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

LISTENING SESSION

BEFORE THE

SPECIAL COMMITTEE ON AGING UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

WASHINGTON, DC

MARCH 24, 2010

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

WEDNESDAY, MARCH 24, 2010

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 2:05 p.m. in room SD–106, Dirksen Senate Office Building, Hon. Herb Kohl (chairman of the committee) presiding.

Present: Senator Kohl.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. Thank you so much for being here today.

This afternoon, we'll examine the dispensing of pain medication in nursing homes across our country, a very serious issue that impacts the daily well-being and comfort of millions of elderly Americans.

It's safe to say that most laws are created to prevent suffering. In the case of the U.S. Drug Enforcement Administration's recent crackdown of nursing homes, it appears that the law exacerbates it. The hours it may take for a nursing home to fully comply with DEA regulations can feel like an eternity to an elderly nursing home resident who's waiting for relief from excruciating pain. Our hope for today's session is that we can find a better strategy that allows the DEA to do its job and enables infirmed nursing home residents to receive their medication in an expedient way.

According to several of our panelists and other industry sources, nursing homes and long-term care facilities have found themselves either heightened—under heightened scrutiny from the DEA, a Federal agency with the vital job of regulating the use and sales of controlled substances.

The DEA's initiatives often save lives and do make a positive impact. The problem is that, while the DEA claims that they are working to keep prescription drugs out of the wrong hands, in reality they are causing widespread confusion, with the result of interruption and delays in timely access to pain medication for vulnerable seniors.

We've heard from many providers in my home State of Wisconsin who say that they are faced with the impossible choice of following the letter of the law and caring for sick residents in the best way they know how.

While I support the DEA's national drug diversion strategy, which prevents prescribed medications from reaching those who would abuse them, it seems that their efforts are misplaced here, with sick seniors paying the price.

Today, we'll hear about pain management for the elderly, the role of nurses in ordering and administering medication, and proposals for possible changes to the regulatory scheme that governs long-term care facilities and pharmacies. We'll hear from the DEA, in order to gain a better understanding of what their intentions are.

I understand that unanimous consent was not given this morning for committees to hold regularly scheduled hearings and meetings today. We appreciate that some of you have come a long way at your own expense to have your voices heard on this important issue. For that reason, although our committee will not be holding a formal hearing this afternoon, this will be regarded as a listening session, so that we can get and understand your positions on this issue.

We'll now turn to our first panel. Our first witness this afternoon will be Michael Schanke. Mr. Schanke is the Owner of Oakridge Gardens Nursing Home Center, and President of Gardenview and the Gardens of Fountain Way Assisted Living in Menasha, WI. Mr. Schanke is responsible for all aspects of daily operations at the Oakridge Gardens Nursing Home and these two assisted living facilities.

He will be followed by Robert Warnock. He is Vice President of pharmacy services for Golden Living, a skilled nursing facility chain based in Fort Smith, AR. He's a certified geriatric pharmacist. Golden Living cares for more than 60,000 nursing home and assisted living facility residents every day across our country in 37 States.

Our next witness will be Dr. Cheryl Phillips, who's President of the American Geriatrics Society. She's also a Geriatrician and Chief Medical Officer of On Look Medical Senior Services. As President of the American Geriatrics Society, she represents 6400 geriatric healthcare professionals committed to improving the health and well-being of older Americans.

Finally, we'll be hearing from Ross Brickley. Mr. Brickley is a certified Geriatric Pharmacist and President of CCRX of North Carolina, Inc. He's a past President of the American Society of Consultant Pharmacists and currently serves as a member of ASCP's Board of Trustees and as the Treasurer of that society.

We're so pleased that you all took the time to be with us today.

We'll commence testimony with you, Mr. Schanke.

STATEMENT OF MICHAEL SCHANKE, ADMINISTRATOR, OAKRIDGE GARDENS NURSING CENTER, MENASHA, WI; ON BEHALF OF AMERICAN HEALTH CARE ASSOCIATION AND NATIONAL CENTER FOR ASSISTED LIVING

Mr. SCHANKE. Thank you, Chairman Kohl and members of the committee.

My name is Michael Schanke. My father and I are proud of the three long-term care facilities that we own and operate in Wisconsin's Fox Valley. We have 180 full- and part-time staff, who care for more than 140 seniors.

I appreciate the opportunity to be here today on behalf of so many of my fellow long-term care providers to share our collective concerns about this issue.

Most importantly, I'm pleased to be here on behalf of my patients and others in facilities nationwide who are facing unacceptable delays in getting much needed pain medication.

I witness firsthand the frustration, fear, and confusion of patients and family members forced to watch their loved ones suffer while my staffs struggle with their hands tied because of these DEA regulations. Usually, the medication they need to relieve a resident's pain sits within our reach inside of our contingency kit.

Imagine what it's like to look into the eyes of a resident or that resident's family as the resident is in clear and sometimes intense pain, and having to tell those people that we can't give medication they've been taking all along, not because we don't have it, but because of a regulation.

Or imagine telling a nursing staff made up of highly educated and trained medical professionals who are with patients around the clock, assessing their conditions in real time, that they are no longer allowed to do the job for which they have been trained.

We've taken numerous steps to comply with the DEA's increased enforcement of the Controlled Substances Act, at times to the detriment of the quality of the life of the patients we serve.

I would like to share with you one specific example of how the DEA rules have interfered with our ability to treat residents in pain. In mid-February, on a Thursday, we had an admission of an 88-year-old lady to our facility from the hospital, following a surgical repair of her L2 vertebrae. As with many of our newly admitted patients, one of our first goals was to manage her intense pain, so that she could begin her rehabilitation program, which would include both physical and occupational therapy.

To treat her pain, the discharging physician ordered two things: a Fentanyl patch along with Percocet every 4 hours, as needed, for breakthrough pain. By Saturday, my nurses noted that she would probably run out of her initial order of Percocet by late Sunday afternoon. We immediately put a call out to her attending physician to inform him of the situation and to begin the process for securing more Percocet to treat her pain. Throughout the weekend, we followed up, on multiple occasions, with both the doctor and the pharmacy to inquire about the status of the Percocet prescription and to ensure that the written prescription had been received by our pharmacy. Because we were unable to receive this confirmation, by Sunday night we had run out of the initial Percocet pre-

scription. In order to provide her with some relief from her intense pain, we used contingency medication that we had in our facility.

By Monday morning, the patient's pain level had reached a 9 or 10 on a 10–0 scale. Her family arrived, witnessed that their loved one was in such intense pain. They began to question why we were not treating her, as they knew we had the orders. We explained to her family that, due to changes in our process resulting from the need to follow DEA requirements, we would be unable to medicate her with her Percocet.

By this time, the patient's pain had become so intense and unmanageable that her family decided to have her transported back to the hospital emergency room, just before noon on Monday. The patient was readmitted to the hospital and treated with morphine and an epidural for pain control. She returned to our facilities 3 days later, after that second hospitalization.

The example illustrates that the ordering process for Schedule 2 medications has become too focused on the paperwork, at the expense of patient care and comfort.

Long-term care facilities work hard daily to meet stringent State and Federal regulations, which include adequate pain management for our patients. However, these rules pit providers' compliance with those rules against compliance with other regulations. The DEA rules also ignore practical realities.

We are fortunate to be in a medium-size community where we have doctors, clinicians, hospital systems, and a family owned pharmacy 5 minutes away. Not everyone has this ideal situation. The DEA rules imply that physicians are available at beck and call, which is not always the case. Healthcare is practiced in a dynamic setting, and the DEA rules are frustratingly static.

In short, the DEA rules concerning Schedule 2 drugs need to be updated to account for the realities of medical practice, nursing-home care, and the three-way system of communication that occurs in the real world across care settings.

Thank you very much for your time and continued attention to this important issue.

[The prepared statement of Mr. Schanke follows:]

STATEMENT
Of

Michael T. Schanke, NHA
Of the Wisconsin Health Care Association / Wisconsin Center for Assisted Living

On Behalf Of

American Health Care Association

National Center for Assisted Living

Before The
U.S. Senate Special Committee on Aging
Hearing On
"The War on Drugs vs. The War on Pain: Nursing Home Patients Caught in the Crossfire"

March 24, 2010

Thank you, Chairman Kohl, Ranking Member Corker, and Members of the Committee, for holding this important hearing focusing on the experiences of patients and caregivers who are caught between two worthy efforts – preventing the diversion of prescription drugs and protecting the patients whose well-being depends upon access to those same controlled substances.

I appreciate the opportunity to be here today representing the American Health Care Association and National Center for Assisted Living (AHCA/NCAL), the Wisconsin Health Care Association and Wisconsin Center for Assisted Living (WHCA/WICAL), and my fellow long term care providers. I consider it a privilege to share our collective concerns, as well as some real world examples of the negative impact that recent, stepped up enforcement of outdated rules and regulations is having on the patients we care for in my hometown of Menasha, Wisconsin.

My name is Michael Schanke. My father, Thomas Schanke, and I are proud of the three long term care facilities that we own and operate in Wisconsin's Fox Valley. As Administrator of Oakridge Gardens Nursing Center, I am responsible for all aspects of daily operations in our Medicare- and Medicaid-certified, skilled nursing facility. The 145 full- and part-time staff we employ at Oakridge Gardens do an incredible job of caring for more than 100 seniors each day, and helping the vast majority – nearly 80 percent of the 300 individuals we treat each year – return home to their communities.

All of us – providers of long term, post-acute, and hospice care; pharmacists; physicians; nurses; and most of all the patients and families who rely on us – hope that this hearing will be a catalyst for a renewed effort to mitigate conflicting federal regulations, and achieve our mutual objectives without compromising patient care, especially in controlling and alleviating patients' acute and chronic pain.

Enforcing Outdated Rules & The Negative Impact on Patients

Working as a nursing home administrator for more than two decades, I have watched this field evolve. Today, long term care facilities like mine care for chronically ill seniors as well as post-acute patients needing rehabilitation therapy after hip or knee surgery or those recovering from a stroke. We are blessed to have outstanding management and support staff working in our facilities, each of whom contributes to the success of our business on so many levels and shares in our reputation as one of the best providers of elder care in the Fox Valley of Wisconsin.

Our hard working, dedicated team of nurses, doctors, therapists, and pharmacists are frustrated by recent changes to what has been standard care practice for decades, upon which many state regulations are based. Those of us in long term care are used to adapting to new rules and regulations; but, as caring, compassionate health professionals, change that negatively impacts our patients is difficult to bear. That is exactly the kind of change that the U.S. Drug Enforcement Administration (DEA) is creating by requiring strict adherence to its outdated rules and regulations for the prescribing and dispensing of prescription drugs in long term care settings.

Certainly, long term care professionals understand and support the DEA's role in preventing the diversion of controlled pharmaceuticals. In fact, DEA's stated goal in bringing narcotics and other drugs under legal control is to ensure that these "controlled substances" are readily available for medical use.[1] While we support DEA's efforts to prevent the sale or theft of prescription medications to drug dealers or abusers and other types of drug diversion, we remain dumbfounded by rules and regulations that are the root cause of unimaginable, unacceptable delays in access to the pain medication patients in nursing homes and assisted living facilities across the country need. It would merely be ironic if current DEA rules limited the availability of controlled substances for medical use. Sadly, current DEA rules are contributing, albeit unintentionally, to the suffering that many patients in pain must endure.

I have witnessed first-hand the negative impact that changes based on renewed DEA enforcement of the *Controlled Substances Act of 1970* are having in facilities like mine. Fear, confusion, and frustration have accompanied these recent changes as patients suffer in pain. Family members either watch helplessly, or berate caregiving staff who are struggling with a process that may only allow access to inadequate or inappropriate pain relief, even though the medication they need may sit in a locked pharmacy box only steps away.

This testimony echoes the survey findings in the Quality Care Coalition for Patients in Pain's (QCCPP's) report entitled, *Patients in Pain: How the U.S. Drug Enforcement Administration Rules Harm Patients in Nursing Facilities.* The QCCPP report, which is being released in conjunction with this

[1]U.S. Department of Justice (DOJ) Drug Enforcement Administration (DEA) Office of Diversion Control Program Description of DEA Diversion of Controlled Pharmaceuticals, Retrieved March 22, 2010 from http://www.deadiversion.usdoj.gov/prog_dscrpt/index.html

hearing, highlights the experiences of other providers, physicians, nurses, and pharmacists. Those reflections parallel the incidents described here. I am sharing these two recent examples of how current DEA rules effectively tie our hands and negatively impact the frail, elderly, and disabled individuals we care for in the hopes that such incidents will not continue to occur. The idea of even one patient lying in excruciating pain for a moment longer than necessary is simply unacceptable. Allowing such pain to continue, when we have the means to stop it, runs counter to the Hippocratic Oath's admonition to "first, do no harm," and everything that we as a civilized society believe is right, especially in caring for the most vulnerable among us.

When we learned of DEA's renewed focus on enforcement of the *Controlled Substances Act*, my facility held a series of educational sessions for our nurses and other nursing home staff. We informed staff that we could no longer accept verbal orders from doctors for Schedule II, III, IV, and V prescription drugs, which are drugs with legitimate medical uses, but considered either addictive or having the potential for abuse. We also explained that we now needed to ensure that a written prescription is completed by the doctor and then faxed by the doctor to the pharmacy before the pharmacy can dispense the order to the facility. In essence, we were telling our staff that the nurse – who has been trained to treat patients, who has been thoroughly educated on the administration of medication, who is licensed by the state, who is with the patient around the clock, who is assessing the individual's condition in real time – can no longer perform one aspect of the job that he or she has been trained and licensed to do – in short, the nurse can no longer fax physician's telephone and chart orders to the pharmacy.

The two specific examples that follow illustrate how these DEA rules and procedures can interfere with immediate and necessary treatments for patients in severe pain.

Challenges in Treating A Newly Admitted Patient

In February 2010, an elderly woman discharged from the hospital after surgery to repair her lumbar (L2) vertebrae was admitted to our facility. As with many of our newly admitted patients, one of our first goals was to manage her intense pain in so that she could begin a rehabilitation program that included both physical and occupational therapy. Typically, post-operative patients endure two or three days of intense pain after leaving the hospital.

In this case, the discharging physician had ordered a Fentanyl® patch along with Percocet® every four hours, as needed to manage pain. The Fentanyl patch provides a continuous level of pain medication in the bloodstream, while the Percocet could be given "as needed" based on an assessment of the individual's uncontrolled pain level. This patient's pain levels required Percocet virtually every four hours, which is not unusual in light of her surgery. We had secured a valid, written prescription for a 30-count of Percocet pills, along with the Fentanyl patch, which were administered as directed beginning with her admission to our facility on Thursday afternoon. Since her pain did not abate significantly, by Saturday it became apparent that the 30-count of Percocet prescribed in the original physician's order would be exhausted by late Sunday given the patient's current use patterns.

Since the patient required more intense pain management than anticipated, we reached out to her attending physician well before we expected the patient would deplete the limited number of Percocet initially ordered. Even with an increased Fentanyl patch dose, by Monday morning, the patient's pain level reached nine or ten on a scale of ten.

Unfortunately, without verification that a written prescription from the doctor had been sent to the pharmacy, we had no other recourse by which we could treat the patient's pain within our facility. Without emergency access to medication, the delayed paperwork effectively tied our hands. Our efforts to comply with recent DEA edicts regarding controlled medications left us, like our patients, at the mercy of this strict and impractical process. The pharmacy's contingency kit, which contained the Percocet medication that could have helped to relieve the patient's severe pain, was sitting within our building, as was her family, who waited by her side confused and frustrated as our staff tried to explain why, under current regulations, they could not access the medicine needed to relieve the patient's intense pain.

The patient's pain had become so intense and unmanageable that she had to be transported by ambulance back to the hospital emergency room just before noon on Monday. Ironically, the pharmacy received the doctor's order around noontime as well, though it was too late to be meaningful for the patient, whose fragile state required readmission to the hospital. The hospital informed us that the patient had to be completely sedated, and that she was placed on a PCA pump (patient controlled administration) intravenous drip, and received an epidural block. Over the next three days, the patient was gradually brought back into consciousness where pain management again became the primary clinical goal. Eventually, this patient returned to our facility. She is still taking Percocet; however, we are pleased to note that she has finally been able to begin her rehabilitative treatment with physical therapy and occupational therapy.

It is extremely important to note that when the patient was admitted to our facility, our nursing staff was given a legitimate physician order for these medications for a diagnosed patient condition that we were instructed to monitor and treat. None of our staff made a decision on his or her own to prescribe any medication for this patient. Our nursing staff must always receive an order from a physician for any medication that we administer to a patient.

The challenges that we faced in controlling this patient's pain are not about the prescribing of effective and appropriate medication, but rather that the process by which we must obtain an order for continuation of a needed medication is significantly more cumbersome than what has been accepted clinical practice.

There can be no doubt about the many unintended consequences that resulted from these delays, including an unnecessary, costly rehospitalization and delay of the patient's rehabilitation, which wasted precious time and resources for the patient, her family, and providers in both care settings. Of greater concern, however, is the fact that the delays we encountered in attempting to comply with these rules caused this patient to experience excruciating pain that we could not address while still remaining compliant with DEA rules

and procedures.

There also can be no doubt that the delay in filling this woman's prescription for medically necessary pain medication was directly related to compliance with current DEA rules, which may have been appropriate at the time the rules were drafted, but no longer seem practical or reasonable. American society has changed since 1970 when the *Controlled Substances Act* was introduced, particularly when we look at the tremendous advances in science, medicine, and technology. So, as we usher in the era where electronic prescribing of medications that target specific diseases could become as commonplace as sending a text message from a mobile telephone is now, it is reasonable to review and reconsider outdated DEA rules and procedures.

Similar delays can occur when dealing with individuals who experience an unanticipated change in condition that causes a sudden, dramatic increase in pain, regardless of the setting in which they reside. These examples detail how DEA's enforcement has delayed access to vital medications in nursing facilities. Furthermore, DEA's strict enforcement has negatively impacted other long term care settings, including assisted living communities in Wisconsin and many other states. Although these issues may not occur as frequently in assisted living as in nursing facilities, the net result is the same. Frail elders suffer needless pain simply because nurses cannot act as agents of the prescriber. The onset of pain can be unpredictable; however, quick access to pain-relieving medications should be predictable for seniors in all long term care settings.

Difficulties in Managing A Patient's Sudden Change in Condition

Not long ago, a patient in our facility began to experience nerve pain so severe that assessment as to whether the pain was related to an existing diagnosis or an entirely new condition was limited. Our nursing staff called the attending physician to describe the situation and establish a recommended course of treatment. Within 48 minutes, the physician had spoken directly to the registered nurse, giving orders to begin pain medication so that further examination could be completed once the individual's pain was in control. That verbal telephone order taken directly from the doctor included the pill count. We did verify that the doctor wrote the prescription and that the pharmacy had received a fax of the written order. Yet, we were informed that the doctor had forgotten to write the number of pills needed on the prescription. Since the number of pills had not been specified on the written order, even though the physician gave the pill count in the verbal order to the nurse and all other required elements were listed on the prescription, the prescription was not considered a valid, legal order according to DEA requirements.

We contacted the doctor immediately so that he could complete the prescription order. Unfortunately, by that time, the doctor had moved on to other tasks within his clinic, which caused an hour-long delay in getting the pain medication to our patient.

Since we could not immediately reach the physician and we knew that the individual's pain was severe and escalating, we pulled the medication from our pharmacy contingency kit. The

medication arrived from pharmacy shortly thereafter. Still, two hours had elapsed from our initial call to the physician to the time pain medication was administered to the patient – twice the amount of time it could have taken. The condition causing the nerve pain was diagnosed; the individual is now being treated with a combination of prescriptions, which include a lower dose of the pain medications initially needed.

Despite direct instructions from the attending physician, the patient's pain went unchecked while the cumbersome process required by DEA had to be restarted simply because the pill count was inadvertently omitted from the initial written prescription. Previously, it was acceptable practice to have the patient begin taking pain medication from the contingency supply after receiving the physician's order in a telephone call between the doctor and nurse. The required paperwork would then be completed by the physician and pharmacy as part of the ordering and tracking process for controlled substances.

The fact is that physicians cannot always respond immediately when contacted since they often are treating other patients. Another fact is that DEA rules and regulations have delayed the delivery of pain medication for this individual on at least two occasions. The facility staff did everything possible to ensure that the doctor and the pharmacist connected so that the patient could receive the Percocet she needed. If the DEA simply recognized the long term care nurse as the "agent of the prescriber," the delays described in the first example would not have occurred; in the second example, DEA acknowledgement of the nurse as agent would have cut the time delay in half, bringing the patient relief from pain an hour earlier.

These examples illustrate what can happen when patient needs are not first.

Quality First = Patients First

My colleagues at the WHCA/WICAL, AHCA/NCAL, and all across the country are committed to delivering high quality care and to providing a safe and secure environment for the millions of Americans living in our nation's nursing facilities and assisted living residences.

We are proud of the advances that we have made. In fact, AHCA and the Alliance for Quality Nursing Home Care have documented that progress in the *2009 Annual Quality Report*. The report analyzes quality in nursing facilities since the 2002 inception of the profession's quality improvement initiative, *Quality First,* and features research and critical analysis by leading experts in the fields of quality and long term and post acute care services. Others have charted our progress as well; for example, data from *Advancing Excellence in America's Nursing Homes* has shown improvement in pain management and other goals of the campaign.

Quality remains our focus – quality of life for patients and staff; and quality of care for the millions of frail, elderly and disabled individuals who require our services. We continue to challenge ourselves to improve, and enhance quality, as we prepare for the increased demand for long term care and

services in the future.

Long Term Care Facilities Are Highly Regulated by State & Federal Government

Adequate pain management is one of the quality measures that skilled nursing facilities must address from a regulatory standpoint. We have invested considerable time and effort in finding ways to adequately and compassionately improve on this measure in particular.

As Members of the Senate Special Committee on Aging are acutely aware, nursing homes are highly regulated, licensed, inspected, and/or certified by a number of public and private agencies at both the state and federal levels. Nursing homes that receive Medicare or Medicaid funding must meet federal standards, many of which trace back to the *Omnibus Budget Reconciliation Act of 1987 (OBRA '87),* which established a comprehensive set of nursing home regulations. The overarching goal of *OBRA '87* is that each individual receives care "to attain or maintain the highest practicable physical, mental and psychosocial well-being."

Safe, effective, and appropriate administration of drugs to long term care patients is a key component of good quality care; it is as fundamental and important as the availability of appropriate drugs. So, it is important for this Committee to recognize that the DEA's increased enforcement efforts have directly inferred with our facilities' mandate to comply with the Center for Medicare & Medicaid Services (CMS) regulations related to requirements for drug administration and practices related to the treatment of patients in pain.

CMS places the responsibility on the facility for patient safety, including safety with regard to the administration of pharmacy services. CMS recognizes that, unlike the typical ambulatory senior, patients in long term care facilities usually are older, in poorer health, and in need of greater care. Facilities are responsible the quality of care that their patients receive and federal guidelines and state licensing agencies require that the patients receive needed medication in a timely manner. In addition to CMS, our facility is regulated and surveyed by Wisconsin State law. The Division of Quality Assurance (DQA) is responsible for assuring the safety, welfare, and health of persons using health and community care provider services in Wisconsin. Within the DQA, the Bureau of Nursing Home Resident Care (BNHRC) is responsible for conducting unannounced health care surveys of nursing homes. The BNHRC reviews facility construction plans, conducts complaint investigations, and makes care level determinations for persons receiving medical assistance in the community or in nursing homes. In addition, the Bureau of Assisted Living (BAL) is responsible for licensing and surveying various assisted living provider types.

