcement agencies, as well as the DEA when appropriate. To that end, our company has an aggressive drug-testing policy for our healthcare workers and staff in an effort to try to protect the patients we serve.

The shared goal of ensuring that controlled drugs are properly ordered, used, stored, and disposed of should continue to be a collaborative effort between all healthcare providers, federal and state health care regulators, and the law enforcement agencies that deal with these matters.

Our presence and statements today should in no way be considered a request to diminish these efforts or dilute the work or effectiveness of the agencies involved in this process. Rather, we wish to work cooperatively with the Committee and the DEA, as well as with federal and state healthcare regulators, to improve the effectiveness of the regulatory system and to enable providers to best protect residents' and patients' interests. The specific issues we want to discuss today concern DEA regulations that directly impact staff, residents, and patients living in SNFs. These regulations have been in effect for many years, but only recently have come to the forefront, due to what is acknowledged to be a more aggressive and strict interpretation of the DEA regulations in the SNF setting.

I will attempt to detail these issues to promote an understanding of how the existing DEA regulations are difficult to comply with in our SNF environment, particularly in light of regulations by the Centers for Medicare and Medicaid Services (CMS) under which we already operate, and which cover the safe and effective handling of medications — including controlled substances. In addition, I will explain how DEA regulations inhibit our ability to meet the expectations of our residents and their families in terms of appropriately addressing their medical and pain-relief needs through prescription drug therapy.

Current DEA regulations require long-term care (LTC) pharmacies to comply with very specific processes to allow the ordering and dispensing of controlled drugs — in particular, Schedule II controlled drugs. Schedule II — also known as C-II — drugs have a high abuse risk and can cause severe psychological or physical dependence. Schedule II drugs include certain narcotic, stimulant, and depressant medications.

These requirements differ from those under which hospitals and hospital pharmacies operate in two very important ways. In hospitals, a physician's order on a patient's chart serves as the legal order and prescription for the pharmacy to fill the controlled substance. Also, in a hospital setting, a nurse is allowed to serve as a physician's agent, and can order the pharmacy to fill a prescription for the controlled substance.

These two provisions help hospital staff and pharmacies meet the immediate needs of their acute-care patients for C-II medications. We believe similar provisions for SNFs would enable us to better meet the needs of residents and patients who become acutely ill in our facilities. In many cases, we would be able to help patients in severe discomfort faster than we can under current regulations.

First, I would note a couple of practical distinctions in skilled nursing versus hospital settings. Under current Medicare and Medicaid regulations, as well as state licensure requirements, SNFs do not have on-site 24-hour physician staffs. Instead, SNFs have a designated, individual practicing physician who serves as a Medical Director.

In some cases, SNFs work with a physician group that designates one physician as the Medical Director. However, the Medical Director is not on site 24-hours, 7-days a week. The Medical Director is available for patient care only in a very emergent set of circumstances — e.g. when the attending physician or covering physician cannot be reached or doesn't respond. Nurses do not call the Medical Director for prescriptions or treatment issues on a routine basis.

Second, each patient in a SNF is required, upon admission, to have an attending physician who is responsible for his or her medical orders — including prescribing any medications. Medicare and Medicaid regulations specify the timing and process for on-site physician visits to SNF patients for payment, coverage, and quality of care purposes.

These are important elements of the interaction of physicians with SNF residents and staff regarding the ordering of medications in SNF settings. Because most physicians in such settings maintain their primary practice in the community (i.e. outside of the SNF), many of their activities are conducted off-site and electronically.

Currently, the typical SNF nurse, LTC pharmacist, and primary care physician order flow for C-II narcotics under Medicare, Medicaid, and most state licensure programs is as follows:

- The regulations provide that a nurse calls a physician to report a new resident admission or a change in a patient's condition.

- The physician gives an order for any medications, including any controlled substance, to the nurse to treat the suspected condition.

- The nurse relays the order to the LTC pharmacist, who is then charged with assessing whether there is another non-controlled medication available that is appropriate to use. If so, the LTC pharmacist or the SNF nurse is required to contact the physician to request an order change.