CMS has established criteria for compliance regarding the way a facility must treat patients in pain or the potential for pain. The individual must receive, and the facility must provide, the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

F-Tags (short for "Federal Tags") provide additional guidance on CMS regulations. An F-Tag is a

designation that CMS uses for the purpose of identifying a portion of each requirement of participation in Medicare and Medicaid services. Currently, there are six F-Tags directly related to pain and pain management, encompassing about 150 pages of regulation and guidance. CMS also suggests that a facility may be non-compliant in other areas, if pain is not managed and a facility has been found to be deficient in a particular area. There are additional F-tags that government surveyors are directed to investigate if related concerns are identified; there are fourteen F-Tags commonly linked with a pain management deficiency under which a facility can be cited.
While our main concern is the patient receiving the best possible quality acre and receiving medication in a timely manner, the potential for increases citations and the related fines associated with survey citations is also a concern for many long term care providers, who already work diligently to avoid such citations.

Beyond CMS oversight, some long term care facilities are certified by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO developed its pain management standards with input from the American Pain Society, consumer groups, and a collaborative effort between JCAHO, the Robert Wood Johnson Foundation, and the University of Wisconsin-Madison Medical School. Those standards, *Pain Assessment and Management Standards,* are used by JCAHO surveyors who assess compliance with those standards through interviews with families and clinical staff and a facility's review of policies, procedures, and examination of a hospital or ambulatory facility's pain management practice. In fact, when JCAHO issued its pain management standard, pain was called "the fifth vital sign."

AHCA/NCAL Recommendations

Patients in long term care settings simply cannot wait for a practical, workable solution to alleviate current delays in accessing the pain medications that they need. Newly admitted patients and those experiencing a sudden change in condition or similar emergency are most affected by delays with controlled drugs due to DEA's strict interpretation of the *Controlled Substances Act.* The two examples detailed in our testimony illustrate that the ordering process for scheduled medications has become more focused on paperwork than addressing the immediate care needs of patients. The new enforcement standard solves no existing problem in our clinical practice of caring for the elderly and will create new problems for our elderly patients (additional pain), if allowed to continue in the present form.

AHCA/NCAL, as a partner in the Quality Care Coalition for Patients in Pain (QCCPP), supports the recommendations proposed by the QCCPP and urges Congress to require that the DEA consider some immediate solutions and an interim fix for the problems at hand.

DEA has the authority now under regulation to clarify that the long term care facility nurse is acting as the agent of a prescriber and may communicate verbal orders to the pharmacy that have been issued by the prescribing practitioner for Schedule III - V drugs, and emergency orders for Schedule II medications. The DEA currently allows a prescriber to fax an order for a nursing home patient,

but prohibits verbal orders except in narrowly defined circumstances.[2] Broadening this set of circumstances would help us through the delays that can occur most often for late-night and weekend admissions.

One proposed solution is for the DEA to permit the long term care nurse to communicate a doctor's orders for Schedule II drugs, in an emergency situation, to the pharmacy; if the pharmacy receives the signed prescription for that order within seven days, then this will confirm that prescription was valid and there will be no need to penalize nurse who administers treatment first. The pharmacy's receipt of a valid prescription order within seven days provides the necessary legal documentation to establish that the prescription was issued for a legitimate medical purpose.

With this recommendation, AHCA/NCAL is asking that nurses who are licensed and trained for medication administration be allowed to exercise their best professional judgment as to whether patient's medical condition warrants immediate attention.

It is extremely important that the rules be updated to account for the realities of medical practice, nursing home care and the three-way system of communication that occurs across care settings. We in the long term care community welcome the opportunity to work with DEA to help them develop rules that address the needs of our patients while maintaining the level of control over controlled substances that DEA expects and requires.

Traditionally, the physician-patient bond is considered sacrosanct among those in the medical community and the public at large. In long term care settings, doctor-patient relations necessarily include the nurse. In a nursing home, the nurse serves as the eyes and ears of the doctor—assessing the patient's condition and reporting this information to the doctor. This crucial element of the equation, in which the nurse plays a pivotal role, is the element that seems to be overlooked by the DEA in its refusal to recognize the nurse as the physician's agent.

Please keep in mind that in an acute care setting, such as a hospital, the nurse ***is*** recognized by the DEA as the physician's agent simply because of a registration number. Nurses who work in long term care settings receive the same training, maintain the same licenses, and most importantly to the patient, serve the same role. For the patient, the practical reality of care setting is the same, and the reality of the pain is just as severe.

The long-term solution is, of course, to change the law, which requires that an authorized or DEA-registered prescriber write and sign prescriptions for all controlled substances, including many pain medications commonly used in treating nursing home patients. The fact that the DEA does not recognize long term care nurses as "agents of the prescriber," nor does it consider facility chart orders as valid prescriptions, remains the core of this issue.

When a physician gives the long term care nurse a verbal order (for a new drug or a changed drug), the nurse records that order in the patient's chart – creating a "chart" order. Traditionally, that chart order was then faxed to the pharmacy, which dispensed the prescription to the facility. DEA

[2] 21 CFR 1306.11

recognition of the chart order as a valid prescription would allow a long term care nurse, who assesses an individual's changed condition and contacts the physician by phone to describe the patient's symptoms and vital signs, to relay any physician-ordered prescription to the pharmacy without delay.

Conclusion

Again, I appreciate the opportunity to offer these comments on behalf of millions of professional, compassionate long term caregivers and the millions of frail, elderly, and disabled Americans they serve each day.

On behalf of AHCA/NCAL, WHCA/WICAL, and my fellow providers, I thank each of the Members of the U.S. Special Committee on Aging for focusing on this important issue and for bringing our concerns to the direct attention of the Drug Enforcement Agency (DEA) and the American public. We welcome the opportunity to continue working with you and the DEA to ensure that America's seniors receive the care that they need and deserve.

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The CHAIRMAN. Thank you very much, Mr. Schanke.

Now, we turn to Mr. Warnock.

STATEMENT OF ROBERT WARNOCK, D.PH., VICE PRESIDENT OF PHARMACY SERVICES, GOLDEN LIVING, FORT SMITH, AZ

Mr. WARNOCK. Chairman Kohl, thank you for inviting me here today.

My name is Robert Warnock. I speak on behalf of Golden Living, a leading healthcare services company that operates more than 300 skilled nursing facilities in 21 States. I am the company's Vice President of pharmacy services. In addition, I am a certified Geriatric Pharmacist and licensed Doctor of Pharmacy.

I'd like to discuss how some Drug Enforcement Agency regulations are imposing barriers to the timely and medically appropriate dispensing of controlled medications in skilled nursing 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 2 drugs can cause needless suffering for patients with legitimate medical needs for those medications.

Additionally, some of these regulations are potentially placing skilled nursing facilities at risk of being noncompliant with CMS regulations governing the patient-care responsibilities of skilled nursing facilities.

That said, Golden Living fully supports and commends the DEA for its role in protecting the public from drug diversion and illegal practices regarding the use of controlled substances. We wish to work cooperatively with the committee and the DEA, as well as Federal and State healthcare regulators, to improve the effectiveness of the regulatory system. However, existing DEA regulations are difficult to comply with in our skilled nursing facility environment, particularly in light of CMS regulations under which we already operate. CMS regulations cover the safe and effective handling of medications.

Conflicting DEA and CMS regulations place skilled nursing facilities in a difficult position. On one hand, DEA regulations increase delays in the provision of needed medication. On the other hand, CMS regulations require that skilled nursing facilities provide immediate care of the patient's needs. Compliance with both sets of regulations is challenging and, at times, impossible.

Current DEA regulations require long-term care pharmacies to comply with very specific processes to allow the ordering and dispensing of Schedule 2 controlled drugs, including the requirement of hardcopy prescriptions signed by a physician. Skilled nursing facilities do not have onsite 24-hour physician staffs. Each patient has an attending physician who is responsible for his or her medical orders. But, most of these physicians maintain their primary practice outside of the skilled nursing facility and conduct many of their activities offsite and electronically.

Manual processes for ordering and approving Schedule 2 prescriptions may be acceptable during regular office hours, when physicians, nurses, and long-term care pharmacists are present in their regular practice setting. After hours, however, pharmacies may be closed, and physicians may not have access to fax ma-

chines, if they are reachable at all. During these times, the required process frequently results in lengthy delays.

DEA requirements for skilled nursing facilities differ from those under which hospitals operate. DEA provisions help hospitals and hospital pharmacies meet the immediate needs of their acute care patients for Schedule 2 medications. In hospitals, a physician's order on a patient's chart serves as a legal order and prescription for the pharmacy to fill the controlled substance. Also, nurses in hospitals are allowed to serve as physicians' agents and can order the pharmacy to fill a prescription for the controlled substance.

Similar provisions for skilled nursing facilities would enable us to better meet the needs of patients who become acutely ill in our facilities or who are in pain at the time of admission. In many cases, we would be able to help patients in severe discomfort faster than we can under current regulations.

We would also ask that DEA follow more of an administrative approach to their work with skilled nursing facilities. In 2009, Golden Living experienced an unannounced inspection of five of our skilled nursing facilities by DEA agents. To our knowledge, these inspections were unusual and unprecedented. The aggressive law enforcement approach used by the DEA agents during these visits, including the use of armed escorts, had a chilling impact on facility operations. It disrupted the staff and their important caregiving responsibilities, and it frightened our patients and our employees.

In cases where there is not an immediate concern or issue, we would suggest that such disruptions may be mitigated if skilled nursing facilities were given advance notice of future DEA visits of this nature.

Thank you for your time today.

[The prepared statement of Mr. Warnock follows:]

Statement
of
Robert R. Warnock, D.Ph. CGP, FASCP
Vice President of Pharmacy Services
Golden Living

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"

March 24, 2010

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.

Robert R. Warnock, D.Ph., CGP

Vice President, Pharmacy Services
Golden Living

Dr. Warnock is Vice President of Pharmacy Services for Golden Living where he oversees the pharmacy services for more than 300 skilled nursing facilities and 40 assisted living centers throughout the U.S.

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).

The CHAIRMAN. Thank you Mr. Warnock.

Dr. Phillips.

STATEMENT OF CHERYL PHILLIPS, M.D., PRESIDENT, AMERICAN GERIATRICS SOCIETY, NEW YORK, NY

Dr. PHILLIPS. Thank you, Chairman Kohl and thank you for taking on this really important issue.

I will speak as a geriatrician and an advocate, as we all are, for the patients and individuals that we're concerned about throughout this.

In addition to being President of the American Geriatrics Society—and very happy to represent that organization—I'm also the past President of the American Medical Director's Association, which is the organization for physicians in long-term care practice. My entire clinical practice, scanning some 20 years, has been in the long-term care arena.

This is a very real, palpable issue; it's not just a theoretical problem. It actually has been, in a variety of States, going on for many years, escalating, most recently, with some of the enforcement activities.

So, I'll start—we've had issues with stories. I, too, will tell the story of Mrs. M, who's demented and 87 and is admitted back to the emergency room on a Friday night, after 4 days in the nursing home. She goes back to the same hospital she came from, because after her hip surgery, her orthopaedic surgeon felt like she needed to have less confusing pain meds and reduced her narcotics.

Every day in the nursing home, her pain was slightly increasing until the day of transfer, when the nurse doing an assessment, working with the physician, communicating with the family, realized that we were not able to manage, in a timely manner; and the family, in frustration, as was mentioned in an earlier example, said, "Enough, already," and sent her back to the hospital.

I was part of a CMS panel that looked at rehospitalizations. One in four Medicare patients who go to the hospital and go to a nursing home are readmitted within 30 days. A big part of this is, in fact, pain management. This represents $4.3 billion a year, at about $10,000 per admission. Not only is it unnecessary cost, it's unconscionable that Mrs. M needs to go back to the emergency room to have what can be provided in a licensed facility with nurses, therapists, physicians, and pharmacists ready to take care of her.

So, what can a physician do if we can't get the narcotic? Well, we can use a non-narcotic option; that's not great. The pharmacy and the nurse can go outside of DEA regulations, give the medicine anyway, face significant sanctions and fine. Or what often happens is, a patient goes without. They're the ones paying the price and suffering.

It is not insignificant, untreated pain in the elderly. We have a lot of myths about pain management in the elderly. When we don't address pain, seniors tend to not eat, they tend to not move, they are less mobile, they're more likely to get pneumonia, they're more likely to fall because of the muscle weakness related to the immobility. They are certainly more likely to have pressure ulcers. It often starts that spiral of decline and death. Pain management in

the elderly is a critical and important medical and social and moral issue.

So, why is it that we have such a problem? As was mentioned earlier, in the hospital I can get called by a nurse who gives me an informed, professional assessment. I can have an interaction in a care plan decision, give an order, and it is executed in the hospital. That same nurse can go across the street to the nursing home, use her same assessment skills, can have the same dialog with me about a patient that I may have seen in the hospital a day earlier, but now I can't give her that order for narcotic management or other medicines that follow under the schedule purview. Instead, I must call a pharmacy. Often it's a 1–800 number for a regional pharmacist, sometimes States away. I will tell, from personal experience, that very often, after hours, that meant I wait for the pharmacist to call me back. I then have to find a fax after hours; I'm not one that carries one in my car. So, after hours or weekends, I need to fax, then, an original signature. Now, I call back the nursing home nurse, who then calls the pharmacist to verify the order. Each one of these steps takes time. Each one of these steps creates the opportunity for significant error. Each one of these means that Mrs. M is sitting in pain. That's if things work well. That's when the stars are aligned.

More often than not, they aren't. Most physicians do not have faxes at home or in their cars. So, after hours, even though we do have 24–7 availability, we don't have the access to make this electronic communication with the pharmacies. Forty percent of physicians now who practice in nursing home settings don't have typical office practices. So, we are not talking about the same dynamic of a physician sitting in a room with a complete support staff.

So, we do recognize that this is a team relationship. This is not delegating work away from the physician to the nurse or the nursing home. This is a collaboration, both of us working in the scope of our licenses, with the most important goal of serving the individual.

We recognize the importance of the DEA's oversight, but I would offer that Mrs. M's pain is not a law enforcement issue. This really is an issue of allowing the nurse to serve as the agent of the physician in this setting of care. We know that diversions occur. They occur everywhere. They are no more likely to be in nursing homes than elsewhere. There are checks and balances in place that others can speak of.

I commend the effort of this. I wholeheartedly appreciate this work. We look forward to working with the DEA. We would like to find a regulatory solution to this. If not, I urge that we move toward a legislative solution to allow the nurse to be the managing agent.

Thank you very much.

[The prepared statement of Dr. Phillips follows:]

STATEMENT OF

CHERYL PHILLIPS, MD, AGSF

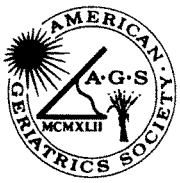
CHIEF MEDICAL OFFICER,
ON LOK LIFEWAYS

&

PRESIDENT,
AMERICAN GERIATRICS SOCIETY

ON BEHALF OF THE

AMERICAN GERIATRICS SOCIETY



BEFORE THE SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

MARCH 24, 2010

INTRODUCTION

Good afternoon Chairman Kohl, Ranking Member Corker and Members of the Committee:

I would like to express my sincere appreciation to Senator Kohl and the members of the Senate Special Committee on Aging for allowing me the opportunity to provide testimony and for their willingness to address the issue of pain management and the prescribing of narcotics in the nursing home setting. It is an important, albeit extremely complex, issue.

My name is Cheryl Phillips, M.D. I am a fellowship-trained geriatrician and chief medical officer of On Lok Senior Services, the originator of the PACE (Program of All-inclusive Care for the Elderly). I also serve as President of the American Geriatrics Society, a non-profit organization of 6,400 geriatrics healthcare professionals dedicated to improving the health, independence and quality of life of all older Americans. I am also past president of the American Medical Directors Association (AMDA), the professional organization that represents physicians in long-term care. I have spent the majority of my clinical career in long term care, including over 20 years in nursing home practice in California. Today, I will briefly outline the need for policies that will ensure that frail elders who reside in nursing homes are not in pain. In my remarks, I will address the clinical need for ensuring that older adults receive pain medication when needed and the reality of clinical practice for doctors with patients in nursing homes.

I am here because every day, across the country, the real-life consequence of the Drug Enforcement Administration (DEA) interpretation of the Controlled Substance Act is that, collectively, we are preventing patients in long-term care settings from receiving much needed pain relief and other medications in a timely manner. We can, and should, be doing better. Let's put a face on that pain.

Mrs. M is an 87 year old female with advanced dementia and a recent hip fracture and subsequent surgery. She has been at the nursing home for the past three days. Prior to her transfer from the hospital her pain meds were decreased because her orthopedic surgeon was worried about confusion. Since then, the family has been concerned that she has been in pain that is not managed with the non-narcotic meds prescribed. On the fourth day of her nursing home stay physical therapists worked "a bit harder" to get her moving more and out of bed. By that evening she was tearful and refusing to eat. When the family arrived they recognized she was in pain and requested something stronger to treat her. After a call to her attending

physician which resulted in an order for morphine sulfate the nurse requested from the pharmacist that she be able to access the emergency drug kit and administer the ordered medication. However, because the physician was not able to provide an after-hours signature the pharmacist said she was not able to release the medication. The family became incensed and threatened to "sue the nursing home". At that point, the nurse called the physician back and the order was given to send the patient, via ambulance, to the emergency room for pain management.

I am sure that you will all agree that transfer to the hospital is not the right solution. It adds to the spiraling cost of health care in this country. And, quite frankly, it is unconscionable that we would transfer an elderly woman with advanced dementia to an emergency room just to manage her pain. Yet, that is a scenario that plays out day in and day out as nursing homes, physicians, nurses, and families grapple with the reality of the DEA actions against nursing homes that fail to obtain a physician signature prior to administering controlled substance pain relief.

PERSISTANT PAIN IN OLDER ADULTS

Persistent pain is a common problem for older adults. A Louis Harris telephone survey found that one in five older Americans (18%) are taking analgesic medications regularly (several times a week or more), and 63% of those had taken prescription pain medications for more than 6 months. Older people are more likely to suffer from chronic conditions often associated with persistent pain, such as arthritis, bone and joint disorders, and cancer.

Pain is especially common among nursing home residents. It has been estimated that 45% to 80% of them have substantial pain that is undertreated. Studies of both the community-dwelling and nursing home populations have found that older people commonly have several sources of pain, which is not surprising, as older patients commonly have multiple medical problems. A high prevalence of dementia, sensory impairments, and disability in this population make assessment and management more difficult.

CONSEQUENCES

There are many myths about pain management for older adults. These myths include such false beliefs that pain decreases as we age and that persons with dementia feel less pain. In

fact, untreated pain has serious medical consequences that include poor oral intake and weight loss, inability to sleep, depression, loss of mobility and increased risk of falls, and increased risk of pressure ulcers. Depression, anxiety, decreased socialization, sleep disturbance, impaired ambulation, and increased health care utilization and costs have all been found to be associated with the presence of pain in older people. Although less thoroughly described, many other conditions are known to be worsened potentially by the presence of pain, including gait disturbances, slow rehabilitation, and adverse effects from multiple drug prescriptions.

Poor pain management in the nursing home setting has significant associated costs. Inadequate pain management is associated with increased emergency room transfers and increased re-hospitalization rates.

In short, failure to address pain in the frail elder can begin the downward spiral that leads to decline and death.

THE IMPORTANCE OF PAIN MANAGEMENT

As a geriatrician I recognize the critical importance of adequate pain management for the elderly. The story of Mrs. M is illustrative of how such failure can result in an unnecessary transfer to a hospital because of inadequate pain control. While this may sound extreme, sadly this scenario is all too common across the country. The Centers for Medicare and Medicaid Services have identified that inadequate pain management is a serious quality problem for patients in nursing home facilities. It is known that effective pain management plays a significant role in improving functional status, quality of life, and quality of care in nursing homes.

BARRIERS TO CONTROLLING PAIN

So, since everyone agrees that pain is a serious problem in the elderly and that nursing home providers must do a better job, why does it continue to be such a challenge? I respect the important work of the Drug Enforcement Administration in its law enforcement efforts to control the distribution and use of illegal narcotics. But I would offer that this is not, and should not be a "law enforcement" issue. Patients in nursing homes today are not much different in severity of illness and in their medical needs than hospitalized patients. In fact, in many regions patients may be admitted directly to the nursing home for skilled services in lieu of acute hospital

admissions. As a practicing physician, when there is a change of condition or acute pain issue in the acute hospital I am able to call directly to the nurse responsible for that patient, provide a verbal order for pain medications, have the patient receive that pain medication, and sign the order the next morning.

In the nursing home, however, this is not the case. If I am called after hours or I am covering for another physician and I am notified of an acute pain issue, I cannot merely leave the order for the pain medication for the nurse to fill and unlike most hospitals, most nursing homes do not have in-house pharmacies. In fact, according to the DEA rules, I must identify the dispensing pharmacy and call the pharmacy, most often through a 1-800 number, and leave a message for the pharmacist to return my call. When I am able to speak in person, I must place my order – followed by a fax of that order with my signature. I must then call the nursing home and relay the same order to the nurse where she awaits delivery of the medication or release from the narcotic emergency box by the pharmacist. Even when this goes as described above in perfect order, it is often 30 minutes to an hour to complete the process. However, rarely are the stars so aligned and this potential for error multiplies, as does the potential for patient suffering. In fact, most physicians do not have access to fax machines after hours, whereas nurses at the facility often have access to fax machines that are pre-programmed to the appropriate pharmacy. Upwards of 40% of physicians who practice in the nursing home do not have traditional office practices. When challenged to provide an immediate faxed order and signature, most physicians simply cannot do this. Most physicians typically either practice nursing home medicine as a part-time addition to their office practice or they provide care to patients in a number of facilities. It is a fact that nursing homes are required to provide 24-hour physician coverage for all their patients, but that rarely means that the physicians are on-site. Just like in hospitals, physicians rely on the nurse – who is trained to assess patient pain – to the necessary information for making treatment decisions – including ordering the appropriate drugs and services.

Therefore, several potential outcomes may occur when the physician is notified after hours about a pain management issue in the nursing home:

- the physician identifies a non-narcotic medication to "hold" the patient until the next business day;
- the pharmacist and nursing home go ahead and fill the narcotic medication and obtain the required signature later – facing significant fines and sanctions for doing so;

- the patient goes without pain medication;
- the patient is sent to the emergency room.

None of these scenarios are acceptable when it comes to ensuring that nursing home residents have access to pain control

Poor access to pain control also creates a disincentive for physicians to practice in the nursing home setting in that we have already seen court cases linking poor pain management to elder abuse. In a landmark case, Beverly Bergman, et al v. Wing Chin, M.D., a physician was found liable for elder abuse and the family was awarded $1.5 million because of, among other things, poor pain management in the nursing home. The fact is that physicians are very aware of the liability risks that accompany poor pain control. When they realize that there are such significant challenges to adequately manage pain in the nursing home, the easiest option for physicians is to merely opt out of nursing home practice. Identifying physicians who are willing to provide quality care in the nursing home setting is a significant challenge across the country; this issue just provides one additional, significant barrier.

SOLUTIONS

There is a solution to all of this. The DEA should recognize nursing home nurses as the "agent" of the physician – just as they recognize them as "agent" of the physician in the hospital. If that were the norm, then orders could be managed appropriately and in a timely fashion. There are adequate checks and balances in place:

- each verbal order, including narcotic orders, must be signed by the physician – just as they are in the hospital.
- Nursing staff is required to provide shift accounting for the doses of narcotics and must chart each administration – again, just as they do in the hospital.

And, just as in the hospital setting, occasional diversions occur. And, just as in the hospital, when a diversion does occur, there are state and law enforcement interventions that follow. Multiple safeguards, which are regularly reviewed as part of the federally mandated survey, are present in long-term care facilities, including narcotic lock boxes, inventory of narcotics at shift change, and documentation of drug destruction.

If this was how our system worked, Mrs. M would have received the clinically appropriate pain medicine in a timely fashion. That is the norm we should strive towards.

CONCLUSION

This is an important issue that we must resolve given its negative impact on the 1.38 million older Americans who currently reside in nursing homes. Our frailest citizens are suffering needlessly. Resolution is critical to ensuring both the quality of care and the quality of life for some of our most vulnerable citizens. None of us can imagine our parents or someone we love in severe pain that cannot be treated in a medical setting with licensed nurses, physicians and pharmacists available – only because the law requires a specific set of paperwork steps that cannot be accomplished after hours.

In closing, the AGS agrees wholeheartedly that physicians and other licensed prescribers must remain in control of the prescribing process and support reasonable efforts to ensure the integrity of this process. However, we call on the DEA to modify its policy so that it reflects that nurses in long-term care are agents of the physician – just like nurses working in the hospital. Absent timely remedial action by the DEA, we then ask that Congress provide a legislative solution to ensure that long-term care patients in acute or escalating pain receive the medications they need without delay. We thank you again for inviting us to participate in today's important hearing.

Respectfully,
Cheryl Phillips, M.D., AGSF
President, American Geriatrics Society

The CHAIRMAN. Thank you very much, Dr. Phillips.

Now we speak—we turn to Mr. Brickley.

STATEMENT OF ROSS BRICKLEY, RPH, PRESIDENT, CONTINUING CARE RX, INC., RALEIGH, NC; ON BEHALF OF AMERICAN SOCIETY OF CONSULTANT PHARMACISTS AND THE QUALITY CARE COALITION FOR PATIENTS IN PAIN

Mr. BRICKLEY. Thank you, Chairman Kohl.

My name is Ross Brickley. I'm a certified Geriatric Pharmacist in practice in North Carolina.

I'm here on behalf of the American Society of Consultant Pharmacists and The Quality Care Coalition for Patients in Pain, a multistakeholder coalition of physicians, nurses, and pharmacists.

Today, we have filed extensive written comments that describe in detail the issues and the background that brings us to this hearing.

In the short time I have to present my testimony, I want to focus on the following:

First, today across the country, long-term care patients are not receiving their controlled medications in a timely basis. Nearly 900 clinicians responded to a survey that the QCCPP sent out last fall, that we are releasing later today. Two-thirds of the respondents said that the DEA rules were impeding patients' access to controlled medications. This number jumped to 86 percent in Ohio, where DEA enforcement activity is the highest.

Second, in addition to delays in treatment, the survey showed the difficulty in accessing controlled medications is changing prescribing practices. Just as Dr. Phillips mentioned, physicians are now writing for noncontrolled medications that are less effective and may create other problems for our frail elderly.

Third, some nursing facility patients are being sent back to the hospital, just as our other panelists have indicated, because they could not get prompt medication treatment in the nursing home.

One example that I had on Monday of this week—and I have all the latest technology in my nursing facilities that I serve—but, a patient was admitted late in the evening, around 6 p.m. He was an end-stage HIV patient on routine narcotic medication; high dose every 6 hours. So, he was admitted with chart orders from the hospital. Those were electronically submitted into my health record. I, electronically, had everything I needed. Unfortunately, I could not legally dispense that medication, because it did not have a quantity or a physician signature on that electronic document.

Subsequently, we worked with the prescribers and such, and eventually, over an 18-hour period later, we finally got the signed prescription so we could legally dispense them and submit them out. I had an automated dispensing device there, one of the most highly technologically advanced devices possible. I could not release that medication, available in the nursing home, until I had that signed prescription in my pharmacy, available to administer.

Those kind of DEA limitations, with the compliance and the paperwork, just as our other panelists have indicated, create challenges and barriers to patient care.

Simply stated, the DEA rules were written nearly 40 years ago for outpatient treatment where a physician at a local, office would see a patient. If a controlled-substance medication was indicated,

the physician would write that prescription, hand it to the patient. The patient would fill it at a local pharmacy. This is a very different setting than what we have in the nursing home environment today.

Chairman Kohl, these issues being discussed today are not new. For decades, the DEA and ASCP have met to discuss these issues, and the DEA has been fully aware of these systems. As early as 1974, the DEA's chief compliance officer, Kenneth Duran, in a letter to ASCP, wrote, "I've long felt that the existing regulations do not adequately speak to the nursing home situation, and members of my staff are presently reviewing applicable regulations to see if we can arrive at a practical solution which does not sacrifice necessary control."

More than two decades later, in March 1996, DEA's Thomas Gitchel wrote, "We realize that there's still some longstanding issues of concern, and it's clear that the drafters of the Controlled Substance Act did not envision the evolution of the practice of pharmacy and medical care to what it has become today."

ASCP and I, personally, have continued to meet with the DEA for the past 10 years. We have no explanation for—after all these years—the DEA has decided to aggressively enforce these outpatient rules. In response to this, long-term care pharmacies have been forced to take drastic action. These are huge patient-care challenges.

The rules that the DEA ask us to follow are simply incompatible and must be changed. In the interim, we need immediate relief, and ask for the following:

First, the DEA must update its rules and policies for prescribing and dispensing controlled medications to reflect the practice realities of nursing home and hospice patients in long-term care facilities. We welcome the opportunity to work with the DEA to help them develop these rules.

Second, to alleviate patient suffering, the DEA has the authority now, under the regulation, to clarify that a long-term care facility nurse is the agent of the prescriber, and may communicate orders to the pharmacy.

Third, if the DEA does not act, we'll call upon Congress to enact legislation that would require the DEA to recognize the long-term care facility nurse as an agent of the prescriber and recognize chart orders as legal prescription orders for controlled substances.

Thank you, Chairman Kohl.

[The prepared statement of Mr. Brickley follows:]

Testimony of

Ross Brickley, RPh, MBA, CGP

on behalf of the American Society of Consultant Pharmacists
and
the Quality Care Coalition for Patients in Pain

before

The Senate Special Aging Committee

March 24, 2010

Introduction

Good afternoon and thank you Chairman Kohl and members of the Committee. My name is Ross Brickley and I am from Garner, North Carolina. I am a Certified Geriatric Pharmacist and the President of CCRx of North Carolina, Inc. a long-term care pharmacy serving nursing facility, assisted living and hospice patients throughout North Carolina and Virginia. I am a Past President of the American Society of Consultant Pharmacists (ASCP) and currently serve as a member of ASCP's Board of Directors and as the Treasurer of the Society. In addition to my leadership positions in ASCP, I am a Past President (2002) of the North Carolina Association of Pharmacists (NCAP).

ASCP is the international professional society of consultant pharmacists whose mission is to promote the appropriate, safe and effective use of medications in the elderly. Our 7,000 members provide long-term care and consultant pharmacist services to seniors and individuals with chronic illness wherever they reside.
I am here today as ASCP's representative. In addition, I am representing the Quality Care Coalition for Patients in Pain (QCCPP).

QCCPP is a multi-stakeholder, multi-disciplinary coalition of over 150 individual and organizational members representing physicians, pharmacists, nurse practitioners, directors of nursing and others who practice in long-term care. National non-profit associations that are active in QCCPP include but are not limited to:

- American Health Care Association (AHCA),
- American Association of Homes and Services for the Aging (AAHSA)
- National Hospice and Palliative Care Organization (NHPCO)
- American Pharmacists Association (APhA)

- National Community Pharmacists Association
- Hartford Institute for Geriatric Nursing
- National Association of Directors of Nursing Administration in Long Term Care
- National Alliance of State Pharmacy Associations
- The Senior Care Pharmacy Alliance
- The Long-term Care Pharmacy Alliance

Members also include state associations, and I am very pleased to report to the Chairman that both the Pharmacy Society of Wisconsin and the Wisconsin Directors of Nursing Council are active QCCPP members.

QCCPP was formed in September 2009 by ASCP in response to the Drug Enforcement Administration's (DEA) unprecedented enforcement activities that began in Ohio and continued in Wisconsin and Virginia last year. QCCPP seeks to ensure that nursing home and hospice patients in long-term care facilities have appropriate and timely access to pain medication by advocating to eliminate access barriers created by DEA rules and policies, and by promoting compliance and best practices by educating providers, prescribers, consumers and caregivers about appropriate prescribing and dispensing practices in long-term care.

My testimony today will focus on four key points:

1. How strict compliance with DEA rules delays patient access to needed controlled medications as revealed in the QCCPP nationwide survey of clinicians.
2. The conflicts between DEA rules and standards of practice in long-term care.
3. How ASCP and others have worked with DEA over many decades to try to resolve these conflicts.
4. Recommendations to move toward a more balanced regulatory approach which ensures that patients' needs come first but also recognizes the need for effective controls to reduce diversion risk.

1. The Impact on Patients: The Results of a Nationwide Survey of Clinicians

In the wake of DEA enforcement activity in Ohio, Wisconsin and Virginia last year, long-term care pharmacies began to implement practice changes to comply with the strict letter of DEA rules, regulations and new policy interpretations. Practice changes began in Ohio, where DEA activity has been most focused, but these changes are being adopted by long-term care pharmacies across the country, including states where we have no knowledge of DEA activity.

To better understand how and to what extent practice changes were affecting patient care, in Fall 2009, QCCPP surveyed nearly 900 long-term care doctors, nurses and pharmacists. The survey focused on pain management because of the prevalence of pain in post-acute and chronic patients in long-term care and patients

at end of life, and because many medications used to treat pain are controlled substances. Within the nursing facility setting, as many as 45 to 80 percent of patients have pain that contributes materially to functional impairment and decreased quality of life.[1]

Our report of our survey findings, entitled "Patients in Pain: How the US. Drug Enforcement Administration Rules Harm Patients in Nursing Facilities," is being released today in conjunction with this hearing. What we found confirmed our fears: DEA's recent activities in long-term care are compelling changes in practice that are significantly affecting the ability of doctors, nurses and pharmacists to provide timely and appropriate treatment to their patients when treatment with a controlled medication is indicated. Nationwide, 65% of clinicians reported that DEA's rules were causing delay, while in Ohio, 86% of respondents said treatment was being delayed. Reported delays in treatment varied in length. An astonishing 40% reported delays of up to one day, while another 40% reported delays of up to two days. Delays of two or more days were reported by 12 percent of these respondents.

While problems are occurring for patients at all points of care, our survey documented that the biggest challenges involve emergency situations—where time is of the essence and the need for the medication cannot be anticipated—and situations that involve transitions in care, where patients are either being admitted or readmitted to the nursing facility from a hospital or other care setting. Our survey also documented problems with timely dispensing and administration of new orders for existing patients, especially when needed after hours or on weekends and holidays.

Our survey captured reports of patients, newly admitted to the nursing facility following surgery, who could not get pain medication for hours even though it had been ordered by a physician and was available in the emergency box stored in the facility. Similarly, we have received several reports of patients having active seizures who could not be treated in the nursing facility with medication, that was ordered by the physician, which was available in the facility. One of these cases involved a 14-year-old in a long-term care facility. Because the patient could not be treated in the facility, the physician ordered the patient sent to the hospital.

Some of the most compelling reports from our survey concerned dying patients. One respondent in our survey identified 14 instances in which patients under hospice care in long-term care facilities waited 8 to 24 hours while efforts were made to obtain prescription orders in compliance with DEA policy. Numerous respondents discussed patients in the active phase of dying, who died in pain because controlled drugs could not be obtained on a timely basis.

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[1] Ferrell BA. Pain evaluation and management in the nursing home. ANN Intern Med 1995;123:681-87.

Our survey also documented that delays in treatment caused by changes in practice required by DEA rules are impeding post-surgical rehabilitation, delaying recovery, extending the need for skilled nursing care, and sending other patients back to the hospital for treatment and readmission. We are not only not providing unacceptable quality of care, we are increasing health care costs for consumers and taxpayers.

Finally, our survey shows that the physicians, nurses, pharmacists and other clinicians who care for our nation's chronically ill, frail and dying patients, are frustrated, angry and in some cases afraid. What DEA requires them to do places them squarely in conflict with their professional obligations, as well as state and federal licensure standards. We have a difficult enough time attracting qualified clinicians to practice in long-term care; it is now even more difficult to retain them.

QCCPP has continued to monitor patient care as long-term care pharmacies continue to implement practice changes needed to strictly comply with DEA rules and policies. Reports from nursing facility staff, physicians and long-term care pharmacies continue to document the difficulty of trying to comply strictly with DEA rules and meeting the needs of our patients.

2. The Conflict between DEA Rules and Policy and Long-term Care Practice Standards

An important question for the Committee members is: Why is this happening now? The simple answer is that DEA regulations for prescribing and dispensing of controlled drugs were originally created nearly 40 years ago and were written for outpatient care and retail dispensing. These regulations addressed the use of controlled medications in inpatient (hospital) and outpatient settings. Although modern long-term care facilities function much more like hospitals, DEA regulations place long-term care into the outpatient category, and apply retail dispensing rules rather than the inpatient rules.

These outpatient rules contemplate that a physician will see a patient in his or her office, and if a controlled medication is indicated, the physician will write out a prescription on a piece of paper, hand the prescription to the patient, and then the patient will hand-carry the prescription to a community or retail pharmacist for dispensing. DEA rules allow only a prescriber to issue a prescription.[2] However, the prescriber or the prescriber's agent may prepare, transmit and communicate prescription orders to the pharmacy,[3] and pharmacists are not permitted to dispense until the prescription order has been received.[4] In an emergency situation, DEA rules permit oral orders for Schedule II controlled substances (CIIs), but DEA

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[2] 21 CFR Section 1306.03(a).
[3] 21 CFR Sections 1306.03(b); 1306.05(a); 1306.11(a),(e)(f)&(g); 1306.
[4] 21 CFR Section 1306.11(a)

does not permit a pharmacist to dispense the drug until the doctor's oral authorization has been received in the pharmacy.[5] Within seven days after authorizing an oral emergency prescription, the prescriber must provide the pharmacy with a written prescription authorizing the emergency order. If the prescriber fails to do so, the pharmacist is required to notify the DEA.[6]

To accommodate patients in long-term care, hospice and patients receiving infusion services, DEA rules were amended to permit a prescriber to fax his or her prescription drug orders to the pharmacy.[7] Additional changes were made to allow physicians to write multiple prescriptions for Schedule II controlled drugs for a single patient[8] and to permit partial dispensing.[9] However, DEA still does not recognize the long-term care facility (LTCF) nurse as the agent of the prescriber and does not recognize chart orders. Thus, even with these accommodations, DEA rules are not appropriate for the nursing facility environment, particularly as it has evolved over time. In such facilities, not only are patients much sicker and often considerably less stable, but the practice standards and regulatory requirements dictate that nursing facilities operate more like a hospital and provide a higher level of patient care than would be found in an outpatient setting.

a. Clinical Realities of Patients in Nursing Facilities

At the time that DEA rules were originally written, nursing homes were largely small, independently operated homes that provided custodial care to older adults who needed some supervision and limited help with activities of daily living. Over the years, the role of nursing homes has changed. Today, long-term nursing home patients are older, sicker and significantly more fragile. In addition, due to changes in hospital reimbursement, many more patients are being discharged from hospitals and being admitted to nursing homes for post-acute care including skilled rehabilitation services. After a relatively brief hospital stay, these patients frequently arrive at the nursing facility with active, acute medical conditions in

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[5] 21 CFR Section 1306.11(d).
[6] 21 CFR Section 1306.11(d)(4).
[7] 21 CFR Section 1306.11(e),(f) & (g).
[8] 21 CFR Section 1306.12(b).
[9] 21 CFR Section 1306.13(b). Under the rules for partial filling of a prescription, a pharmacist can dispense multiple "partial" fills from a single prescription. The prescription is valid for 60 days. Although the rule permits a pharmacy to partial fill a prescription for a Schedule II controlled drug for a patient in a long-term care facility or for a patient with a terminal illness diagnosis, pharmacies run into obstacles when they try to bill for these partial fills. First, DEA requires pharmacies to use the same prescription number for each partial fill – this is in conflict with the uniform standards used for pharmacy claims processing. Second, within the uniform standards used for claims processing, there is no code that permits billing for partial fills as defined by DEA. Consequently, pharmacists report that their claims for partial fills are often rejected by payers.

somewhat unstable condition. These admissions can happen at any time of the day or night and often occur after hours. Finally, nursing facilities also provide hospice care. More than one-third of hospice patients die within seven days of admission to a nursing facility. Patients at end of life require frequent adjustments of medication dosage, frequency of administration, and product formulation.

Given the needs of this patient population, pain management is a significant focus of care. Over a quarter of all nursing home patients are receiving pain medication, and medications for pain management are the second most-commonly prescribed products.[10] Patients' illnesses often fluctuate and may worsen while they are being treated, or may recur after treatment is completed. Pain may be continuous or intermittent. Causes often cannot be resolved fully and therefore pain may continue. Other impairments may affect, or be affected by pain. Thus, pain management in the nursing home population is fluid, not static. Because of the combination of new acute conditions, exacerbations of chronic conditions, complications, and co-morbidities, nursing home patients may have frequent unpredictable episodes of pain, and may have acute worsening of pain despite receiving a treatment regimen that previously kept them stable. Often, multiple adjustments are needed frequently and repeatedly until a satisfactory regimen can be identified.

Recognizing the importance of pain management in the nursing facility setting, the Centers for Medicare and Medicaid Services (CMS) has issued surveyor guidelines that focus on how nursing facilities assess, monitor and treat pain. The survey protocol recognizes that because pain can significantly affect a person's well being, facilities must recognize pain and address it promptly.[11] If a facility fails to assess, monitor and treat a patient's pain promptly, it can be sanctioned for substandard quality of care.

b. Regulatory and Practice Standards in Long-Term Care

Pharmaceutical care within the nursing home environment is highly regulated. Pharmacists are licensed by states and must comply with both state and federal regulations governing the dispensing and storage of all medications. At the federal level, although CMS does not regulate pharmacists, CMS regulations governing pharmaceutical care in nursing facilities is extensive.

Under CMS regulations, nursing facilities must provide pharmaceutical services to

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[10] US. Department of Health and Human Services, Prescription Drug Spending by Medicare beneficiaries in Institutional and Residential Settings, 1998-2001; June 2007.
http://aspe.hhs.gov/daltcp/reports/2007/pdspend.htm

[11] CMS Manual System, Pub. 100-07 State Operations Provider Certification, Transmittal 41, April 10, 2009, DETERMINATION OF COMPLIANCE WITH F309 FOR PAIN MANAGEMENT (Task 6, Appendix P). Online at
http://www.cms.hhs.gov/transmittals/downloads/R41SOMA.pdf

meet the patients' routine and emergency needs.[12] The provision of pharmaceutical services includes assurances of accuracy in acquiring, receiving, dispensing, and administering of medications and biologicals for each patient.[13]

Long-term care pharmacists, such as myself, work with nursing facilities to design and implement systems to help ensure that regulatory standards are met within the realities of our practice setting. Federal regulations explicitly mandate that every patient's medical care must be supervised by a physician.[14] Physicians must participate in all aspects of the patient's care, including monitoring changes in the patient's medical status and providing consultation or treatment when called by the facility. However, most physicians who practice in long-term care do not maintain a full-time presence in a single long-term care facility. Recognizing that a patient's physician will not be onsite on a full-time basis, federal regulations require that nursing facilities must promptly notify a patient's attending physician of significant changes in their condition, of the need for alterations to treatment, as well as the results of laboratory, radiological and other diagnostic test findings.[15] The purpose of these regulations is to ensure that the patient's physician is notified regarding all changes in a patient's condition so that prompt, appropriate action may be taken if indicated for the patient's care.[16]

Long-term care facility nurses play a pivotal role in ensuring that physicians are notified of their patients' needs. Thus, at admission as well as when there are changes in a patient's condition, it is the licensed LTCF nurse who is responsible for communicating vital information to the physician so he or she can make an appropriate treatment decision. The LTCF nurse also is legally and professionally responsible for documenting the physician's treatment orders in the patient's medical record, ensuring that those orders are implemented and that the patient's response to treatment is monitored and documented.

Often, physicians' treatment orders involve medications. Physicians may start a new medication, discontinue a current medication, or change a dose. Within our practice setting, the standard of practice is similar to a hospital setting. Nurses receive orders from physicians and then document them on the patient's chart, usually on a special triplicate form that allows the nurse to transmit a copy to the pharmacy by facsimile. These faxed forms are called chart orders. As a general rule, physicians do not specify a quantity on chart orders because, as in hospitals, the order needs to be filled in compliance with the facility's approved drug delivery

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[12] 42 CFR 483.60.
[13] 42 CFR 483.60(a).
[14] 42 CFR 483.40(a)(1).
[15] 42 CFR Section 483.10(b)(11).(See also 42 CFR Section 483.75(J)(2)(ii) and (k)(2)(i) and (ii) regarding labs and diagnostic tests).
[16] CMS Interpretative Guidelines for Surveyors at F505, F511. Online at http://cms.hhs.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf

system and approved policy and procedures.

When chart orders are received in a long-term care pharmacy, the pharmacy processes them and dispenses the medication as ordered by the physician. Once delivered to the facility, the LTCF nurse ensures that that the medications are properly stored, handled, and accurately administered to the patient as per the physician's orders.

To ensure that nursing facilities have access to emergency medications as required by federal regulations, long-term care pharmacies typically provide nursing facilities with a limited number of medications such as analgesics (including controlled drugs) and antibiotics in what are termed "contingency" or "emergency" kits. The use of emergency kits also is governed by state law and regulation. In some states, such as my own, we actually transfer the drugs to the facility in accordance with state law via DEA Form 222, but in most states, the drugs in the e-kit remain the inventory of the pharmacy. In an emergency situation, the presence of a small supply of emergency drugs in the facility allows the nurse, upon receipt of the physician's oral orders to access the medication and administer to the patient without delay.

Long-term care pharmacies also work with facilities to ensure that medication ordering is accurate and timely. For example, to avoid a patient running out of needed maintenance drugs, pharmacies have systems that help the facilities to track when a prescription needs to be refilled. To improve efficiency and accuracy, we routinely complete prescription templates containing the patient's name, the medication, and directions for use, and send these to the patient's treating physicians by fax. The physicians review these forms, complete them, sign them and send them back to the pharmacy by fax. This helps the facility to avoid situations where the patient has to go without medication or where medications need to be ordered on an emergency or stat basis. Increased standardization of process also reduces medical errors and can reduce costs.

In addition to the vendor pharmacist, nursing facilities are required by CMS regulation to employ or obtain the services of a licensed pharmacist to provide consultation services on all aspects of the provision of pharmacy services in the facility. At least once per month, the consultant pharmacist must perform a drug regimen review (DRR) for each patient. The pharmacist must report any irregularities to the attending physician or director of nursing. Furthermore, these reports must be acted upon. The consultant pharmacist review is an additional check to ensure that patients are only receiving medications for which there is an appropriate medical indication for use.[17]

With respect to controlled substances in long-term care facilities, CMS regulations require that every facility have a system to account for the receipt, usage,

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[17] 42 CFR 483.60(b); CMS Interpretative Guidelines for Surveyors at F425.

disposition and reconciliation of controlled medication. Reconciliation must be done periodically and when loss is identified, in accordance with state law. In addition, CMS regulations and survey guidance require that Schedule II medications and other medications subject to abuse be maintained in separately locked, permanently affixed compartments. The access system used to lock Schedule II medications and other medications subject to abuse cannot be same access system used to obtain the non-scheduled medications and the facility must have a system to limit who has security access and when access is used. Thus, Schedule II drugs such as morphine and oxycodone are usually double-locked, with a locked narcotic drawer inside a locked medication cart or locked medication room. All controlled drugs are counted and reconciled at every shift change by two nurses, the oncoming and the exiting nurse; and the count and reconciliation are recorded and maintained as part of the facility's record keeping system. We also have procedures in place to document the use of controlled medications from the emergency drug kit, which is also locked and can be accessed only by authorized staff. Pharmacists and facilities continuously work together to detect tampering and to improve diversion monitoring and detection.

c. Conflict Between Long-term Care Practice Standards and DEA Rules

As noted above, in nursing facilities, it is the "standard of practice" for the LTCF nurse to act as the physician's agent by taking his or her verbal orders, documenting them in the patient's record as a "chart order," and then transmitting the chart orders to the pharmacy either by fax or by telephone. Nurses, pharmacists and physicians are all trained in these standard procedures.