- The LTC pharmacist must contact the physician, or the physician must contact the LTC pharmacist directly. This contact must be verbal, or the physician must fax the LTC pharmacist a completed and signed prescription for the controlled medication order. If the physician calls in the order, he or she also must send a written and signed prescription to the pharmacy, which must receive it within seven days of the verbal order.

- Due to the high acuity of our SNF residents, controlled drug orders frequently are needed immediately. As provided for under federal and state health care regulations, most SNFs have worked with their LTC pharmacies to establish an emergency drug kit that contains frequently prescribed medications that are needed to meet acute patient needs. If a physician and a SNF nurse determine that a patient's need is immediate — and therefore it is appropriate to access the facility's emergency supply of medications, a separate prescription is required. This separate prescription must be for a quantity no greater than a 72-hour supply and must contain a notation that the prescription is for an "emergency supply" of medication. Additionally, it must comply with all other aspects of a controlled drug prescription.

- The LTC pharmacist must receive an emergency prescription signed by the physician, or must speak with the physician directly, before a SNF nurse removes the medication from the emergency supply and administers it to the patient. In this scenario, if authorization by the physician to the pharmacist is verbal, the physician must then follow up with two separate prescriptions for the ordered medications to the pharmacy — including one for the emergency supply and one for the routine supply that will be necessary for continued care of the patient.

Although manual and inefficient, these processes may be acceptable during regular office hours when all three parties are present in their regular practice settings. After hours, however, when pharmacies are closed and physicians may not have access to fax machines, these processes frequently result in delays — specifically, delays in the proper communication of orders, delivery of compliant prescriptions, and the timely provision of appropriate medication relief to patients.

These "after-hours" issues can further be complicated when physicians provide coverage for one another, which is a common practice. Also, each SNF has a Medical Director who may be contacted if access to a patient's primary care physician is delayed. These coverage physicians and Medical Directors both may be required to become part of the ordering process, resulting in further delays in the prescription order and receipt of the medications. Ultimately, this further delays the ability of SNFs to deliver medications to patients.

I would like to address what appears to be a misapprehension among some regarding the practice of SNF nurses reaching out to another physician when they cannot immediately reach a patient's physician for a C-II drug order. I have heard this practice described as "doctor shopping" for an overly sympathetic physician willing to write prescriptions for these controlled medications.

Given the regulatory structure SNFs operate in, my observation is that this simply is not the case. First, current Medicare and Medicaid regulations address this potential practice. The Medicare and Medicaid SNF regulations require all patients to choose a primary care physician to coordinate their care. Also, unlike in outpatient settings, in SNFs, a patient's primary care physician and the facility's coverage physician or Medical Director are the only physicians who can order medications for residents. Further, the State and Federal regulatory processes SNFs operate under, which I will describe next, have been established to ensure compliance.

In addition to DEA oversight, skilled nursing facilities also are regulated by the Centers for Medicare and Medicaid Services. CMS regulations cover all aspects of medication ordering, procurement, delivery, administration, storage, and disposal.

CMS regulations stipulate special requirements for storage and accountability of controlled drugs. These requirements restrict access to C-II medications and place increased scrutiny on the use of these medications in SNFs. Specifically, C-II medications must be stored in separately locked and secure areas to which access is limited to certain members of the staff who are authorized and licensed to handle controlled medications. Compliance with these regulations results in all C-II and most other controlled medications being accounted for during each shift by licensed nurses. Additionally, strict requirements are in place for the discontinuation and destruction of C-II medications.

CMS also sets very stringent requirements on the care of SNF patients. Meeting the medical, social, and spiritual needs of these patients is foremost. In its regulations, the agency specifically addresses the treatment of pain and the goal of providing a pain-free quality of life for patients. A delay in treating patients' pain or other conditions not only places their health in jeopardy, but also places the SNF at risk for survey deficiencies.

Conflicting DEA and CMS regulations for SNFs that on one hand increase delays in the provision of needed medications and on the other hand require that SNFs provide immediate care of the patients' needs place SNFs in a difficult position. Compliance with both sets of regulations is challenging and, at times, impossible due to their conflicting requirements.