Under DEA rules, however, a chart order is not a valid prescription for a controlled drug because it generally lacks the prescriber's signature upon issuance and does not include a quantity, both required elements. In the past, DEA allowed us to accept the faxed chart order, provided we obtained a valid written prescription order from the prescriber before dispensing the drugs. We accomplished this by taking the faxed chart order and, as we do for refills, populating a pre-printed form with the name of the drug, patient's name and directions for use; we then faxed the form to the prescriber with a request to review, complete and sign it and fax it back to the pharmacy. We used this same process for CII prescriptions for patients being transferred from the hospital to the nursing home. This process helped ensure that the physician's verbal orders to the facility nurse, which are transcribed in and become part of the clinical record, are accurately recorded and reflected in the subsequent documentation that is maintained in the pharmacy.[18]

Today, however, DEA is no longer allowing us to pre-populate fax-back forms that enable the pharmacy to prompt the prescriber to return a valid prescription order

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[18] An example of a pre-printed form used in my pharmacy, is attached as Appendix A.

to the pharmacy. Instead, DEA has indicated that only the physician can generate the actual paper prescription.

The issue with chart orders is closely tied to a second issue, which concerns DEA's interpretation of who can be the agent of the prescriber. As noted previously, DEA rules state that only an authorized individual prescriber can issue a prescription for a controlled drug but a prescriber or his or her agent can prepare the prescription and transmit or communicate the prescription to the pharmacy. The Controlled Substances Act defines "agent" broadly as, "an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser . . ."[19,20] DEA has stated that the prescriber's secretary, who is not a trained clinician, can be the prescriber's agent. However, DEA does not recognize the nurse in the long-term care facility as the agent of the prescriber even though the nurse is required by regulation and professional standards of practice to take, document, and implement the prescriber's orders.

The first and only time that DEA's interpretation that the LTCF nurse cannot be a prescriber's agent appeared in writing was in a 2001 Federal Register Notice to solicit information on "Preventing the Accumulation of Surplus Controlled Substances in Long-Term Care Facilities."[22] In a section of the Notice entitled, "How Would the Use of Automated Dispensing System Address this Circumstance?" DEA suggested that it was inappropriate for nurses to communicate physician's orders to the pharmacy, and recommended instead that nurses communicate patients' health care needs directly to pharmacists who could then communicate the information to the physician. The physician could then give his treatment orders to the pharmacy and in turn, the pharmacy could communicate them back to the nursing facility.[23]

ASCP and others responded to this Federal Register Solicitation with written comments, pointing out significant problems with DEA's suggested approach. Among other problems is the fact that the pharmacist would not be in a position to answer any of the physician's questions regarding the patient's health care needs and has no access to the patient's chart. Following the receipt of comments to the solicitation, doctors continued to communicate their orders to LTCF nurses, and LTCF nurses continued to prepare and transmit those orders to pharmacists according to LTC standards of practice.

To our knowledge, DEA never moved to finalize or formalize a policy on this issue and never published a policy statement in any DEA or government publication. For example, DEA published two practice manuals, one for pharmacists and one for

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[19] Controlled Substances Act, Sec. 802.
[20] DEA Practitioner's Manual, 2006 Ed., Page18, available online at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf
[22] 66 Fed. Reg. 20833-34 (April 25, 2001).
[23] 66 Fed. Reg. 20833-34 (April 25, 2001).

practitioners, in 2004 and 2006 respectively. These manuals are supposed to provide comprehensive and definitive guidance on prescribing and dispensing of controlled drugs. Yet, in neither manual did DEA discuss the status of LTCF nurses or suggest that a physician could not rely on an LTCF nurse to transmit a prescription to the pharmacy.[24] Even in 2009, after DEA began to enforce this policy, DEA declined our request to send a letter to all registrants explaining that a physician could no longer rely on an LTCF nurse to prepare and transmit his prescription order to the long term care pharmacy. Within the past month, however, DEA did inform nurses in Ohio that "nurses working in long-term care facilities cannot legally fax or 'call in' a chart order for scheduled drugs. This is viewed as 'prescribing' without DEA authorization and could subject them to prosecution under the Controlled Substances Act."[25]

DEA's recent articulation of a more restrictive interpretation is creating enormous challenges for physicians, nurses and pharmacists and has made our long-standing systems designed to facilitate accurate, efficient and timely dispensing and administration of medications to nursing home and hospice patients in long term care, irrelevant. For example, for new admissions, nursing facilities can no longer utilize the discharge summaries sent to them by hospitals that contain the patient's medication orders from the hospital as a basis for initiating therapies, even when they have been approved by the admitting physician. Instead, nursing facility staff and long-term care pharmacies have to try to secure written, paper prescriptions from the hospital. This is not easy. Some hospitals believe that it is not appropriate to transfer a patient from a hospital to a nursing home with paper prescriptions. In Wisconsin, a pharmacist had to prevail upon a local hospital to reprogram its computers to override a code that actually prohibited the creation of paper prescriptions for patients being transferred from the hospital to long-term care facilities.

Once the nursing home receives the patient and the written paper prescriptions, the nursing home still has to ensure that the orders get written into the patient's chart and that they are communicated to the pharmacy. However, if the nurse is not the agent of the prescriber and cannot legally transmit the orders, who can? Without any guidance from DEA, we advised our members that the best way to meet DEA's legal requirements would be to have the nurses transmit the patient's chart orders to the pharmacy to allow the pharmacy to prepare the medications for delivery to the home. Then, upon delivery, the pharmacy could swap out the medications for the actual paper prescriptions. Yet, even this process is questionable given DEA's recent communication to Ohio nurses. If the only way for the pharmacy to obtain a legal prescription for a controlled substance is to wait until a physician is able to send a fax to the pharmacy, patients will simply have to wait longer to get their medications, and unfortunately some will die before medication arrives.

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[24] http://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html.
[25] "Are You in Compliance with Federal Prescription Law requirements Applicable to Long-term Care facilities?" Memorandum. Attached as Appendix B.

Emergency situations remain extremely challenging. In emergency situations, where time is of the essence, under DEA rules long- term care nurses are not permitted to access medications stored in the nursing facility in the pharmacy's emergency drug box based solely on a physician's order. Rather, DEA agents have made clear that an emergency dose cannot be accessed until (1) the physician has personally contacted the pharmacy and given the pharmacist a valid oral authorization *and* (2) the LTCF nurse has called the pharmacy and confirmed the receipt of the physician's verbal authorization. Even when all parties are acting in good faith to make these calls, delay is inevitable and in many cases, significant. Further, DEA has told nurses that if they remove a controlled drug from the E-box to treat a patient based on the doctor's order but before the physician has contacted the pharmacy, the nurse can be prosecuted for diversion.

4. Efforts to Work Collaboratively with DEA to Resolve these Long-standing Issues

It is important for Committee members to understand that the issues being discussed today are not new. ASCP, as well as other pharmacist and physician organizations, and the National Association of Boards of Pharmacy have been engaged in a decades-long dialogue with DEA regarding the acknowledged poor fit between DEA outpatient rules and the clinical, operational and practice realities of prescribing and dispensing medications to patients in long term care facilities. As early as 1974, the DEA's Chief Compliance Officer, Kenneth A. Durrin, in a letter to ASCP's former legal counsel, Arnold S. Goldstein, dated June 25, 1974 wrote:

> I have long felt that the existing regulations do not adequately speak to the nursing home situation and members of my staff are presently reviewing the applicable regulations to see if we can arrive at a practical solution which does not sacrifice necessary control.
>
> Your offer of assistance from the American Society of Consultant Pharmacists is most welcome and you can expect to hear from us shortly concerning our review of the regulations in this area . . . .[26]

More than two decades later, DEA's leadership continued to acknowledge that the existing regulatory framework was ill-suited to the needs of patients in long-term care. In a March 8, 1996 letter to ASCP's former Executive Director, Tim Webster, DEA's Chief of the Liaison and Policy Section, S. Thomas Gitchel, wrote that DEA "remains committed to working with the American Society of Consultant Pharmacists (ASCP) to identify measures that can be taken to facilitate the provision of controlled substance medications to patients in Long Term Care Facilities

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[26] Letter from Kenneth A. Durrin, Chief, Compliance Investigations Division, U.S. Drug Enforcement Administration to Arnold S. Goldstein, June 26, 1974. Attached as Appendix C.

(LTCF)." After noting positive changes intended to alleviate some of the identified problems, Mr. Gitchel wrote:

> "We realize that there are still some long-standing issues of concern and it is clear that the drafters of the Controlled Substances Act (CSA) did not envision the evolution of the practice of pharmacy and medical care to what it has become today. As you know, we have been unable to resolve some of these issues because it is DEA's opinion that to do so would require a change in the CSA [Controlled Substances Act]."[27]

I became personally involved in discussions with DEA in 2001 when I assumed leadership of ASCP's DEA Task Force. At a meeting on November 13, 2002, DEA employee Vickie Seeger told the Task Force that the DEA has "new staff attorneys that are re-evaluating the 2001 DEA interpretation that an LTC nurse cannot serve as the agent of the physician." Subsequently, in a meeting, on March 23, 2003, DEA staff encouraged ASCP to work with the State Boards of Pharmacy to secure recognition of "chart orders" as valid prescription orders and to "recognize nurses as the agents of the physician."

Accordingly, ASCP and the National Association of Boards of Pharmacy (NABP) created a Joint Task Force to revise the NABP Model State Pharmacy Practice Act to include specific rules for long-term care pharmacy. NABP and ASCP issued a joint report that, among other things, recommended the recognition of chart orders as valid prescription orders in institutional settings and clarifying that an agency relationship between a prescriber and a staff nurse can exist, in compliance with state law, at an institutional facility, provided that the agent is authorized by facility policies and procedures.[28]

NABP voted to approve these changes at its May 2006 meeting. NABP's resolution seeking recognition of the nurse as agents of the prescriber in long-term care facilities is very informative. Among other things, NABP notes that the issue of legal agency is not limited to long-term care facilities but is also found in hospice and other alternate care sites. Second, NABP notes that DEA's interpretation, as it presently exists, creates barriers to quality and timely patient care by requiring multiple contacts among prescribers, LTCF and alternate care site nurses and pharmacists with regards to controlled substance medications. NABP also

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[27] Letter to R. Tim Webster, Executive Director, American Society of Consultant Pharmacists from G. Thomas Gitchel, Chief Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, March 8, 1996. Attached as Appendix D.

[28] NABP/ASCP Joint Report: Model Rules for Long-Term Care Pharmacy Practice at 6, online at http://www.ascp.com/advocacy/state/upload/JointReportMarch2607.pdf

requested DEA's assistance in clarifying the basis for its interpretation that no legal agency relationship exists between the LTCF nurse and a physician. [29]

NAPB's Model State Pharmacy Practice Act and Model Rules (Model Rules), as amended, help to guide us toward a resolution of these long standing issues. First, the Model Rules clearly define "institutional facility" to include long-term care facilities, nursing homes, developmental disability centers, hospices and other institutions in addition to hospitals. [30] The Model Rules also provide a useful definition of "chart order." Specifically, chart order is defined as:

> A lawful order entered on the chart or a medical record of an inpatient or patient of an Institutional Facility by a Practitioner or his or her designated agent for a Drug or Device and shall be considered a Prescription Drug Order provided that it contains:
>
> (1) the full name of the patient
> (2) Date of Issuance
> (3) Name, strength and dosage form of the Drug prescribed
> (4) Directions for use; and
> (5) If written, the prescribing Practitioner's signature *or the signature of the Practitioner's agent* (including the name of the prescribing Practitioner); or if electronically submitted, the prescribing practitioner's electronic or digital signature.[31]

There are a number of states that have adopted regulations based upon the NABP Model Rules. For example, the Arkansas Board of Pharmacy recently reaffirmed its interpretation of Regulation 7 in the Arkansas State Board of Pharmacy Law Book. Regulation 7 has been a part of the Arkansas pharmacy law as written for a number of years. It includes language that specifically recognizes nurses as agents of the prescribing physician where designated by the physician and the long-term care facility when prescribing scheduled drugs.[32]

In New York, in an emergency situation, an oral order from the authorized practitioner is sufficient to enable a nurse in a long-term care facility to administer medication to a patient. New York requires that the practitioner's oral order be reduced to writing and that the underlying need for an emergency order be documented. Further, the practitioner must sign the order noted in the patients

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[29] Letter from Carmen Catizone, MS, RPh, DPh, Executive Director, National Association of Boards of Pharmacy to Mark Caverly, Chief Liaison and Policy Section, Drug Enforcement Agency, dated September 8, 2006. Attached as Appendix E.
[30] Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy, August 2009, Section 105(ttt). Online at http://www.nabp.net
[31] Id. at Section 105(t).
[32] Arkansas Regulation 7 - Drug Product Prescriptions, online at: http://www.arkansas.gov/asbp/pdf/lawbook/REGULATION_07_July_2009_Final.pdf

chart within 48 hours.[33] However, notably, it is the institutional dispenser who has 24 hours to notify the pharmacy each time the emergency kit is unsealed, opened or shows evidence of tampering. This system ensures that patients are treated first!

In 2008, ASCP attempted to rekindle its dialogue with DEA leadership. In a meeting that I attended on July 24, 2008, ASCP presented DEA staff with a memorandum which once again outlined our requested policy changes.[34] We had a very respectful and productive discussion of issues. We left that meeting understanding that DEA was actively considering formal policy changes and that DEA understood the patient care implications of the continued disconnect between DEA rules and our practice setting. Throughout 2008, our communication with DEA indicated that they were still actively considering our policy changes.

When reports surfaced in 2009 of DEA raids in Cleveland, Claudia Schlosberg, ASCP Director of Policy and Advocacy, Ginny Roberts, another long-time ASCP member, and I again sat down with DEA. Our meeting was held on April 7, 2009. We needed to understand why after so many years, DEA was suddenly strictly enforcing its regulations and a policy interpretation that had never been formalized or communicated to its registrants. We discussed at length DEA's interpretation that the LTCF nurse could not be the agent of the prescriber. DEA's Mark Caverly explained that absent "a direct employment relationship" there could be no agency relationship between a physician and an LTCF nurse. We asked for clarification. For example, could an LTCF nurse be the agent of the Medical Director if they both worked for the same facility? We were told, "No – there must be a direct employment relationship."

We also needed DEA to understand that most physicians see the nurse as their agent and that they would not know that DEA took a contrary view absent written notice. We asked DEA to draft and send a "Dear Registrant" letter, explaining its policy and providing guidance regarding how prescriptions would need to be written and transmitted to pharmacies. We also explained that strict compliance with DEA outpatient rules would result in delays in patient treatment. We asked DEA to allow us flexibility on the Schedule III-V drugs. Mark Caverly agreed to issue the Dear Registrant letter and also asked us to give the agency 90 days to consider our request for flexibility on the Schedule III-V drugs before we informed the industry of needed practice changes. We agreed to reconvene in 90 days to further discuss the issues and to hear DEA's response. However, no further meeting was scheduled. In late May, DEA informed us that they would not be able to meet with us. While they did finally issue a Dear Registrant letter, it said nothing about the nurse as agent issue. Furthermore it gave no clue to prescribers that standards of practice and

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[33] New York Codes, Rules & Regulations, sections 80.46 and 80.75.

[34] ASCP Memorandum, "Nurse as Agent and Chart Orders," submitted to the U.S. Drug Enforcement Administration, July 24, 2008. Online at http://www.ascp.com/advocacy/federal/upload/DEA_Chart_Orders_Fact_Sheet.pdf

operation for long-term care prescribing and dispensing, standards that have been in place for decades, were about to change dramatically.

Since Summer 2009, ASCP and the QCCPP have worked hard to educate our members regarding the rules for prescribing and dispensing in long-term care and DEA's new interpretations. Promoting compliance has been difficult. We have held seminars, written reference guides, and we have even produced a training video for nurses. We are urging our members to comply with DEA mandates, but in doing so, as documented by our survey, we are not serving our patients. Doctors, nurses and pharmacists are understandably reluctant to adopt these new practices and processes that not only increase burden, but lead to patient harm. Further, we have identified many issues that we are unable to clarify without further guidance from DEA. In the past year, we have asked DEA to respond to a number of questions that have come directly from our membership. We are still waiting for answers.[35]

Conclusion and Recommendations

As a certified geriatric pharmacist who has spent my career trying to promote clinical excellence and operational efficiencies in pharmaceutical care to our nation's frail elderly and those at end of life, I am extremely concerned about the consequences of DEA's unwillingness to make policy changes that would accommodate our practice setting. We are going backwards in time. In my own pharmacy, for example, we are now dealing with a proliferation of paper prescriptions. We are also dealing with multiple copies of prescriptions that are all for the same order. DEA has deemed illegal the systems we developed and put in place to prompt physicians to issue timely reorders, to provide written authorizations for oral emergency orders, and to ensure that the nursing facility's records and doctor's orders are consistent and reconciled. For emergency situations, my company has made significant investment in automated dispensing technology that is housed in the nursing facility. These machines provide extra security and provide a compete record of all transactions. Yet, even with these extra safeguards, the patients served in these facilities still experience delays in getting medications because DEA still insists that a valid prescription drug order be presented at my pharmacy and be validated by the facility before the patient is treated. DEA rules force us to abandon our systems and rely on the record keeping and administrative capabilities of individual physicians. The notion that every physician who practices in long-term care, even if they are only seeing one patient, can replicate these systems within their own practice and still have time to treat patients makes little sense. What we are doing is creating dangerous and costly possibilities for additional errors in medication prescribing and dispensing.

There is consensus within the medical, nursing and pharmacy professions that the status quo is not acceptable or sustainable. We cannot allow frail, chronically ill and dying patients who have legitimate needs for controlled medications to wait and

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[35] A list of questions that ASCP has sent to DEA is attached as Appendix F.

suffer without relief. We are seeing too many cases where delays in treatment are occurring because of the difficulty of completing communications and documentation in advance of treatment. While we are extremely sensitive to the need to reduce diversion risk, we do not see these new required procedures as reducing the kind of diversion risk that we find in our facilities and pharmacies. Quite the contrary, we are seeing an increase in paper prescriptions, duplicate prescriptions and prescription orders that contain errors or deviate from the orders documented in the patient's chart. Most importantly, patients are not getting treatment and are suffering unnecessarily. This must end.

Accordingly, ASCP and the QCCPP make the following recommendations:

1. DEA must update its rules and policies for prescribing and dispensing controlled drugs to reflect the practice standards of nursing home and hospice patients in long term care facilities. We welcome the opportunity to work with them to help them develop rules that are address the needs of our patients while maintaining the level of control over controlled substances that DEA expects and requires.
2. To alleviate patient suffering now, an interim solution is needed immediately. Under federal regulations at 21 CFR 1306.11 a prescription may be communicated to the pharmacy by the practitioner's agent or employee. DEA has the authority now under this regulation to clarify that an LTCF nurse is the agent of the prescriber and may communicate oral orders to the pharmacy that have been issued by the prescribing practitioner for CIII-V drugs and for emergency orders for Schedule II medications. In the case of prescriptions for Schedule IIs, in an emergency situation, the physician's compliance with the requirement that he or she provide the pharmacy with a written, valid prescription order within seven days provides the necessary legal documentation to establish that the prescription was issued for a legitimate medical purpose. DEA should issue new policy in writing and post it on the DEA website. This proposal meets DEA's concerns, but also ensures that patients' needs are addressed first.
3. If DEA or the Administration does not act, we call upon Congress to enact the "Long-term Care Patients' Access to Medically Necessary Controlled Substances Act." This draft legislation would require DEA to recognize the LTCF nurse as an agent of the prescriber, recognize chart orders as valid legal prescriptions for controlled drugs and allow pharmacists to assist practitioners to issue and complete valid prescription drug orders in a timely manner.

Thank you Chairman Kohl and members of the Committee for your commitment to our nation's senior citizens and your interest in helping us resolve these issues.

APPENDIX A

Ross Brickley Testimony Before Senate Special Aging Committee, 3/24/10

Pharmacy
Phone: (866)
Fax: (866)

Dear Doctor: [redacted] Today's Date: 03/20/2010

We have received a request for a "Schedule II" medication for your patient as indicated below. Federal regulations now allow us to accept facsimile copies of your order as authorization to fill a C-II medication in a long term care facility. If it agrees with your intended order, please complete any missing information, sign the form and fax it back to us as quickly as possible (please do not fax to the long term care facility). If you have any questions, please do not hesitate to contact one of our pharmacists at:

(866)999-7962

Per D.E.A. regulations, the faxed copy must be received in the pharmacy before the Schedule II medication may be dispensed.

For a defined "emergency" situation, we are permitted to dispense an emergency supply with verbal authorization, but it must be followed-up with a separate prescription. Therefore, you may receive two separate prescriptions with different quantities.

LONG-TERM CARE PRESCRIPTION

Patient Name: [redacted] Facility: [redacted] New Rx #_____

Patient DOB: Medication: KADIAN CAP 20MG CR

Quantity: 30

Sig: 1 BY MOUTH EVERY MORNING *DO NOT CRUSH*

Physician Name: D.E.A. #:

Address: Fax Number:

City: State: NC Phone Number:

Zip:

Physician Signature: _____ **Date:** _____

PLEASE SIGN & FAX DIRECTLY TO THE PHARMACY AT: (866

CONFIDENTIALITY NOTICE: The information contained in this facsimile message is intended only for the use of the individual(s) or entity(s) to which it is addressed and may contain information that is confidential and/or legally privileged under state and federal law. If you are not the intended recipient of this facsimile message or an agent or employee responsible for delivering it to the intended recipient, you are hereby notified that any unauthorized dissemination or copying of the information contained therein is strictly prohibited. If you have received this communication in error, please notify the sender. Do not deliver, distribute, or copy this message, and do not disclose its contents or take action in reliance of the information it contains. Thank you.

APPENDIX B

Ross Brickley Testimony Before Senate Special Aging Committee, 3/24/10

Are You in Compliance with Federal Prescription Law Requirements Applicable to Long-Term Care Facilities?

In the past year, the United States Department of Justice, Drug Enforcement Administration (DEA) has advised the Board of Nursing that it has uncovered multiple situations in which licensed nurses are signing prescriptions/chart orders for scheduled drugs, in long-term care facilities, on behalf of physicians, and transmitting these prescriptions/chart orders to pharmacies. Under federal law schedule II-IV medication prescriptions, applicable to chart orders are not allowed, and prescriptions must be completed in a specific manner in order to be legally valid. The prescription must be *prepared and signed* by a physician. 21 CFR 1306.05 (schedule II); 21 CFR 1306.21 (schedules III-IV). For this purpose, a nurse employed by a nursing home or other long-term care facility, who is not employed by the physician, is not viewed by the DEA as being the agent of the physician. Thus, the nurse cannot legally sign and transmit a chart order and/or a prescription to a pharmacy. See 21 USC 802(3).

The DEA has made clear that nurses working in long-term care facilities cannot legally fax or "call in" a chart order for scheduled drugs. This is viewed as "prescribing" without DEA authorization. A nurse who prescribes a controlled substance could be charged under Title 21, USC Section 841(a)(1), which states, "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally (1) to manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance."

If you have questions regarding federal prescribing law, you may contact the DEA Cleveland Office, 310 Lakeside, N.W., Suite 395, Cleveland, Ohio 44113, Telephone: (216) 274-3600. *

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DRUG ENFORCEMENT ADMINISTRATION
Washington, D.C. 20537

APPENDIX C

Ross Brickley Testimony Before Senate Special Aging Committee, 3/24/10

JUN 26 1974

Mr. Arnold S. Goldstein
Law Offices
262 Washington Street
Boston, Massachusetts 02108

Dear Mr. Goldstein:

This is in response to your letter of June 1, 1974 requesting that DEA consider regulatory changes to accommodate the dispensing of Schedule II controlled substances for nursing home patients.

I have long felt that the existing regulations do not adequately speak to the nursing home situation and members of my staff are presently reviewing the applicable regulations to see if we can arrive at a practical solution which does not sacrifice necessary control.

Your offer of assistance from the American Society of Consultant Pharmacists is most welcome and you can expect to hear from us shortly concerning our review of the regulations in this area. Thank you for your interest in this matter.

Sincerely,

Kenneth A. Durrin

Kenneth A. Durrin, Chief
Compliance Investigations Division

U.S. Department of Justice

Drug Enforcement Administration

APPENDIX D

Ross Brickley Testimony Before Senate Special Aging Committee, 3/24/10

Washington, D.C. 20537

MAR 0 8 1996

Mr. B. Timothy Webster
Executive Director
American Society of Consultant
Pharmacists
1321 Duke Street
Alexandria, Virginia 22314-3563

Dear Mr. Webster:

The Drug Enforcement Administration (DEA) remains committed to working with the American Society of Consultant Pharmacists (ASCP) to identify measures that can be taken to facilitate the provision of controlled substance medications to patients in Long Term Care Facilities (LTCF). We feel that the regulations permitting partial filling of prescriptions for Schedule II controlled substances and the filling of such prescriptions pursuant to a prescription transmitted by facsimile should have alleviated many of the concerns of Consultant Pharmacists, and, in fact, we have received positive feedback from many of your members. We realize that there are still some long-standing issues of concern, and it is clear that the drafters of the Controlled Substances Act (CSA) did not envision the evolution of the practice of pharmacy and medical care to what it has become today. As you know, we have been unable to resolve some of these issues because it is DEA's opinion that to do so would require a change in the CSA. On several occasions, I have asked Consultant Pharmacists to provide us with possible solutions to this dilemma, but I find them to be at a similar impasse.

I think that it would be productive to spend a day discussing the issues that your members feel are most pressing and to try to come up with some viable solutions. I believe that we may be able to resolve some of the issues through regulatory changes, but before we attempt to do so, we need to be better informed about the practice of Consultant Pharmacy as it relates to LTCFs. I would like to invite you, as well as four or five Consultant Pharmacists selected by you and appropriate members of your staff to participate in this meeting. In addition, DEA will invite several representatives from associations representing LTCFs to attend. I would suggest that the meeting be held in the vicinity of DEA Headquarters in late Spring or or early Summer, so that we have sufficient time to identify participants and issues to be discussed.

I look forward to your response to this proposal and to continuing to work with ASCP on matters of mutual concern.

Sincerely,

G. Thomas Gibchel, Chief
Liaison and Policy Section

APPENDIX F

Ross Brickley Testimony Before Senate Special Aging Committee, 3/24/10

Questions To The Drug Enforcement Agency that Remain Unanswered

1. Can a pharmacist prepare a prescription drug order on a fax back form based on a chart order faxed by a nurse who took the verbal order from the physician or based upon a physician's verbal order called into the pharmacy - and then fax it to the prescriber for review and signature? It is important to understand that the chart order that is received (or verbal order from the physician) is the "order of the prescriber" and that the pharmacist is merely committing it to writing so that physician can review and sign it.
2. The federal register and pharmacy manual defines long term care as a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients. Is assisted living covered in this definition?
3. If a valid, written, signed prescription for controlled drugs is sent with the patient from the hospital to the nursing home, can the nurse in the nursing home fax those prescriptions to the LTC pharmacy and can the pharmacy dispense based upon those prescriptions? If not, why not? How should these paper prescriptions be transmitted to the pharmacy?
4. Can a LTC nurse in a nursing facility be the agent of the Medical Director of that nursing home? If the Medical Director is out of the facility (EG after hours), and receives a call from the facility nurse - can the nurse transcribe and fax medication orders from that physician/medical director - since they are both employed by and working for the same entity?
5. If a large medical practice in the community is organized as a professional corporation, and all the doctors and nurses work for the corporation, can the nurses in this practice act as agents of the doctors even though there is no direct employment relationship between the physician and the nurse. Are nurses employed by an HMO (e.g. Kaiser), permitted to serve as agents of the physicians who work for the HMO? If so, why can't a nurse in the nursing facility be the agent of the facility's medical director?
6. Can a physician enter into a specific, written agreement with the facility to establish an agency relationship between the physician and the facility nurses?
7. Can a physician enter into an employment relationship with a nurse in a nursing facility and pay the nurse to be his agent? What does DEA require to demonstrate a direct employment relationship?
8. What changes can a pharmacist make to prescription order for a controlled drug? Can a pharmacist correct or add an element to the prescription drug order, such as a quantity limit, if the pharmacist is able to confirm the information with the physician by telephone. For example, the pharmacist may note a mistake with respect to dosing or identify another safety issue - may the pharmacist, after confirming with the physician, make a change to the prescription drug order as long as it is properly documented?
9. In an emergency situation, must a nurse call the pharmacy to confirm that a drug order has been received by the pharmacy before pulling the drug from

the e-kit if she has already received a direct verbal order from the doctor to administer the medication? If so, what is the authority for requiring the nurse to do this? (DEA has no jurisdiction over facilities and nurses).

10. Can pharmacies accept after hours, oral orders from practitioners for CIII-Vs using a voicemail system or must the practitioner always speak "in person" with the pharmacist.
11. What authority allows DEA to register nursing facilities?
12. If a nursing facility is registered, will DEA allow the pharmacy to dispense based upon an order (rather than a prescription)? If not, why not? Why is this allowed in hospitals and not nursing homes?

The CHAIRMAN. Thank you very much, Mr. Brickley.

You've all been fairly clear and consistent in your expressions of the problem, as you see it.

Hospital nurses may accept verbal orders from physicians for administration of controlled substances, but nursing home nurses may not, according to the DEA. Do you believe the DEA is making a reasonable distinction between these care settings? If you don't believe so, explain, maybe again, why not.

Would you like to try, Mr. Schanke, and then we'll move on?

Mr. SCHANKE. In terms of the distinction, I don't see one. We have RNs with the same education and background and, many times, the same experience, whether in a hospital or in a nursing home. In the nursing home, my RNs are able to accept verbal orders for execution of treatment on any number of items. Why we're segregating, now, this scheduled medication specifically, it doesn't make sense to me, from a purely process standpoint.

The CHAIRMAN. Yes. Now, some of you may know precisely how this thing is working out across the country. This has not always been the case. This is, what, a new DEA activity, is that right, Dr. Phillips?

Dr. PHILLIPS. Actually, I would offer—this has been an intermittent activity. Back—I remember having 2-o'clock-in-the-morning struggles with dispensing pharmacies, back 2001, 2002, in Northern California. It was typically pharmacies who either had had pushback from the DEA or who were particularly focused on this interpretation. So, prior to, I would say, in the last year or two, it has been spotty enforcement and spotty action, and you might have one pharmacy in one county not paying attention to this DEA interpretation, where another county and different pharmacy would, which also made it very chaotic for physicians and other practitioners in the long-term care environment.

So, it's been a very real issue. It's not just a brand new issue. It has certainly escalated in the past year or two.

The CHAIRMAN. OK.

Mr. Warnock, would you make some comments?

Mr. WARNOCK. Thank you, Senator.

Agree with what my colleagues have said. The increased enforcement clearly has taken place recently. That is when we started having this extra attention paid. That's when we started having issues really come to the forefront in patient care.

The other piece that I would make the argument is when these regulations were written, we never imagined—and I've been in long-term care for 30 years—we never imagined having the kinds of residents and patients that we now accept into a skilled nursing facility. These literally are an arm of the hospital. So, these rules clearly were designed to take care of custodial-care patients who didn't have immediate, emergent needs, and that's not the kind of residents we have any more.

The CHAIRMAN. In trying to understand why they are moving so clearly in the direction in which they are moving, can any of you offer their justification for it? We'll be hearing from the DEA on the next panel, but, you know, you always try and look at it from the other person's point of view and understand what they're doing and why they're doing it.

Mr. Brickley, you have some thoughts on that?

Mr. BRICKLEY. Yes. Putting the shoe on the other foot, Senator, you know, the Controlled Substance Act of 1970 is what it is. It was written then. It was written for a different patient-care population. As I noted in my reference, even in 1973 and 1974, the DEA recognized that there were components of the Controlled Substance Act that did not apply, did not fit with our setting. So, I can't contest of the DEA following the letter of the law.

The CHAIRMAN. Dr. Phillips?

Dr. PHILLIPS. Yes, if I may. I believe there's also some myths and misunderstandings of how clinical practice occurs in nursing home settings. It is not, as been mentioned, but may be seen by the DEA as, an outpatient kind of setting with absent doctors and nurses sort of running the show. That, in fact, is not the reality. Physicians are responsible for patients, 24/7. We work in a collaborative team-based environment with nurses, therapists, pharmacists, the entire spectrum of the license panel. So, decisions are still made in orders by physicians who are overseeing the care through the agent, in other contexts of care of the nurse in the nursing home.

So, I think part of the challenge is getting the understanding, this is an environment of team-based integrated care for very frail, vulnerable individuals with considerable oversights at every step of the way, in both prescribing, dispensing, and administering and counting for all of the narcotics and other medications present.

The CHAIRMAN. Now, is it fair to say that all of you would like to have the same method of prescribing pain medication in nursing home facilities as we have in the hospitals? Is that right? Is that what you're advocating?

Mr. SCHANKE. Yes.

The CHAIRMAN. Mr. Schanke?

Mr. SCHANKE. Absolutely.

The CHAIRMAN. That's what you're advocating.

Mr. Warnock?

Mr. WARNOCK. Yes, sir.

The CHAIRMAN. Dr. Phillips?

Dr. PHILLIPS. Yes, sir.

The CHAIRMAN. Mr. Brickley?

Mr. BRICKLEY. Yes, Chairman.

The CHAIRMAN. Any of you see any cautionary reasons why that shouldn't be done? Do you have any imagined problems that might occur if we were using the same procedure?

Mr. SCHANKE. Well, I'll jump in. We've been doing it for a while, and we've got established procedures, in terms of tracking scheduled meds, in particular, from shift to shift, new orders, expired orders. We take managing the scheduled medications extremely seriously, just for many of the reasons the DEA wants us to, and we should be. We're concerned about making sure we don't have diversion issues and that the meds are used properly for our patients. So, extending the nurse as agent of physician to us is not going to change any of the sort of foundational things we already do to make sure we handle them safely, securely, and they're administered properly.

The CHAIRMAN. What are your legal liabilities here? I mean—any of you—what happens if, in fact, in your facility, if we were doing

it as hospitals do it, and somebody badly overprescribes? Are you—is there a legal—Dr. Phillips is there a legal liability here?

Dr. PHILLIPS. Well, there are both licensure and law enforcement oversight and oversight of the DEA. So, if I am a negligent practitioner-prescriber, I'm accountable, whether it's in the community, the nursing home, or the hospital. That doesn't change by the setting; I still am obligated under my license and my oversight in my practice.

So, I think that that piece is not a good argument, that this one setting of care—I applaud the DEA's desire to address diversion and all issues of diversion which occur in the hospital, the office, the community and nursing home—need to be dealt with. But, it is not singularly the nursing home where the risk lies. Yet, we are creating the burden of this on the backs and the broken legs of our patients. That's the real tragedy, and I think it's the unintended consequence.

The CHAIRMAN. Yes.

Any comments from this panel on anything, whatever? Mr. Warnock or Mr. Brickley?

You've been really good and complete in describing the problem, and I think we all appreciate that very much.

Mr. WARNOCK. Thank you, Senator. The only thing I would like to express, and I think it's been expressed very well here today, but I don't want to leave without saying. It is very important that we solve this problem. These people deserve better than what we're giving them today, and we need to provide better for them.

The CHAIRMAN. Well, that's very good.

We're going to have the representative from the DEA here on the next panel. If—probably redundant, but if you—if you wanted me to ask him a—just in the interest of trying to get to a resolution—one question, what would you suggest, Dr. Phillips?

Dr. PHILLIPS. I guess I would ask, Why the nursing home? What is it about this setting that makes it, in particular, a focus for the DEA's interpretation, when licensed nurses are practicing under the same scope of practice, the nurses are—the physicians are interacting under their same scope of practice, under the same State and Federal regulations, why this setting of care is being identified and targeted?

The CHAIRMAN. Why is this any different from a hospital setting?

Dr. PHILLIPS. Exactly.

The CHAIRMAN. Is that right?

Mr. SCHANKE. Yes.

The CHAIRMAN. Would that be your question?

Mr. SCHANKE. Yes.

The CHAIRMAN. I am your faithful servant.

Dr. PHILLIPS. Very good.

The CHAIRMAN. Thanks a lot, folks, you've been good.

Dr. PHILLIPS. Thank you.

Mr. SCHANKE. Thank you.

The CHAIRMAN. So, we come to our next panel here today. We welcome our two witnesses.

Our first witness on this panel will be Joseph Rannazzisi. Mr. Rannazzisi is the Deputy Assistant Administrator in the Office of Diversion Control at the Drug Enforcement Administration, located

in the U.S. Department of Justice. As Deputy Assistant Administrator, he is responsible for overseeing and coordinating major pharmaceutical and synthetic drug investigations, drafting and enforcing regulations, as well as establishing drug production quotas.

We welcome you here today.

Next, we'll be hearing from Carmen Catizone. Mr. Catizone is the Executive Director of the National Association of Boards of Pharmacy, and the Secretary of the Association's executive committee. The National Association of Boards of Pharmacy is the international association that assists members in developing and implementing standards for public health.

We welcome you both here.

Mr. Rannazzisi, we'll start with you.

STATEMENT OF JOSEPH RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE, WASHINGTON, DC

Mr. RANNAZZISI. Good afternoon, Chairman Kohl.

On behalf of Acting Administrator Michele Leonhart and the men and women of the Drug Enforcement Administration, thank you for holding this hearing on this important issue regarding the issue of prescribing controlled substances to patients in long-term care facilities.

DEA is charged with enforcing the Controlled Substances Act and its implementing regulations, which were designed, first and foremost, to protect the public health and safety.

DEA accomplishes this mission, in part, through administrative and regulatory oversight of more than 1.3 million individuals and businesses registered to handle controlled substances. The registrant population consists of manufacturers, importers, wholesalers, distributors, pharmacies, and practitioners.

With very few exceptions, however, DEA does not regulate long-term care facilities. This is due, in part, to the fact that these facilities typically do not have State controlled-substance registrations or hold DEA registrations.

Controlled substances are powerful and potentially dangerous drugs when used improperly and without the proper practitioner oversight. That said, the CSA has, in its very core, the unique ability to provide a protective umbrella throughout the controlled-substance distribution chain. By design, the CSA provides built-in checks and balances to ensure that controlled substances are dispensed for legitimate need, while protecting the public health and safety from diversion.

The CSA, in implementing regulations, therefore established specific limitations on who is authorized to prescribe, and under what conditions. The regulations set forth very precise elements that must be included in a prescription to reduce errors and solidify the authenticity of the prescription.

For example, a practitioner—a term clearly defined in the Controlled Substances Act—is the only person who can prescribe a controlled substance. Furthermore, the practitioner must be licensed by the State in which he or she practices and must be registered by the Drug Enforcement Administration. Once these conditions

have been met, a practitioner can only prescribe a controlled substance after a determination has been made that the drug is needed for legitimate medical purpose and is prescribed in the usual course of professional practice.

Though the responsibility for proper prescribing and dispensing of a controlled substance rests with the practitioner, it's the pharmacist who's the final gatekeeper. Under the Controlled Substances Act, a corresponding liability rests with the pharmacist to ensure that every prescription they fill is valid. They are the last line of defense before a controlled substance leaves the closed system of distribution.

DEA understands that the laws and regulations may need to adapt whenever possible, to keep pace with advancements in technology, science, or medicine. DEA regularly works with, and solicits input from, the medical and scientific community. We also seek input from the general public through the notice and comment portion of the regulatory process. Over the years, DEA has promulgated several regulations to address the unique and specific needs of patients in long-term care facilities.

For example, a pharmacist can typically only dispense a Schedule 2 controlled substance upon receipt of an original written prescription signed by a practitioner. However, if a patient is a resident of a long-term care facility, the practitioner can fax the written prescription to the pharmacy.

As far back as 30 years ago, DEA recognized the need to address emergency situations in long-term care facilities by authorizing placement of emergency kits in those locations. These kits, however, are the responsibility and property of the DEA-registered pharmacy and not the facility.

In 2005, DEA implemented regulations to allow retail pharmacies to install and operate automatic dispensing machines within long-term care facilities. These systems provide a means for patients to receive their medications in a more expedient manner.

In 2007, DEA implemented a regulation which permits a practitioner to issue multiple prescriptions for Schedule 2 controlled substances. This option can provide patients with up to a 90-day supply of medicine. In the event of an emergency, DEA has authorized pharmacists to dispense Schedule 2 controlled substances upon receipt of a valid oral order from a prescribing practitioner.

Finally, DEA has drafted an interim final rule that will allow for the electronic prescribing of controlled substances, and that rule should be posted today at the Office of the Federal Register and should be published within the next week or so.

The current statutory and regulatory regime provides practitioners and pharmacists with a wide variety of mechanisms to deliver medications both safely and timely to patients in long-term care facilities. The Drug Enforcement Administration recognizes the importance of providing safe and effective medications to patients in need. As technologies evolve, or other circumstances dictate, DEA has and will continue to implement regulations whenever possible, to allow for proper prescribing and dispensing of controlled substances.

Chairman Kohl, thank you again for your interest on this important matter and ensuring that patients who reside in these facili-

ties receive appropriate standard of care that they deserve. The Department of Justice and the Drug Enforcement Administration are committed to working with Congress on this and other matters.

Thank you for this opportunity to appear today, and I look forward to answering any questions you may have.

[The prepared statement of Mr. Rannazzisi follows:]

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

MARCH 24, 2010

Statement of
Joseph Rannazzisi
Deputy Assistant Administrator
Drug Enforcement Administration
Before the U.S. Senate Special Committee on Aging
March 24, 2010

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., breakthough 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 dispending 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.

The CHAIRMAN. Thank you very much.
Mr. Catizone.

STATEMENT OF CARMEN CATIZONE, DPH, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, MOUNT PROSPECT, IL

Mr. CATIZONE. Thank you, Chairman Kohl.

With me today is—also, is William Winsley, Executive Director of the Ohio Board of Pharmacy and President-Elect of NABP. Mr. Winsely is uniquely qualified to speak on the issues today, because of his extensive background in pharmacy practice and regulation. His was the first State to be challenged by these issues.

NABP appears before you today as an objective third party, with our only interest being the patient and the integrity of the medication distribution and dispensing systems. As an association of State regulatory agencies, we are not involved in the economics of the profession of pharmacy, and therefore, are removed from any direct concern with the economic impact on long-term care and long-term care practitioners that compliance with Federal and State laws and regulations may have, unless patient care suffers as a result of burdensome regulation.

Mr. Chairman, it's important to temper today's hearing with the realization that emotions are running high and some of the dire consequences predicted to occur will not occur and, in all likelihood, if they do occur, will not be to the extent that they have been predicted. Furthermore, the accusations which characterize this struggle have clouded the issue and have obstructed necessary avenues of communication. Some of the statements today also falsely accuse the DEA and law enforcement authorities of actions that are simply not true.

We concur that patient care is affected, but we also acknowledge that diversion is a serious issue. To what extent each of these unfortunate outcomes is occurring, and the reasons for their occurrence, are at the heart of this hearing.

As NABP approached this issue, we sought to ignore the inflammatory comments and tried, instead, to determine what the facts are and what possible solutions exist. In this regard, we posed two questions to those with whom we spoke.

To the practitioners in the long-term care industry, we asked whether compliance with the statutes and regulations of the DEA, which are considered intractable, could occur, but has not occurred because of the cost and inconvenience to the industry.

To the DEA and regulatory authorities, we asked whether the basis for declaring that industry standards were illegal was statutory and regulatory, or interpretation of statutes and regulations.

To be perfectly honest, Mr. Chairman, NABP believes that the inflexible positions advanced are not entirely accurate or absolute. Furthermore, addressing the issues under consideration today in an isolated way, even if approached with the wisdom of Solomon, might prevent the child from being split, but ultimately would result in further complications and conflicts, because the issues encompass significant areas and interpretations of the Controlled Substances Act.

To this end, the member States of NABP have called for us to invite the DEA and all stakeholders, those in long-term care and other practice settings, to work with us to review and pose revisions to the Controlled Substances Act. Those revisions would address the issues under consideration today, as well as other issues that need to be addressed because of significant changes in practice in patient care, technology, and regulation.

To the immediate question under review by this committee and affecting patient care in long-term practices, NABP recommends the following course of action: that DEA establish a new registration category for long-term care facilities, as defined by the States, with similar privileges and responsibilities as now exist for hospitals. If this could be enacted, the dilemma surrounding chart orders and agent of the prescriber could move toward a resolution.

Presently the NABP Model Act, and a report developed in collaboration with the American Society for Consultant Pharmacists, define long-term care facilities within the definitions of an institutional facility. That definition includes hospitals, and would place upon long-term care facilities the same legal and regulatory standing.

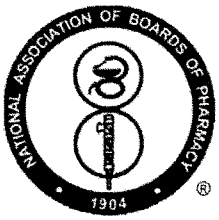
It should be noted, however, that diversion, unacceptable standards of care for our elderly, and outdated regulations would not be resolved by this immediate action. For those broader and more encompassing issues, we again recommend a more comprehensive analysis and review of the Controlled Substances Act.

NABP is hopeful that this committee will support our effort and, through whatever authority available to it, bring the parties to the table to engage in this much-needed and valuable effort on behalf of the patient and integrity of the medication distribution and dispensing systems.

Thank you for the opportunity to comment today.

Mr. Winsley and I would be glad to answer any questions you may have, Mr. Chairman.

[The prepared statement of Mr. Catizone follows:]



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Statement of
Carmen Catizone, M.S., RPh, DPh
Executive Director
National Association of Boards of Pharmacy

Before The
Senate Committee on Aging
March 24, 2010

Statement of Carmen Catizone
Executive Director
National Association of Boards of Pharmacy

Senate Committee on Aging
Long Term Care
March 24, 2010

Good afternoon Chairman Kohl and Members of the Special Committee on Aging. Thank you for the opportunity to be here today and discuss with you the concerns surrounding the dispensing of controlled substances to patients in long term care facilities.

I represent the National Association of Boards of Pharmacy (NABP), the association of state and provincial pharmacy regulatory boards and jurisdictions in the United States, Guam, Puerto Rico, the Virgin Islands, Canada, Australia, and New Zealand. Our purpose is to assist states and provinces in protecting the public health.

With me today is William Winsley, executive director of the Ohio Board of Pharmacy and President-elect of NABP. Mr Winsley is uniquely qualified to speak on the issues before your committee today because of his extensive background in pharmacy practice and regulation and his was the first state to be challenged by these issues.

NABP appears before you today as an objective third party with our only interest being the protection of the patient and maintenance of the integrity of the medication distribution and dispensing systems. As an association of state regulatory agencies, we are not involved in the economics of the profession of pharmacy and therefore are removed from any direct concern with the economic impact on long term care and long term care practitioners that compliance with federal and state laws and regulations may have unless patient care suffers as a result of burdensome regulation.

Mr Chairman and Committee members it is important to temper today's hearing with the realization that emotions are running high and some of the dire consequences predicted to occur have been extrapolated beyond reason and in all likelihood will probably not occur or will not occur to the extent indicated. Furthermore, the accusations which characterize this struggle have clouded the issue and obstructed necessary avenues of communication. We concur that patient care is affected but also acknowledge that diversion is a serious concern. To what extent each of these unfortunate outcomes is occurring and the reasons for their occurrence are at the heart of this hearing.

As NABP approached this issue we sought to ignore the inflammatory comments and tried instead to determine what the facts are and what possible solutions exist. In this regard we posed two questions to those with whom we spoke:

To the practitioners and long term care industry, we asked whether compliance with the statutes and regulations that the DEA indicated are intractable could occur but has not occurred because of the cost and inconvenience to the industry. To the DEA and regulatory authorities we asked whether the basis for declaring that industry standards were illegal was statutory and regulatory or interpretation of statutes and regulations.