CMS also performs routine regulatory inspections of every SNF, approximately every year. The agency has the authority to specifically review medication storage and dispensing procedures, and also may review controlled drug handling processes in the SNFs. Non-compliance with these regulations results in survey citations that may include monetary fines and even facility closure, if severe problems are noted. This regulatory process places SNFs in a position to be among the safest and most monitored locations in which controlled drugs are used.

In addition to annual CMS surveys and other ongoing enforcement activities by state agencies, in 2009 Golden Living also experienced an inspection of five of our skilled nursing facilities by DEA agents. To our knowledge, these inspections were unusual and unprecedented.

The law-enforcement approach used by DEA agents during these visits had a chilling impact on facility operations and disrupted the staff in their important daily start-up responsibilities and activities. Moreover, the agents' process was, at times, frightening for both our patients and staff.

The inspections were unscheduled, and our only notification was an "Administrative Inspection Warrant" the SNF staff were given upon entry by the inspectors (and their armed escorts) into the facilities. We were not given clear information as to the reason for the visits and/or the target of the inspection. We have provided a copy of the Administrative Inspection Warrant to this Committee's staff.

Added to state and federal surveys and inspections for CMS, oversight from other government agencies — such as those conducted by the DEA — can be disruptive to our residents and their families, as well as to our staff members and their efforts to provide residents with quality care. Although we welcome the opportunity to meet with government regulators and assist them with their function, every visit from government regulators decreases the time our staff members can focus on delivering patient care, which is their primary responsibility.

In cases where there is not an immediate concern or issue, we would suggest that such disruptions may be mitigated — and outcomes ultimately may be more productive — if SNFs were given advance notice of future DEA visits of this nature. Where other government agencies follow that procedure, Golden Living and the agencies find the outcomes to be productive and conducive to developing a level of trust that serves everyone's interests.

In follow-up to those visits, we would welcome the opportunity to meet with the DEA to discuss ways our existing processes and procedures may be adjusted or enhanced to reach our mutual goals, in light of other federal and state regulations. One such change could be for the DEA to recognize SNF nurses as agents of physicians for the prescription of C-II drugs. Another could be enabling the use of a SNF chart order as a legal prescription for these drugs as is the case in hospitals.

We are committed to providing high-quality patient care while ensuring the required, appropriate level of administrative security over the prescribing, ordering, storage, administration, and destruction processes for all medications and controlled drugs in our SNFs.

In summary, existing DEA regulations for SNFs as they are currently being implemented hinder the ability of SNFs to provide patients with high-quality, acutely needed medication treatment. The adoption of a few changes regarding the regulations surrounding C-II drug prescriptions in SNFs — as noted above — would dramatically enhance our ability to meet the needs of our acutely ill patients.

Several states have recognized the value of these recommendations. Recently, the Arkansas State Board of Pharmacy regulations passed a resolution reaffirming its years-long recognition of SNF nurses as agents for a prescribing physician, as well as its decision to allow the use of a chart order as a legal prescription.

We welcome the opportunity to meet with DEA representatives to discuss concerns such changes may pose and find solutions that would satisfy all parties and increase the ability of all SNFs to care for the acute needs of their residents and patients.

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Previously, he was a partner in an independent long term care pharmacy in the Atlanta area, and served as the Regional Clinical Director of the Southeastern Region at Omnicare, Inc, in Covington, KY.

He is the past Secretary/Treasurer and member of the Board of Directors of the American Society of Consultant Pharmacists (ASCP). An ASCP member since 1984, he is past president of the Georgia chapter. He served as Chair of the Organizational Affairs Council, and is a past member of the Professional Affairs Council and Government Affairs Committee.

Dr. Warnock earned a Bachelor of Science Degree in Pharmacy from the University of Georgia College of Pharmacy in 1978. He was awarded the Doctor of Pharmacy (D.Ph.) designation by the Tennessee State Board of Pharmacy in 1979. He is a Certified Geriatric Pharmacist (CGP).