To be perfectly honest, NABP believes that the inflexible positions advanced are not entirely correct or absolute. Furthermore, addressing the issues under consideration today in an isolated way, even if approached with the wisdom of Solomon might prevent the child from being split but ultimately would result in further complications and conflicts because the issues encompass significant areas and interpretations of the Controlled Substances Act (CSA). To this end, NABP's member states adopted a resolution at their fall regional meetings, for final consideration at our May Annual Meeting, calling for NABP to invite the DEA and all stakeholders, those in long term care and other practice settings, to work with us to review and pose revisions to the Controlled Substances Act that address the issues under consideration today as well as other issues that need to be addressed because of significant changes in practice and patient care, technology, and regulation. NABP is hopeful that this Committee will support this effort and, through whatever authority available to it, bring the parties to the table to engage in this much needed and valuable effort on behalf of the patient and integrity of the medication distribution and dispensing systems.

To the immediate questions under review by this Committee and affecting patient care in long term care practices, NABP recommends the following course of action: the DEA establish a new registration category for LTC facilities, as defined by the states, with similar privileges and responsibilities as now exist for hospitals. If this could be enacted the dilemma surrounding "chart orders" and the "agent of the prescriber" could move forward toward a resolution. Presently, the NABP Model Act and a report (Attached) developed in collaboration with the American Society of Consultant Pharmacists (ASCP) define LTC facilities within the definition of "Institutional Facilities." That definition includes hospitals and would place upon LTC facilities the same legal and regulatory standing. It should be noted however, that diversion, unacceptable standards of care for our elderly and outdated regulations would not be resolved by this immediate action. For those broader and more encompassing considerations, we again recommend a more comprehensive analysis and revision of the CSA as we indicated earlier.

Thank you for the opportunity to appear here today and share our insight. Mr Winsley and I would be glad to respond to any questions that you or members of the Committee might have for us.

The CHAIRMAN. Thank you very much, Mr. Catizone.

Mr. Rannazzisi, you've heard Mr. Catizone testify that DEA might well, and should, allow—should create a new registration category for nursing homes that will allow them to operate more like hospitals do, with respect to ordering controlled substances. Do you have a sense that your agency is prepared to work with the pharmacy boards, other regulators, as well as the provider community on such a solution?

Mr. RANNAZZISI. Yes, sir.

Let me explain our registration process a little. If a State decides to register, or give controlled substance authority to, a nursing home, depending on the extent of that controlled-substance authority, we would be obligated to register them. So, yes, we would register them. We'd work with them, and we have no problem registering them. However, our registration is based on the State-controlled substance authority that's granted to the prospective registrant. So, it would be up to the States to make that first step, to give them controlled-substance authority, and then we would create a new class of registrant to encompass the nursing homes.

The CHAIRMAN. What kind of an impediment does that present, Mr. Catizone?

Mr. CATIZONE. Mr. Chairman, if the providers support this initiative and work with their State board of pharmacy, we see no impediment on behalf of the boards of pharmacy. The impediment would come from the provider community that might oppose this. But, if the panelists today were honest and sincere in trying to treat the patient, then we would see it moving forward quite quickly.

The CHAIRMAN. So, you see this as being quite doable.

Mr. CATIZONE. Yes, sir.

The CHAIRMAN. Do you, Mr. Rannazzisi?

Mr. RANNAZZISI. Absolutely. As long as the State controlled-substance authority is in place, yes, sir. It would just take us time to—not a lot of time, but time to create that new registrant category, but we'd be very expeditious in the creation of that.

The CHAIRMAN. So, how do you imagine that we—if you have a set of—how do you imagine that we might move toward a resolution here that long-term care facilities find satisfactory, as well as yourself? What's the next step?

Mr. RANNAZZISI. If we're talking about the registration of the long-term care facilities, the next step would be the States to make the decision whether they're going to provide long-term care facilities with controlled—State controlled-substance registration. Once that is done, and they've been provided with that authority, we'll do the rest.

The CHAIRMAN. That's a good answer.

You heard the providers on the first panel discuss the practical dilemmas they face, trying to relieve pain and suffering among their residents. What efforts are you making to reach out to long-term care providers in order to help them do what is expected of them?

Mr. RANNAZZISI. As I said in the testimony, the long-term care providers are not our registrants. We don't have any regulatory control over them. We don't inspect them. Our registrants in this

community would be either the practitioners that are prescribing or the pharmacy services corporations that are actually servicing the long-term care providers.

Now, we do a number of different presentations. I think in 2009, we did over 25 presentations to all different groups in the medical community—the boards, American Medical Association, Mayo Clinic, National Community Pharmacists Association, the National Conference—we bring in medical and pharmacy board representatives, the American Society of International Interventional Pain Physicians, the list goes on and on—about 25 different presentations, and we talk about all aspects of the Controlled Substances Act, and we answer questions related to the Controlled Substances Act.

In this situation, there are two registrants that relate directly to the long-term care facilities that are not registrants: the practitioners and the pharmacists, the pharmacists being the gatekeeper for the prescriptions, to determine whether they're valid or not. I think that the pharmacists have a very good background, with 40 years of the Controlled Substances Act, about determining what is a valid prescription. Inherent in the Act is a determination that a prescription is valid, on both the practitioner's side and the pharmacist's side. A prescription, to be valid, is issued for legitimate medical purpose in the usual course of professional practice; that's the standard that the doctors are held to. The pharmacists have a corresponding responsibility to ensure that that prescription is valid, and they're held to that same standard. The nurse is just a facilitator to make sure the medication is received and given to the patient. If the pharmacist and the practitioners understand the valid prescription requirement, there shouldn't be a problem with the nursing homes.

The CHAIRMAN. Do you see it that way, Mr. Catizone?

Mr. CATIZONE. Yes, Chairman Kohl.

The CHAIRMAN. Well, I get the sense that we may be moving in the right direction here. Before we, perhaps, begin to wind up this hearing, I would to take the somewhat unusual step of asking the Doctor to come back and sit down for a minute. Tell us, Dr. Phillips, if you feel that we've made a lot of progress, some progress, no progress. What do you think?

Dr. PHILLIPS. I am delighted to hear—I am—I guess I'm a little bit taken back by the sense that somehow we have been inflammatory or exaggerative, because, in fact, these pain events were happening last year, they were happening yesterday, they're happening today, and there will be hundreds of them happening tomorrow, so it is a very real issue.

I'll speak from personal experience, and maybe a little bit of ignorance. I had started this issue in California and tried to look at a State solution, back 5 years ago, and our State Board of Pharmacy said it was a DEA issue, and they had to go to defer to the DEA. Now, I'm hearing from the DEA that, in fact, it's a States issue. So, I guess a little bit of caution on my part is, Are we going to do one of these, "It's my turn, no, it's my turn," before it actually gets resolved? Where the authority lies, I'm unclear. But, I am concerned that we'll do a little bit of push-pulling back and forth between the States and the DEA.

The CHAIRMAN. Go ahead, if you can.

Mr. RANNAZZISI. Again, inherent in the registration process is a requirement that a controlled—the controlled-substance authority be granted by the State before DEA can issue a registration. Once that State decides how they're going to grant that controlled-substance authority and the exact authority that they'll be granted, we will proceed with the registration process. It depends on the State.

The CHAIRMAN. Mr. Catizone.

Mr. CATIZONE. Chairman Kohl, we will issue that explanation to the States, as well as our recommendation that they recognize this. Clearly, a letter from this committee or from you, sir, would help that process—that we could send to all the States, and work with the Congressmen and Senators in their States, as well, saying that this is an important initiative, we need to move quickly. That would move the issue very quickly.

The CHAIRMAN. All right, well, I'll be happy to do it.

Dr. Phillips, you've got a nice smile on your face.

Dr. PHILLIPS. Well, I think that's a wonderful next step, and I'm delighted and appreciate both the efforts of the DEA, the pharmacy, and also our panel of providers. With your input, this will actually start to move.

Thank you.

The CHAIRMAN. I think that's great. I'm moved to speculate and think that if we could have had you all working on healthcare, we would have done it in a month. It wouldn't have taken——

Dr. PHILLIPS. You should have asked us, huh? [Laughter.]

The CHAIRMAN. Without all the animosity.

You've all done a great job. We thank you all for being here. I think that this has been a very, very good session that we've had this afternoon.

Dr. PHILLIPS. Thank you.

The CHAIRMAN. Thank you so much.

[Whereupon, at 3 p.m., the hearing was adjourned.]

APPENDIX

MR. SCHANKE'S RESPONSES TO SENATOR BROWNBACK'S QUESTIONS

Question. It is acceptable for nurses in long-term care to take phone and "chart orders" for all other medications and treatments—antibiotics, anti-coagulants, insulin, etc. Some of these medications have life threatening implications if the order is incorrect and/or administered inappropriately. Given the dispensing controls that are in place for narcotics, can't we accomplish the same physician involvement by having them sign the "chart order" with the required information during their next visit without requiring the extra step of a retail prescription form?

Answer. The current procedures for continuation of orders and implementation of new orders for existing patients and newly admitted patients are effective for all medications and treatments. There is no reason to believe that the same would be not be true should we have the ability to include narcotics and other "schedule" medications in those procedures. The information required for a narcotic order will still be obtained concurrently with the immediate implementation of the physicians order for the pain medication. If we had the ability to use the "chart order" or a phone order there would be much less potential for a delay in the administration of the pain medication. Delays continue to occur while we wait for DEA required paperwork/verbal communication to find its way from physician, direct to pharmacist, back to nursing staff before we can give the needed pain medications.

Question. Do you think it is time to change the CSA act to reflect the practice of Long Term Care, similar to what occurs in hospitals? The hospital nurse is employed by the hospital, yet can take orders for narcotics over the phone without the need for a written or verbal prescription to the pharmacist.

Answer. I do think it is time for the CSA act to reflect the practice of Long Term Care. Nursing staff in Long Term Care facilities must communicate with the physician and receive that physician's instructions for any and all treatments and medications, whether new or existing. There is no practical difference in starting/continuing an order for insulin or starting/continuing an order for a pain medication. Insulin can be ordered by a physician over the phone to my nursing staff and followed up with a signature. A simple pain medication cannot be ordered over the phone, but must have specific paper work completed before we can consider giving it.

The DEA's enforcement of outdated rules does not prevent diversion. We do not have a diversion problem in the Fox Valley according to my local police force and our area wide drug enforcement unit. In fact, there has been only one instance of diversion of a controlled medication investigated by either agency in the last three years and that was an Assisted Living Facility not a Skilled Nursing Facility. As was stated at the hearing, diversion is no more likely to occur in a nursing home than it is in any other setting. I would submit that our internal controls and procedures make it very difficult to commit diversion and more difficult to continue diversion as evidenced by the virtual absence of policy activity in this area. We take the management of controlled medications seriously; our hope is that the DEA will take our patient's pain needs just as seriously.

MR. WARNOCK'S RESPONSES TO SENATOR BROWNBACK'S QUESTIONS

Question. It is acceptable for nurses in long-term care to take phone and "chart orders" for all other medications and treatments—antibiotics, anti-coagulants, insulin, etc. Some of these medications have life threatening implications if the order is incorrect and/or administered inappropriately. Given the dispensing controls that are in place for narcotics, can't we accomplish the same physician involvement by having them sign the "chart order" with the required information during their next visit without requiring the extra step of a retail prescription form?

Answer. Yes, it is acceptable for all non-controlled drugs to be ordered verbally and chart orders are the official orders for these drugs. I agree that we could treat controlled drugs just as we do all other drugs and the risk of diversion would not change appreciably.

Question. Do you think it is time to change the CSA act to reflect the practice of Long Term Care, similar to what occurs in hospitals? The hospital nurse is employed by the hospital, yet can take orders for narcotics over the phone without the need for a written or verbal prescription to the pharmacist.

Answer. Yes, I believe this is the most reasonable and easily implemented solution to this issue. I only hope we can find a path to accomplish this change quickly so we can move forward with better care of our patients more quickly.

MS. PHILLIPS RESPONSES TO SENATOR BROWNBACK'S QUESTIONS

Question. It is acceptable for nurses in long-term care to take phone and "chart orders" for all other medications and treatments—antibiotics, anti-coagulants, insulin, etc. Some of these medications have life threatening implications if the order is incorrect and/or administered inappropriately. Given the dispensing controls that are in place for narcotics, can't we accomplish the same physician involvement by having them sign the "chart order" with the required information during their next visit without requiring the extra step of a retail prescription form?

Answer. Yes, we can give telephone orders for these other medications and yes, they often DO have life-threatening implications if not administered correctly, And yes, one piece of what we are saying is that we (physicians) do have to sign the orders within 7 days and thus would also have to sign any orders for narcotics ordered as well. There is a check and balance process in place. Every verbal order must be signed and the pharmacy will not release meds without an order—so even if the nurse were diverting, it would be identified when the physician was asked to sign the order.

Question. Do you think it is time to change the CSA act to reflect the practice of Long Term Care, similar to what occurs in hospitals? The hospital nurse is employed by the hospital, yet can take orders for narcotics over the phone without the need for a written or verbal prescription to the pharmacist.

Answer. Yes, very much. What we are hoping is that the nurse will become the "agent" as it is in the hospital.

MR. BRICKLEY'S RESPONSES TO SENATOR BROWNBACK'S QUESTION

Question. It is acceptable for nurses in long-term care to take phone and "chart orders" for all other medications and treatments—antibiotics, anti-coagulants, insulin, etc. Some of these medications have life threatening implications if the order is incorrect and/or administered inappropriately. Given the dispensing controls that are in place for narcotics, can't we accomplish the same physician involvement by having them sign the "chart order" with the required information during their next visit without requiring the extra step of a retail prescription form?

Answer. The current monthly physician order sheet recaps do not contain all of the data required by the DEA (i.e. quantity, DEA #, patient address, Physician address etc..) Although we could ask 70–80 software companies to re-design the monthly physician order re-caps, there is still the patient care barriers for new controlled substance orders for existing or new admissions to the long term care facilities. Only by getting the DEA to recognize a nurse as the agent of the prescriber and to recognize a "chart order" as a valid prescription order will be able to promptly dispense controlled substances for these frail, elderly residents.

Question. Do you think it is time to change the CSA act to reflect the practice of Long Term Care, similar to what occurs in hospitals? The hospital nurse is employed by the hospital, yet can take orders for narcotics over the phone without the need for a written or verbal prescription to the pharmacist.

Answer. Yes, it is clearly time to update the Controlled Substance Act to reflect the practice standards that are being followed in LTC facilities. The chart orders and medical record systems are very similar to a hospital setting so it makes sense to modify the CSA to treat LTC facilities similar to hospitals.

MR. RANNAZZISI'S RESPONSES TO SENATOR BROWNBACK'S QUESTIONS

Question. It is acceptable for nurses in long-term care to take phone and "chart orders" for all other medications and treatments-antibiotics, anti-coagulants, insulin, etc. Some of these medications have life threatening implications if the order is incorrect and/or administered inappropriately. Given the dispensing controls that are in place for narcotics, can't we accomplish the same physician involvement by having them sign the "chart order" with the required information during their next visit without requiring the extra step of a retail prescription form?

Answer. A proper response to this question requires two important distinctions be made: (1) the statutory and regulatory scheme applicable to controlled substances includes stringent controls not applicable to— non-controlled substances; and (2) the characteristics of a physician's order for a substance to be dispensed to a patient, and the circumstances surrounding that order, determine whether the order is deemed a "chart order" or a "prescription," which in turn determines whether dispensing a controlled substance is authorized under the Controlled Substances Act (CSA).

Even after meeting all applicable requirements under the Federal Food, Drug, and Cosmetic Act controlled substance medications can only be dispensed to patients pursuant to the stringent controls imposed by the CSA, because controlled substances (as opposed to non-controlled substances) have the potential for abuse, and are frequently diverted into the illicit market.

Next, an appreciation for the differences between a "chart order" and a "prescription" is necessary. A Drug Enforcement Administration (DEA)-registered hospital is a "practitioner" within the meaning of the CSA; therefore it is permissible for such a hospital to dispense controlled substances directly to patients without a prescription. 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 who is an agent or employee of the DEA-registered hospital. This may occur, for example, through the issuance of a "chart order." In this context, the term "chart order" should be distinguished from the term "prescription." A prescription, unlike a chart order, must contain all of the information specified in 21 C.F.R. § 1306.05, including, among other things, the signature of the physician on the day that the order is authorized.

Unlike hospitals, Long Term Care Facilities (LTCFs) are not DEA registrants. Therefore, if a "chart order" at a LTCF contains all of the required elements of a prescription, including the signature of a physician on the day that the order is signed, then the chart order itself could serve as a valid prescription. The required elements, which are set forth in 21 C.F.R. § 1306.05, are as follows:

- Signature of issuing practitioner
- Date of issuance (which must be the same day that the prescription is signed)
- Full name and address of patient
- Drug name
- Strength
- Dosage form
- Quantity prescribed
- Directions for use
- Name, address, and DEA registration number of issuing practitioner

Depending on the schedule of the drug, there may also be time limitations on how long a prescription is valid as well as the number of refills. For example, under 21 CFR § 1306.22(a), "No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times." Additionally, the determination that use of a controlled substance is medically necessary in any particular case must be made by a practitioner acting in the usual course of professional practice. *See United States v. Moore,* 423 U.S. 122 (1975); 21 CFR 1306.04(a). Such determinations cannot be delegated to LTCF staff.

Practically speaking, though, chart orders at non-DEA registered LTCFs typically do not contain all of these required elements of a prescription. In particular, chart orders at LTCFs often lack the signature of the issuing practitioner, which is critical to substantiate that he/she did in fact authorize controlled substance medication(s) for a specific legitimate medical need.

Prescriptions must contain all of the elements listed above primarily because controlled substances, in contrast to non-controlled substances such as antibiotics, anticoagulants, and insulin, have potential for abuse and are frequently diverted into the illicit market. Therefore, the dispensing of controlled substances is generally

subject to tighter controls and more regulatory oversight than non-controlled substances.

Question. Do you think it is time to change the CSA act to reflect the practice of Long Term Care, similar to what occurs in hospitals? The hospital nurse is employed by the hospital, yet can take orders for narcotics over the phone without the need for a written or verbal prescription to the pharmacist.

Answer. The CSA already allows for such a result if the relevant state has granted controlled substance authority to LTCFs in the same way it does for hospitals. Hospitals have state controlled substance authority, and are registered with the DEA—commensurate with that authority—to handle controlled substances. Individual states make the determination whether to issue licenses to qualified persons or facilities to handle controlled substances and under what limitations, and DEA registered practitioners may only engage in those activities that are authorized under state law for the jurisdiction in which they are located. If an LTCF were to satisfy a state's requirements for licensure as a hospital, such an LTCF could apply for DEA registration similar to that of a hospital. If so, registration of the LTCF by DEA would permit independent controlled substance authority, allow the facility to maintain a common stock of controlled substances on the premises, and the LTCF may be able to utilize chart orders like a hospital if allowed under state law and commensurate with federal regulations. Registration by DEA would also subject the facility to DEA oversight, recordkeeping requirements, and security requirements. In order for this option to be fully realized, however, states would first need to enact laws or regulations to permit this type of activity by LTCFs.

Nonetheless, even in the absence of state authorization in this area, the current statutory and regulatory regime provides practitioners and pharmacists with a wide variety of means to deliver controlled substances both safely and timely to residents of LTCFs. Over the years DEA has implemented regulations, consistent with the CSA, that were specifically tailored to assist practitioners and pharmacists by making it easier to prescribe and dispense controlled substances to residents of LTCFs. Currently, several options exist for a practitioner to prescribe controlled substances to their patient in a LTCF setting. The following is a summary of existing regulatory exceptions made to ensure that residents' medical needs at LTCFs are met:

- For a controlled substance in schedules II–V a practitioner can manually write a prescription for his or her patient. The prescription must be dated as of the date signed, and is 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 issuing practitioner. 21 C.F.R. § 1306.05(a).
- The CSA provides that a controlled substance in schedule II—the most stringent schedule for substances having a medicinal purpose and high abuse potential—may only be dispensed pursuant to a written prescription of a practitioner. 21 U.S.C. § 829(a). However, should an emergency situation arise, this statutory provision contains an exception that allows practitioners to issue emergency oral prescriptions with the regulatory requirement that the oral prescription be immediately reduced to writing by the pharmacist and contain all the information required for a written prescription, except for the signature of the prescribing individual practitioner, and must be followed up within seven days by a written prescription from the practitioner to the dispensing pharmacy. To facilitate the receipt of controlled substances under these circumstances, DEA has allowed pharmacies to establish "emergency kits" in the LTCF 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.
- Another means by which residents can receive medications more efficiently is a federal regulation that contains a provision specifically designed to accommodate LTCFs. The regulation 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 places the supply of controlled substances on location for convenient dispensing to a patient. 21 C.F.R. § 1301.27.
- Though practitioners cannot issue refills for schedule II controlled substance prescriptions, 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 CFR § 1306.12.
- An exception for delivery of a schedule II prescription to a pharmacy for LTCFs also exists at 21 CFR § 1306.11(f). Under this regulation a written prescription containing all the information required by 21 C.F.R. 1306.05, including the signature of the practitioner, may be transmitted via fax by the practitioner or practitioner's

agent. Partial filling of schedule II prescriptions is also allowed for LTCF residents or an individual with a terminal illness as long as the amount dispensed does not exceed the total amount prescribed and occurs within 60 days (21 CFR § 1306.l3(b).

• Schedule III–V prescriptions may also be written but may be refilled up to five times in a six-month period as directed by the prescriber. A fax of a written schedule III–V prescription may also be transmitted to a pharmacy by the practitioner or the practitioner's agent. Prescriptions for schedule III–V substances may also be orally transmitted by the practitioner to a pharmacy. Partial filling is also permissible for schedule III–V prescriptions not to exceed six months from date of issuance.

DEA has also published an Interim Final Rule allowing for the electronic prescribing of controlled substances. The effective date of this rule was June 1, 2010. This rule provides yet another tool for practitioners to use when prescribing a controlled substance for their patient, including those who reside in an LTCF. This rule allows practitioners to use a computer, laptop or PDA device to send a prescription to a pharmacy from a remote location instantaneously.

MR. CATIZONE'S RESPONSES TO SENATOR BROWNBACK'S QUESTIONS

Question. It is acceptable for nurses in long-term care to take phone and "chart orders" for all other medications and treatments—antibiotics, anti-coagulants, insulin, etc. Some of these medications have life threatening implications if the order is incorrect and/or administered inappropriately. Given the dispensing controls that are in place for narcotics, can't we accomplish the same physician involvement by having them sign the "chart order" with the required information during their next visit without requiring the extra step of a retail prescription form?

Answer. The question involves an area of expertise best answered by the DEA. Our understanding is that the Controlled Substances (CSA) and accompanying regulations specifically prohibit the activities noted.

Question. Do you think it is time to change the CSA act to reflect the practice of Long Term Care, similar to what occurs in hospitals? The hospital nurse is employed by the hospital, yet can take orders for narcotics over the phone without the need for a written or verbal prescription to the pharmacist.

Answer. NABP believes that the CSA has been effective in protecting patients and combating drug diversion since its creation and adoption. However, pharmacy practice in long term care and other settings has changed dramatically since the inception of the CSA more than 30 years ago. The member State Boards of NABP are requesting a review of the CSA and amendments to recognize the changes in pharmacy practice across all settings, including long term care.

AOPHA

THE ADVOCATE OF NOT-FOR-PROFIT
SERVICES FOR OLDER OHIOANS

855 South Wall Street
Columbus, OH 43206

March 23, 2010

The Honorable Herb Kohl
United States Senate
Washington, D. C.

Dear Chairman Kohl:

As an association representing Ohio's not-for-profit long-term care service providers, AOPHA is grateful for your interest and commitment to finding resolution to the DEA's enforcement of the Controlled Substances Act (CSA), and the negative impact it has on the residents entrusted to our care.

It is acceptable practice for nurses in hospice and long-term care to receive phone and/or "chart orders" from physicians for all medications and treatments—antibiotics, anti-coagulants, insulin, etc. Many of these medications have life threatening implications if the order is misunderstood, incorrectly written and/or administered inappropriately. Schedule II narcotics have strict dispensing controls which provide a "paper trail" from the pharmacy to the facility. To indicate that the nurse is not acting as the "agent" of the physician only in relationship to Schedule II-V medications is not logical; and, we can accomplish the same physician involvement by having him/her sign the chart order with the required information during their next visit. The goal of all agencies should be to facilitate the care of the frail, sick and dying. Direct communication between the physician and the nurse in the facility is critical both to quality care and ensuring that licensed nursing facility and hospice providers comply with state and federal requirements. Failure to comply with regulatory requirements, including delays in notifying a physician or in responding to the residents' needs can affect the facility's state licensure and federal certification status. The DEA's enforcement of the Controlled Substances Act has interfered with the ability of the facility to provide timely, appropriate, pain relief.

AOPHA applauds the Senate Special Aging Committee's hearing "The War on Drugs Meets the War on Pain: Nursing Home Residents Caught in the Crossfire." As members of the Quality Care Coalition for the Prevention of Pain, we offer any assistance you or your Committee may need.

Sincerely,

Fran Savard

Fran Savard, RN, ASN, BSM
Director Regulatory Relations and Data Services

This statement is to the Senate Special Aging Committee for inclusion in the record of the oversight hearing entitled, "The War On Drugs Meets the War on Pain: Nursing Home Residents Caught in the Crossfire."

I have been Medical Director of several nursing homes in Western North Carolina for nearly 30 years. I have yet to see a case of patient (or family) abuse or diversion of Schedule II medications. What I have seen is numerous instances where patients in severe pain suffered significant delays in obtaining relief for their suffering due to bureaucratic obstacles in getting their prescribed treatment.

There is already a well tested and functional system for dealing with this problem - that's the system used in all hospitals in the US. The process of physician medication ordering at SNFs is nearly identical to the process used in hospitals. The logical approach would be to adopt the hospital system for prescribing these medications to SNFs as well.

Please help us care for what is probably the most frail and vulnerable segment of our population by facilitating the treatment of their suffering, rather than obstructing it.

Sincerely,
Ron Fisher MD

WRITTEN

STATEMENT OF

Jonathan Musher, MD, CMD

ON BEHALF OF THE

AMERICAN MEDICAL DIRECTORS ASSOCAITION

BEFORE THE SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

HEARING: THE WAR ON DRUGS MEETS THE WAR ON PAIN: NURSING HOME RESIDENTS CAUGHT IN THE CROSSFIRE

MARCH 24, 2010

Mr. Chairman and Committee Members,

I am Jonathan Musher, MD, CMD, Past President of the American Medical Directors Association (AMDA) and Immediate Past Chair of AMDA's Foundation. I am Chair of Family Medicine at Suburban Hospital, Johns Hopkins Medicine, a family practitioner, and fellowship trained geriatrician with a private practice in Chevy Chase, Maryland. My expertise spans the spectrum of acute care and long term care services, from inpatient and ambulatory care through home and hospice care, to skilled nursing care.

AMDA represents more than 7,000 medical directors, long term care physicians, and others who practice in nursing homes, as well as other venues in the long term care continuum (LTCC), which includes home health care, assisted living settings, hospice, and other sites of care for the frail elderly. AMDA focuses its work on clinical practice guidelines and best practices to improve the care for frail elders, vulnerable adults, and children in the long term care continuum.

AMDA physicians see an average of 100 nursing facility patients per month, per member (approximately 8.5 million visits in 2000 or 42 percent of the total number of nursing facility visits that year). According to a 2009 survey of our membership on their prescribing habits, each AMDA physician writes an average of 341 prescriptions per month for their long term care patients. Our physicians are prescribing 169 Class II-V controlled substances per month.

Over the past year, we have received many phone calls and e-mails from our state chapters and physician members concerning Drug Enforcement Administration (DEA) policy stating that a nurse is not viewed as an agent of the provider. As a result, physicians are being required to bypass giving a class medication order to a nurse and give that order directly to a dispensing pharmacist. We fear that recent enforcement activities of the DEA threaten critical discussions between the nurse and physician on behalf of the residents as well as the medication management process (a system that has had safety checks and balances for quite some time that have protected patients from medication errors).

To fully understand the implications of this DEA enforcement, it is necessary to describe the role of the physician medical director, the physician/nursing home or hospice nurse relationship, the typical physician practice in this

setting, and checks and balances within the prescribing process.

Under federal statute (specifically the Nursing Home Reform provisions of the Omnibus Budget Reconciliation Act of 1987, or OBRA '87), each nursing facility must have a licensed physician to act as medical director. The medical director is charged with a wide range of clinical oversight and duties to protect the frail elders, vulnerable adults, and children in long-term care facilities. Those responsibilities include:

- **Implementation of resident care policies.** The medical director's job includes involvement in such wide-ranging clinical policies as the use of medications, determination of requirements for physician and non-physicians to practice in the nursing home, and many others. Again, this is a check and balance process where the medical director ensures that every attending physician who prescribes controlled substances has a DEA license. This is part of the physician credentialing process in the nursing home. The medical director is the clinical watchdog for the manner in which policies are applied to promote overall quality of care for patients.
- **Coordination of medical care in the facility** is another responsibility for the medical director, whose job includes ensuring that the facility is providing appropriate care to patients. The medical director also includes clinical oversight and supervision of physicians, non-physicians, and ancillary services provided by pharmacy and radiology. He or she also makes certain that federal guidance is being met, and that there is appropriate assessment, care planning, and pain management for every patient within the facility.
- **Providing appropriate care to patients** also is a role for the medical director. Physicians provide orders that ensure patients have appropriate comfort and supportive care measures as needed; for example, when experiencing significant pain or in palliative or end-of-life situations. The physicians periodically review all medications and monitor both for continued need based on validated diagnosis or problems and for possible adverse drug reactions. The medication review considers observations and concerns offered by nurses, consultant pharmacists, and other team members including the patients and families. This review addresses beneficial and possible adverse impacts of medications on the patients, including monitoring scheduled drug usage in the facility. The physicians also respond

promptly to notification of any acute and other significant clinical condition changes in the patients. The medical director oversees these activities.

- The medical director also works with attending physicians and other practitioners and staff to **provide appropriate, timely medical orders and documentation.** Physicians provide timely medical orders based on an appropriate patient assessment, review of relevant pre- and post-admission information, and age-related and other pertinent risks of various medications and treatments. They also provide legible written medication orders to avoid misinterpretation and potential medication errors. These orders include pertinent information such as the medication strength and formulation (if alternate forms are available); route of administration; frequency and, if applicable, timing of administration; and the reason the medication is being given.

In addition, regulations at 42 CFR 483.40 (a)(1) state that the medical care of each resident is supervised by a physician. As the clinical leader, the physician works in consultation with nurses and the interdisciplinary team to determine appropriate services and programs for a resident that are consistent with the person's diagnoses, condition, prognosis, and wishes. This team approach to care has been in existence for approximately 30 years. Such practices have the potential for improved patient access, enhanced communications, and better patient outcomes.

However, while the physician's role in the prescribing process is clear, there continues to be some confusion about the nurse's role. Because physicians typically are not in a long term care setting 24 hours a day/7 days a week, the licensed nurses play a critical role in communicating with the physician about patients' conditions, symptoms, and responses to treatment. Assessment by an onsite licensed nurse must be as thorough as is clinically indicated. The first step is to identify the presence and nature of the patient's change in symptoms, disease, condition, impairment, response to treatments, and/or risks of adverse events or other problems. This information may be obtained from patient self-report, staff or practitioner observation, or physical examination, in addition to/or from the results of diagnostic or laboratory tests. Sufficient information is collected from these

various sources to enable the care team to define the problem and identify possible causes.

Recognition of a clinical problem that may need further assessment and intervention also relies on the clinical skills of the interdisciplinary care team, including the attending practitioner and the nursing staff. In the nursing facility setting, it is the licensed nurse who assesses the patient prior to notifying the practitioner. This is part of the nursing process *and* the communication process.

As a next step, the nurse must gather and assess information about the patient's current medications and treatments, as well as his or her responses and adverse reactions to previous medications and treatments; then the nurse communicates this to the patient's practitioner. The nurse also looks for evidence that a nonpharmacologic treatment has been tried in the past and either has been successful or has failed.

During the care planning process, a critical discussion occurs between the nurse and physician on behalf of the patient. If possible, the physician will talk to the patients about how they feel. However, a nurse is the one who provides the physician with the patient's vital signs and other clinically relevant information necessary for the physician to formulate a treatment plan. If the physician needs to discuss the pharmacology of medications, he or she can call the pharmacist; but in most cases, this is not necessary.

Based on the results of the assessments and the clinical information gathered, the care team constructs a plan of care, and that may include ordering a controlled substance for the patient. In addition, the plan calls for monitoring the patient over time to determine whether the medication is working. Depending on the results of this monitoring, the physician may need to increase dosage or give the medication more frequently. At any rate, vital to this process—and to positive outcomes for the patients—is that skilled people at the patient bedside level in the nursing home are monitoring the patient and communicating with the physician.

All of this points to the fact that nurses in the nursing home do not act independently *but rather act as the direct agent for the physician, providing important clinical information and responding to the physician's questions*

and then transcribing the physician's verbal order. This is critical because the nurse is able to assess patients' pain and, in turn, can furnish the necessary information to allow the physician—*not the nurse*—to order the appropriate drugs and services. The nurse, after discussing the patient with and receiving an order from the physician, is now sending a prescription to the dispensing pharmacist *on behalf* of the physician. And the nurse is fulfilling an important step by providing the patient's history and helping to evaluate the situation that enables the physician to determine the most appropriate treatment option. The nurse transcribes the verbal /telephone orders exactly as given by the physician into the patient's facility chart. He or she then transmits the medication or treatment orders on behalf of the prescribing physician to the pharmacy in order to obtain the medications for the patient. This is just communicating the physician's order(s) and in no way constitutes a "nursing" order.

From the physician perspective, today's practice in nursing homes is similar to hospital practice. The patient population in the nursing home setting is chronically ill--many at the end of life--with exacerbating, unpredictable illnesses. Even the most seasoned practitioner cannot anticipate when these patients might need either to begin a Class II-V controlled substances or require an increased amount of Class II-V controlled substances. It is not surprising that situations frequently occur at all hours of the day and night where the need for the initiation of a Class II-V controlled substances, or a dose adjustment, arises. Nurses are present in the long term care facility 24 hours a day/7 days a week to assess symptoms and can effectively communicate changes in a patient's condition to the physician when they occur.

Recent DEA actions threaten this team approach to care. In turn, these actions would affect the quality of patient care, since the DEA is no longer recognizing the nurse as an agent of the physician in the long term care setting. Specifically, the DEA actions would affect **existing checks and balances that minimize the risk for diversion.** Multiple safeguards currently are present to assure the safe use of narcotics in the nursing home. Every physician must apply for and have an active DEA license in order to prescribe controlled substances. DEA licensing is monitored by both the nursing home and the medical director. One of the checks and balances in long-term care facilities is that the medical director ensures that the

physician who prescribes a controlled substance has an active DEA license as part of the physician credentialing process. In addition, the nursing home is made aware of physicians who do not have a DEA license; and facilities cannot take a controlled substance prescription from these unlicensed physicians.

A second check currently is in place at the pharmacy dispensing level. Pharmacists will check that the prescribing physician has an active DEA license before dispensing a controlled substance.

Additionally, other safeguards are present including narcotic lock boxes, an inventory of narcotics at shift change, and documentation of drug destruction. These systems are regularly reviewed as part of the federally mandated survey process.

DEA enforcement actions are **causing delays in care**. Our physicians are reporting delays in getting medically needed prescriptions to the patient, thus causing unnecessary pain and suffering. Our physicians are willing to take the steps the DEA has requested; however, these added steps are delaying the dispensing and receipt of medications and interfering with the checks and balances already in place in the nursing home setting. Nursing home physicians are very accustomed to receiving phone calls from hospital and nursing home nurses describing patient symptoms, and then deciding whether a face-to-face assessment is necessary or whether the problem can be handled by phone. In the hospital verbal orders for narcotics of all legal classes are acceptable (to be signed by the physician the next time he or she is in the hospital).

Yet, in the nursing home, verbal orders for Class II narcotics are unacceptable with the exception of emergency situations; and even then only a limited quantity of the drug may be prescribed. The Controlled Substance Act (CSA) provides for faxing of Class II prescriptions for long term care patients. Unfortunately, this procedure often is impractical or even impossible; and this has had the unintended consequence of interfering with the timely receipt of appropriate pain medications for nursing home and hospice patients, many of whom are in extreme pain and must wait hours or even days for pain medications. The need for prompt treatment of a distressing symptom, such as pain or dyspnea, is a significant patient care

issue that could be resolved in most cases by recognizing the nursing home nurse as the practitioner's agent.

A typical nursing home physician is an office-based primary care physician with a busy practice who performs visits at several long term care facilities. Very few nursing homes have staff physicians, and none have physicians in-house on nights and weekends. Nursing homes often use more than one pharmacy to supply their medications. Thus, the off-site physician would not only need access to a fax machine but also to information regarding the fax numbers of multiple pharmacies. The potential for error multiplies as does the potential for patient suffering. Nurses at the facility, however, generally have access to a fax machine pre-programmed to the appropriate pharmacy, creating a tighter and safer system. They also have the ability to follow-up easily with the dispensing pharmacy and check to make sure that the medication ordered is the one that actually was delivered for the patient.

AMDA has collected real life stories from its membership related to this issue. One AMDA physician in Pennsylvania shared that a nurse in a nursing home reported to him on a newly admitted patient post hip surgery who had been on a controlled substance for pain management in the hospital. The nurse communicated with the physician (who was seeing patients in his office) the hospital records, transfer records, complete nursing assessment, and the patient's self-reported level of pain. The patient was admitted for rehabilitation and was scheduled to start physical therapy. The patient's self-report of pain was 9 out of 10, indicating very severe pain. The physician ordered a lesser quality (non-controlled) pain medication to "hold the patient over" until the controlled substance would arrive. The physician, in fact, did fax in an order for the pain medication to the pharmacy, which is a large "hub and spoke" provider pharmacy out of state where orders get processed. Due to the emergency nature of the situation, the physician also tried to call the pharmacy's "800" number, but he did not get an answer—as this is not like a local retail pharmacy. All of this occurred at approximately 12 noon. The nurse at the nursing home did not know if the physician, in fact, had faxed in the order or had been able to reach the pharmacy. This level of communication has been removed by the DEA's enforcement. At 1 a.m. the physician received a call from the provider pharmacy to verify the faxed order for the controlled substance, 13 hours after he sent it in. At 2 a.m. he received another call from the local pharmacy that would deliver the

medication, once again verifying that he was the one who faxed the order, before they would deliver the medication. It was now 14 hours after the nurse communicated that the patient was in a high level of pain. This physician reported to us that the previous system, where the nursing home nurses faxed the orders directly into the provider pharmacy, never had resulted in such problems and medications were processed and delivered in a timely fashion.

Another AMDA member from Ohio reports that she had a patient with an end-stage disease whose condition suddenly exacerbated. The patient's need for pain medication escalated. The physician ordered an increase in the amount of the pain medication to administer hourly, as it was clear the patient was in the last hours of their life. The physician knew the facility would run out of the controlled substance on hand, and she attempted to obtain more by complying with the DEA regulation. She was traveling between facilities and was unable to fax an order to the pharmacy. She attempted to call in the order, but it took her quite some time to reach the pharmacist—again, it was a large provider pharmacy, which is the usual system for the nursing home setting. By the time the order was processed and delivered, the patient had died and had spent the last hours of life in excruciating pain. Had the nurse in the facility been allowed to fax over the order, a system that has worked for us for over 30 years, this would not have occurred. We are supposed to be protecting these frailest of our population. How did we get to a point where we have to comply with paperwork that results in sacrificing patient safety and comfort? A doctor's first charge is "to do no harm." These regulations cause us to go against that most basic of creeds.

DEA enforcement increases the potential for errors. DEA enforcement compromises the quality and accuracy of communications regarding vital patient health care needs between the nursing facility staff who are observing and monitoring the patient and the patient's physician. There is a delivery system in place that affords those who deliver the care to be aware of what is happening. For example, when the physician calls the pharmacy, he or she now has to follow up with a fax. In the current system, the nurse serves as the check and balance by transcribing the physician's order and noting this in the patient's chart. Under the recent enforcement scenario, multiple people are waiting for delivery of the fax and waiting for

confirmation of the fax. Unless the physician and the nurse are communicating constantly about the fax, one of them may be unaware if it was sent or received or which medication was ordered.

Action is needed now to allow patients to receive their medications in the long-term care continuum. While policymakers talk about needed reforms, many have focused on the transition between hospitals and nursing homes and the need to prevent readmissions. AMDA is committed to this issue; and we are working toward improving care transitions and care coordination, most recently with the publication of a national model of care, "Transitions of Care in the Long Term Care Continuum" (http://www.amda.com/tools/clinical/TOCCPG/index.html).

AMDA's members are accountable for nursing home patients. Without timely access to needed medications, they have no choice but to transition these patients back to the hospital, wasting countless healthcare dollars on an avoidable transition—money that can be better spent on necessary care. According to the report, *Reducing Avoidable Hospitalizations of Nursing Home Residents: A Centers for Medicare & Medicaid Services Special Study. Feb 4, 2008,* if we can reduce avoidable transitions by just half, we would save $2.3 billion annually. Reducing avoidable hospitalizations represents an opportunity to improve care and reduce costs. And some of the costs avoided can be reinvested in the infrastructure for nursing homes to provide high quality care, certainly a goal that would we all wish to be met with health care reform.

AMDA has offered and continues to offer to work with the DEA to resolve these issues. AMDA also extends the invitation for you or members of your staff to tour a long term care facility at your convenience.

AMDA would like to recommend the following solution:

AMDA believes that nurses should be viewed as the agent of the provider. This would continue to allow the important dialogue between the physician and nurse, which is essential for proper care and treatment. It also would allow for the necessary checks and balances regarding ordering, receiving, and administering controlled substances to the patients under our care. "Agent of the physician" is not a matter of an employment arrangement. Rather, it is a matter of a clinical relationship in a structure where nurses act as intermediary medical agents and are

employed by an organization that also verifies the credentials of the member physicians, has departments headed by a director of nursing, and has medical directors that provide oversight. Nursing facility nurses are similar to the hospital nursing staff, having progressed through the same training, and should receive the same considerations.

Thank you for your consideration of this serious problem. The optimal pathway to quality care for frail elders, vulnerable adults, and children is access to committed, knowledgeable, available physicians and nurses who provide the best care. I urge your immediate action to allow all of our patients to maintain access to needed medications. AMDA is ready to work with you in any way possible to deal with this pain management and care delivery crisis before it becomes a catastrophe.

American Medical Directors Association

Exhibit A

AMDA Exhibit A
Senate Special Committee on
Aging Hearing 3-24-2010

DANIEL HAIMOWITZ, M. D.
1 GARDENIA ROAD
LEVITTOWN, PENNSYLVANIA 19057
(215) 943-2222

Diplomate
American Board of
Internal Medicine

March 22, 2010

Gabriela Geise
Government Affairs Representative
American Medical Directors Association
11000 Broken Land Parkway - Suite 400
Columbia, MD 21044

Dear Ms. Geise,

I am writing to you concerning a problem I had with getting an elderly patient prompt, adequate pain medications. This problem was directly due to the new DEA enforcement policy.

A nurse in a nursing home called me about a newly admitted patient post hip surgery that had been on a controlled substance for pain management in the hospital. I was seeing patients in my office, so the nurse reported appropriate details from the hospital records, transfer records, complete nursing assessment, and the patient's self-reported level of pain. The patient was admitted for rehabilitation and was scheduled to start physical therapy. The patient's self-report of pain was 9 out of 10, indicating very severe pain. I was forced to order a lesser quality (non-controlled) pain medication to "hold the patient over" until the controlled substance would arrive. I did, in fact, fax in an order for the pain medication to the pharmacy, which is a large "hub and spoke" provider pharmacy out of state where orders get processed. Due to the emergency nature of the situation, I also tried to call the pharmacy's "800" number, but did not get an answer–as this is not like a local retail pharmacy. All of this occurred at approximately 12 noon.

The nurse at the nursing home did not know if I had faxed in the order or had been able to reach the pharmacy. This level of communication has been removed by the DEA's enforcement. This enforcement also would not allow the nurse to use stronger pain medications from the emergency box at the nursing home. At 1 a.m. in the morning, I received a call from the provider pharmacy to verify the faxed order for the controlled substance, 13 hours after it had been sent in. At 2 a.m. I received another call from the local pharmacy that would deliver the medication, once again verifying that I had faxed the order, before they would deliver the medication. It was now 14 hours after the nurse communicated that the patient was in a high level of pain!

The previous system, where the nursing home nurses faxed the orders directly into the provider pharmacy, never had resulted in such problems and medications were processed and delivered in a timely fashion. I hope you can provide some help to both me and my patients to rectify this most unfortunate situation.

Sincerely,

Daniel Haimowitz MD FACP CMD

Daniel Haimowitz, MD, FACP, CMD

AMDA Exhibit A Senate Special Committee on Aging Hearing 3-24-2010

Valley Medical Primary Care, Inc.

Meenakshi Patel, MD, FACP, MMM, CMD
Anton C. Vasiliu, MD, CMD
Gurjeet Kahlon, MD, CMD

6611 Clyo Road –Suite E
Centerville, Ohio 45459
(937) 2[illegible]-8282

Dear AMDA,

I wanted to share a story with you in regards to the regulations for Class II-Class V controlled substances.

One of my patients had an end-stage disease whose condition suddenly exacerbated. The patient's need for pain medication escalated. I ordered an increase in the amount of the pain medication to administer hourly, as it was clear the patient was in the last hours of their life. I knew the facility would run out of the controlled substance on hand, so I attempted to obtain more by complying with the DEA regulation. I was traveling between facilities and was unable to fax an order to the pharmacy. I attempted to call in the order, but it took her quite some time to reach the pharmacist.

By the time the order was processed and delivered, the patient had died and had spent the last hours of life in excruciating pain. Had the nurse in the facility been allowed to fax over the order, a system that has worked for us for over 30 years, this would not have occurred.

We are supposed to be protecting these frailest of our population. How did we get to a point where we have to comply with paperwork that results in sacrificing patient safety and comfort? A doctor's first charge is "to do no harm." These regulations cause us to go against that most basic of creeds

Sincerely,

Meenakshi Patel, MD, FACP, MMM, CMD

The War on Drugs Meets the War on Pain:

Nursing Home Residents Caught in the Crossfire

Statement for the Record

by

The American Association of Homes and Services for the Aging

For Submission to the

Senate Special Committee on Aging

March 24, 2010

American Association of Homes and Services for the Aging
2519 Connecticut Avenue, NW Washington, DC 20008-1520 | aahsa.org | 202.783.2242

Statement for the Record

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

The American Association of Homes and Services for the Aging (AAHSA) appreciates this opportunity to submit a statement for the record on the negative implications to nursing facility residents and hospice patients of efforts by the Drug Enforcement Agency (DEA) to enforce strict regulations under the Controlled Substances Act (CSA) regarding prescriptions for pain medications and other controlled substances.

The members of the AAHSA (www.aahsa.org) help millions of individuals and their families every day through mission-driven, not-for-profit organizations dedicated to providing the services that people need, when they need them, in the place they call home. Our 5,700 member organizations, many of which have served their communities for generations, offer the continuum of aging services: adult day services, home health, community services, senior housing, assisted living residences, continuing care retirement communities and nursing homes. AAHSA's commitment is to create the future of aging services through quality people can trust.

Although AAHSA's membership spans the continuum of long-term care, the majority of our members affected by the DEA's failure to recognize "chart orders" provide nursing facility (NF) and skilled nursing facility (SNF) care, either alone or in combination with other services. We, therefore, will focus our comments on the impact to the residents in these long term care facilities.

In short, the DEA's strict enforcement of outdated regulations does not comport with the realities of today's nursing home population and care practices. More importantly, the Agency's enforcement of these regulations is harming frail and elderly nursing home residents. The effect of the DEA's actions has been to force residents to wait hours—even days—to receive adequate symptom relief to treat pain, seizures, psychiatric and end of life symptoms, among others. The DEA's actions also pose a needless and potentially life-altering 'Catch-22' situation for facility nurses, who, when presented with a sick or dying resident in dire

need of pain relief, are faced with an untenable choice. These nurses must decide whether to risk their professional license by documenting and following the attending physician's verbal order and providing pain medication, or to comply with the DEA regulations by waiting for the written order to complete the journey from physician, to pharmacy, and back to the facility, thereby violating professional standards of practice and nursing home regulatory requirements regarding adequate and timely pain management.

I. The Nursing Facility Regulatory Environment

The nursing facility of today is a very dynamic care environment. Nursing facility admissions occur at all hours of the day and night, and on weekends. The trend toward increasingly shorter hospital stays has translated into frailer and more medically complex individuals being admitted to nursing facilities, many of whom are post-surgical and in need of immediate and ongoing pain relief to promote healing and rehabilitation. There are also residents for whom palliative care, in the form of pain relief at the end of life, is being provided by nursing facilities. In either case, access to adequate pain medication on a timely basis is critical to providing appropriate care and complying with regulatory mandates. The following discussion outlines the current regulatory requirements applicable to nursing facilities.

a. OBRA '87

The nursing home quality reform provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) enacted the most sweeping changes to nursing facility operations since the passage of Medicare and Medicaid. One of the most significant transformations resulting from the passage of OBRA '87 was the shift in focus of regulatory oversight from facilities' capacity to provide care and "paper compliance" with requirements, to actual resident outcomes; that is, the actual care provided.

OBRA '87 also placed nursing facilities in the unique position of the being the only health care provider to be mandated to guarantee specific resident or patient outcomes. Under requirements for both Resident Assessment (C.F.R. § 483.20) and Quality of Care (C.F.R. § 483.25), nursing facilities must "provide and assure that each resident receives the necessary care and services to attain and maintain [his/her] highest practicable physical, mental, and psychosocial well-being." Highest practicable physical, mental, and psychosocial well-

being is "determined through the comprehensive resident assessment and by recognizing and competently and thoroughly addressing the physical, mental or psychosocial needs of the individual."

The interpretive guidelines for these requirements (State Operations Manual, Appendix PP) states, "The facility must ensure that the resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process." This language not only assures that resident outcomes will be stressed as a measure of quality of care, but also places a clear responsibility on nursing facilities not just to maintain the status quo, but to act aggressively to improve residents' health status.

Historically, nursing facility populations have been largely comprised of the very frail and chronically ill. The complexities of caring for these individuals include the frequent occurrence of ongoing multiple conditions for which they are simultaneously being treated, and by the numbers of residents with cognitive impairment - estimated to be more than 70%.

Nursing facility residents are at high risk for experiencing pain that can impact and impair function, including mobility, mood, and/or their ability to sleep, all of which serve to diminish quality of life. The presence of concomitant multiple conditions can also result in simultaneous pain emanating from different causes. Common procedures, such as changing a wound dressing, moving a resident or physical or occupational therapies may also be painful for many residents. Because of the significant effect pain can have on a person's well-being, it is incumbent upon nursing facilities to recognize and address pain promptly.

Nursing facilities participating in the Medicare and/or Medicaid Programs must meet over 180 federal requirements, ranging from resident rights, quality of life and quality of care, to dining, and physical environment. Several of the federal regulatory mandates demonstrate existing and extensive safeguards and/or systems of checks and balances regarding the use, administration, documentation, oversight, storage, communications, and other accountability procedures related to medications. Included are requirements for Pharmacy Services (42 C.F.R. § 483.60); Drug Regimen Review (42 C.F.R. § 483.60(c)); Labeling, Storage of Drugs, Biologicals

(42 C.F.R. § 483.60(d)); Unnecessary Drugs (42 C.F.R. § 483.25(l)); Medication Errors (42 C.F.R. § 483.25(m)); Medical Direction (42 C.F.R. § 483.75(i)(2)-Medical Director); and Immunizations (42 C.F.R. § 483.25(n)).

Since 2001, the Centers for Medicare and Medicaid Services (CMS) has been engaged in an ongoing initiative to increase the accountability of both the survey process and providers by strengthening the investigative protocols and guidance to surveyors for several Long Term Care Facility Requirements of Participation. Among the guidelines subject to this review and revision by CMS and the respective expert panels were all of those related to pharmacy and medication services.

b. Pain Management

The most recent new or revised guidelines to be implemented, effective March 31, 2009, were those issued under 483.25-Quality of Care for *Review of a Resident Who has Pain Symptoms, is being Treated for Pain, or Who has the Potential for Pain Symptoms Related to Conditions or Treatments.* In accordance with these guidelines, facilities are mandated to "recognize when residents are experiencing pain and identify circumstances when pain can be anticipated; evaluate the existing pain and the cause(s), and manage or prevent pain, consistent with the [resident's] comprehensive assessment and plan of care, current clinical standards of practice, and the resident's goals and preferences." The intent of this protocol is to assure that "the facility has provided and the resident has received care and services to address and manage the resident's pain in order to support his or her highest practicable level of physical, mental, and psychosocial well-being . . . ."

The guidelines clarify the facility's responsibility to monitor the effects of interventions and modify the approaches as indicated; and to communicate with the health care practitioner when a resident is having pain that is not being adequately managed or is having a suspected or confirmed adverse consequence related to the treatment. The Requirements also mandate physician and other interdisciplinary involvement in pain management, i.e., that care be "provided in accordance with accepted professional standards of quality (42 C.F.R. § 483.20(k)(3)(i)) for pain management"; and that "care is provided by qualified persons." (42 C.F.R. § 483.20(k)(3)).

c. Existing Safeguards and Protections

Current safeguards exist to help identify medication issues. These include:

- The licensed consultant pharmacist performs at least a monthly medication regimen review for each resident and identifying any existing irregularities;

- The licensed pharmacist must establish a system of records of receipt and disposition of all controlled medications in sufficient detail to enable an accurate reconciliation;

- Facilities must have a system to account for "the receipt, usage, disposition, and reconciliation of all controlled medications;"

- Facilities must maintain records of the use and disposition of all controlled medications "with sufficient detail to allow reconciliation and must conduct and demonstrate periodic reconciliation of records of receipt, disposition and inventory for all controlled medications;"

- Facilities, in coordination with the licensed pharmacist, must assure safe and secure storage, limited access, mechanisms to minimize loss or diversion, and safe handling of all medications;

- Resident care must be supervised by a physician. The physician must provide and review the orders and total program of care on admission and review at each visit;

- Sufficient nursing staff must be maintained. Nursing must review medications when transmitting the orders to the pharmacy and/or prior to administering medications;

- The interdisciplinary team must review the medications as part of each resident's comprehensive assessment (Resident Assessment Instrument (RAI)) and/or care plan;

- Each resident's entire medication regimen must be managed and monitored to assure that only those medications clinically indicated are prescribed and received;

- The pharmacist is required to review prescriptions prior to dispensing; and

- Oversight must include observation of the preparation and administration of medications.

i. Pharmacy Services/Drug Regimen Review

The requirements for Pharmacy Services (42 C.F.R. § 483.60), mandate that a licensed consultant pharmacist perform a monthly medication regimen review for each resident (or more frequently depending upon the resident's condition), and identify any existing irregularities regarding indications for use, dose, duration, and the potential for/existence of adverse consequences or other irregularities, including the integrity of medication-related records (e.g., MAR, physician order sheets, telephone orders); and report any identified irregularities to the attending physician and director of nursing. The pharmacist's findings are considered part of each resident's clinical record.

ii. Controlled Substances

The applicable regulation regarding controlled substances provides that "[t]he facility must employ or obtain the services of a licensed pharmacist who establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled." (42 C.F.R. § 483.60(b)).

Interpretive guidance for the regulation further specifies facilities' responsibilities regarding the system to account for the receipt, usage, disposition, and reconciliation of all controlled medications. It must include, but not be limited to, "a record of receipt of all controlled medications with sufficient detail to allow reconciliation (e.g., specifying the name and strength of the medication, the quantity and date received, and the resident's name)." Facilities are permitted to store some controlled medications in an emergency medication supply box (E-box or E-kit) in accordance with state requirements. The facility's policies and procedures must also address the reconciliation and monitoring of this supply.

In addition, facilities must maintain records related to the use and disposition of all controlled medications "with sufficient detail to allow reconciliation (e.g., the medication administration record [MAR], proof-of-use sheets, or declining inventory sheets), including destruction, wastage, return to the pharmacy/manufacturer, or disposal in accordance with applicable State requirements." Periodic reconciliation of records of receipt, disposition and inventory for all controlled medications must be demonstrated "(monthly or more frequently as defined by facility procedures or when loss is identified). The reconciliation identifies loss or diversion of controlled medications so as to minimize the time between the actual loss or diversion and the time of detection and follow-up to determine the extent of loss. Because diversion can occur at any time, the reconciliation should be done often enough to identify problems. Some State or other federal requirements may specify the frequency of reconciliation." If discrepancies are identified during the reconciliation, the pharmacist and the facility must develop and implement recommendations for resolution. If the facility's systems have not been effective in preventing or identifying diversion or loss, guidelines directs the pharmacist and the facility "to review and revise related controls and procedures, as necessary, such as increasing the frequency of monitoring or the amount of detail used to document controlled substances."

iii. Labeling and Storage of Drugs and Biologicals

Facilities, in coordination with the licensed pharmacist, must assure safe and secure storage, limited access, mechanisms to minimize loss or diversion, and safe handling of all medications.

"Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable." (42 C.F.R. § 483.60(d)).

Facilities must "store all drugs and biologicals in accordance with State and Federal laws, in locked compartments under proper temperature controls, and permit access to the keys by only authorized personnel. Facilities also are required to provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when 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 C.F.R. § 483.60(e)).

iv. Nursing Services

Facilities are required to have sufficient nursing staff to provide nursing and related services, available on a daily basis, "to meet residents' needs for nursing care in a manner and in an environment which promotes each resident's physical, mental and psychosocial well-being . . . ." At a minimum, "staff" is defined as licensed nurses (RNs and/or LPNs/LVNs), and nurse aides. (42 C.F.R. § 483.30).

Facilities must provide services by sufficient numbers of licensed nurses and other nursing personnel on a 24-hour basis. Facilities "must designate a licensed nurse to serve as a charge nurse on each tour of duty" and must "use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week." Also, "[t]he facility must designate a registered nurse to serve as the director of nursing on a full time basis." Full-time is defined as 35 or more hours a week.

Nursing facilities are also required to post daily nurse staffing information in a prominent place, "readily accessible to residents and visitors" at the beginning of each shift. (42 C.F.R. § 483.30(e)). The posted information must include the facility name; the current date; the resident census; and the total number and the actual hours worked by licensed and unlicensed nursing staff directly responsible for resident care: registered nurses; licensed practical nurses or licensed vocational nurses (as defined under State law); certified nurse aides (CNAs).

v. Physician Services

Physicians attending to long-term care facility residents are obligated to review the resident's total program of care, including medications and treatments, at each visit; write, sign, and date progress notes at each visit; and sign and date all orders. (42 C.F.R. § 483.40).

With respect to emergency situations, there is no federal requirement for the onsite presence of a physician 24 hours per day. Rather, nursing facilities must provide or

arrange "for the provision of physician services 24 hours a day, in case of emergency." (42 C.F.R. § 483.40(d)). Most frequently, on-call emergency contacts are accomplished via telephone. If a resident's own physician is unavailable, the facility is directed to attempt to contact that physician's designated referral physician before assuming the responsibility of assigning a physician. Arranging for physician services may include assuring resident transportation to a hospital emergency room/ward or other medical facility if the facility is unable to provide emergency medical care at the facility. (42 C.F.R. § 483.40(d)).

vi. Unnecessary Medications

The Requirements at 42 C.F.R. § 483.25(l), Unnecessary Drugs, mandate that residents' drug regimen be free from unnecessary drugs. An unnecessary drug is any drug used in excessive dose or for excessive duration; without adequate monitoring; without adequate indications for use; or in the presence of adverse consequences.

Facilities also must ensure that residents "who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and that residents "who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs."

The intent of this requirement is that each resident's entire medication regimen be managed and monitored to promote or maintain the resident's highest practicable well-being; that residents receive only those medications, in doses and for the duration clinically indicated; and that if a medication regimen contributes to an unanticipated decline, it is recognized, evaluated, and modified. In accordance with the guidelines, the attending physician "plays a key leadership role in medication management by developing, monitoring, and modifying the medication regimen in conjunction with residents and/or representative(s) and other professionals and the direct care staff," i.e., the facility's interdisciplinary team. The facility is mandated to work in collaboration with the prescriber and the pharmacist. The facility's medical director collaborates with the facility to help develop,

implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.

vii. Medication Errors

The parameters for Medication Errors at 42 C.F.R. § 483.25(m), include "the observed preparation or administration of drugs or biologicals which is not in accordance with physician's orders; manufacturer's specifications (not recommendations) regarding the preparation and administration of the drug or biological; and accepted professional standards and principles which apply to professionals providing services; accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils."

II. The Nursing Home Operating Environment

Unlike hospital physicians, approximately 40% of physicians working in the long term care field do not maintain an office-based practice. Many work from their vehicles and do not have staff or a fully-equipped office. As a result, facility nurses play a vital role in communicating information to physicians about residents under their care, recording the physician's verbal orders, ensuring that those orders are carried out, and monitoring the resident's condition. For residents admitted to a facility following discharge from a hospital, the nurse is responsible assuring that the hospital's discharge orders are followed and contacting the resident's physician to obtain medication orders—hospitals do not provide individuals with prescriptions for medications if they are discharged to another institutional care environment. For existing residents of a facility, if an assessment of a resident indicates a change in the resident's condition possibly requiring a change in medication or other treatment, the nurse contacts the physician, usually by telephone, to describe the resident's symptoms, relay data such as vital signs, and provide whatever additional information the physician needs to make a treatment decision. In both cases, the nurse then records the physician's verbal order in the resident's clinical record, creating what is known as a "chart order," and makes sure that the physician's orders are acted upon (similar to the process that occurs in the hospital setting). Thus, if a physician orders a new drug or makes any change in a resident's medication regimen, the nurse creates and faxes the chart order to the long-term care

pharmacy for dispensing. Through this process, nurses ensure that medications are acquired on a timely basis to meet residents' changing and emergent medical needs. In such respects, the nurse is acting as the *de facto* agent of the physician.

Direct communication between the physician and the facility nurse is critical both to quality care and resident well-being, as well as compliance with state and federal regulatory requirements governing quality and timeliness of medical and pharmaceutical care. Failure to comply with regulatory requirements, including delays in notifying a physician of a change in the resident's status or in responding to a resident's needs can affect the facility's state licensure and federal certification status. Such delays place the resident at risk for rehospitalization and violate quality of care standards. If the failure to comply with a regulatory requirement causes actual harm to a resident, the facility could be fined, or even decertified, resulting in the loss of federal funding and, ultimately, closure.

III. The Controlled Substances Act and Its Implementing Regulations

The CSA became law in 1970, and regulates the manufacture, importation, possession, use and distribution of certain substances, which are organized into five schedules. The implementing regulations governing prescriptions for controlled substances followed shortly after enactment of the CSA and can be found at 21 C.F.R. Part 1306. Under these regulations, a valid prescription must be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. (21 C.F.R. § 1306.05(a)). Additionally, the prescription may only be communicated to a pharmacist for fulfillment by the individual practitioner, or an employee or agent of the individual practitioner. (21 C.F.R. § 1306.03(b)). In the case of Schedule II prescriptions for nursing facility residents, 21 C.F.R. § 1306.11(f) permits the practitioner or the practitioner's agent to transmit the prescription to the pharmacy by facsimile; however, the prescription must be signed by the prescriber in accordance with 21 C.F.R. § 1306.05. While nurses in hospital settings are considered by the DEA to be agents of the practitioner, the DEA has stated that nurses in long-term care settings are not agents of the practitioner. As a result, because chart orders do not meet the requirements of a valid prescription and nursing facility nurses are not agents of the residents' physicians, the DEA considers chart orders to be illegal.

The DEA's regulations provide that pharmacies may dispense controlled substances upon verbal orders in "emergency situations" as provided in 21 C.F.R. § 1306.11(d). The definition of "emergency situations" is the responsibility of the Food and Drug Administration (FDA), but the enforcement authority for 21 C.F.R. § 1306.11 in general is vested in the DEA. The DEA has so narrowly construed the emergency situation exception as to make it of little use to nurses who are faced with new residents whose hospital-administered pain medication has worn off, or existing residents who have experienced a sudden onset of acute pain or other condition requiring the administration of controlled substances.

Some argue that more physicians practicing in the long-term care environment would eliminate the delays caused by the DEA's strict enforcement of controlled substances regulations. That argument, however, is overly simplistic and unrealistic. The delays being experienced by providers are the result of outdated regulations and an overly complicated process for compliance. Further, long-term care simply has not been an attractive specialty for most physicians owing primarily to the inevitable age-related decline of the patients - for nursing facility residents, positive outcomes synonymous with "cure" can rarely be achieved. Even if incentives to encourage more physicians to practice in the long-term care field were implemented, it would be years before newly minted practitioners are able to accept nursing facility residents as patients. In the interim, nursing home residents pay the price in the form of unnecessary pain and suffering that cannot be treated in a timely manner.

IV. Conclusion – The DEA Must Recognize Chart Orders and Nurse as Agent

The delays that nursing home and hospice providers are experiencing in obtaining controlled substances prescriptions for their residents under the recent enforcement actions by the DEA are unconscionable. These actions, designed to reduce theft and diversion of Schedule II-V controlled substances, are instead resulting in sick and dying residents being left for hours—and even days—without adequate symptom relief to treat pain, seizures, psychiatric and end of life symptoms, among others. Such delays are resulting in unnecessary pain and suffering by the frail and elderly, and placing providers in the unfathomable position of having to choose between good clinical practice and complying with a mandate that is completely contrary to both their own mission and to the regulatory structure under which

they are certified to serve. The administrative barriers now faced by long-term care facilities to providing appropriate, timely, and effective pain relief represents a classic example of a breakdown in communications between federal agencies, leaving the residents and patients in the middle with little or no recourse.

As a result, AAHSA urges the Committee to support legislation designed to recognize "chart orders" and the functional role of nurses as the *de facto* agent of physicians whose patients reside in nursing facilities.

125 Airport Road ♦ Concord, NH 03301 ♦ (603) 226-4900

March 8, 2010

Congressman Paul Hodes
1317 Longworth House Office Building
Washington, D.C. 20515

Dear Congressman Hodes,

This letter comes to you from a State-wide network of elders called Seniors Aid New Hampshire (SANH). We are residents of long term care and independent living homes in New Hampshire. We come together via conference calls and occasional get-togethers to discuss issues that are very important to us as senior citizens.

One issue that holds the utmost importance to us is the Drug Enforcement Administration's (DEA) tightened interpretation of the Controlled Substances Act. This heightened enforcement of the rules involving doctors, pharmacies and nurses, and the strict controls of how pain medication can be delivered to us has resulted in unnecessary suffering and threatens our right to be pain-free.

We certainly agree with the DEA's desire to protect us by preventing drug-theft and abuse in our homes. However, the DEA is now interpreting the law in a way that prevents nurses and doctors from getting us the pain medication we need in certain emergency situations. By forbidding doctors from issuing verbal orders for pain medications during non-business hours, the DEA is effectively blocking our right to be pain-free.

Most of our homes do not have a pharmacy or a doctor in house. If doctors can't issue orders to in-house nurses over the phone, we are sometimes made to wait until the next day to obtain pain medication that we may need. The needless suffering caused when pain is not treated requires a lot of recovery time to 'catch up' and get it under control. No one should have to wait and suffer with pain that can be controlled with medication. We also cannot bear to hear a roommate who may be suffering from untreated pain. We find untreated pain to be unacceptable.

While the law needs to ensure that the system is working to make sure that there are proper controls on medications, something needs to be done to help meet our needs. Please help us recover our right to be pain-free as soon as possible. We appreciate your consideration and the time and effort that you put into fighting for our interests. Thank you very much for the hard work you do for all of us.

Sincerely,

The Members of Seniors Aid NH
C/O New Hampshire Health Care Association
125 Airport Rd.
Concord, NH 03301

125 Airport Road ♦ Concord, NH 03301 ♦ (603) 226-4900

March 8, 2010

Senator Jeanne Shaheen
520 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Shaheen,

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Sincerely,

The Members of Seniors Aid NH
C/O New Hampshire Health Care Association
125 Airport Rd.
Concord, NH 03301

Seniors Aid New Hampshire

- Seniors Aid New Hampshire (SANH) is a diverse group of residents who live in nursing homes, assisted living and independent living communities in all regions of New Hampshire.

- SANH formed in 2007 around a mutual interest in fighting hunger in New Hampshire. The group held its first annual fundraiser on behalf of New Hampshire Food Bank in February and March of 2008. Since that time they have raised more than **$60,000** for NH Food Bank.

- SANH members have expanded their interests and efforts to include participation in the legislative process and working directly with elected officials and key decision makers.

- In October 2009 and February 2010, SANH members held conference calls with Congressman Paul Hodes. They participated in lengthy question and answer sessions with Congressman Hodes, shared their concerns and asked his help on a variety of issues.

Issues:

- Among the issues that SANH members are interested in are:
    - "The right to be pain free" – DEA policy that blocks access to pain medication in certain scenarios.
    - The low $56 monthly "personal needs allowance" paid through the Medicaid program.
    - The impact of Medicaid and Medicare cuts on quality of life and staff reimbursement.

History:

- In 2006 the New Hampshire Health Care Association (NHHCA) held seven regional forums with nursing home and assisted living residents. The goal was to solicit direct resident feedback on what issues residents felt were crucial to improving their quality of life.

- Three primary topics emerged:
    - Residents want to be strong and autonomous.
    - Residents want to have the opportunity to do meaningful work.
    - Residents want the ability to communicate and work with their peers from all regions of the state.

- Working with their members, NHHCA set up a network with e-mail and conference calls to enable residents to share information and collaborate.

- Using the network, residents wrote letters to their peers around the state inviting them to join in projects. The first example of this was the fundraiser for NH Food Bank.

WWW.NCPANET.ORG

Statement of the

National Community Pharmacists Association

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

United States Senate Special Committee on Aging

March 24, 2010

THE VOICE OF THE COMMUNITY PHARMACIST

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Chairman Kohl, Ranking Member Corker, and Members of the Committee. The National Community Pharmacists Association (NCPA) is pleased to provide a statement for the hearing record on the impact of current DEA activities on the ability of community pharmacies to serve the medication needs of residents of long term care facilities, especially as it relates to the dispensing of controlled substances. We commend you for holding this hearing given the impact that these policies are having today on the quality of care being received by these individuals.

NCPA represents the interests of pharmacist owners, managers, and employees of more than 22,700 independent community pharmacies across the United States. NCPA has a strong interest in this issue because independent community pharmacies provide prescription drugs and related services to more than 50 percent of all long-term care beds in the United States.

DEA Enforcement Actions Impacting Resident Care

The DEA has recently started enforcing an interpretation of the Controlled Substances Act (CSA) that has made it more difficult to provide needed prescription medications to long term care residents in a timely manner. For years, it has been standard practice in long-term care facilities to allow the nurse to relay information between the physician and the pharmacist. For example, the nurse, acting as the physician's agent, may fax prescriptions for Schedule II-V substances written by the physician for a resident in a long-term care facility to the dispensing pharmacy. This delegation results in prompt patient care, which is particularly important in the context of pain management.

DEA's refusal to continue to recognize the long-established nurse-as-agent paradigm in the long-term care setting—as exists in the hospital setting—threatens the timely administration of critical medications used to treat residents' pain. In nursing homes, hospice, and other long-term care environments a physician is not always physically on site. As a result, nurses play a vital role in monitoring the resident's condition, communicating information such as vital signs to physicians, recording the practitioner's verbal orders, and ensuring that those orders are carried out.

Currently, long-term care facilities serve a resident population that is chronically ill with multiple concurrent disease states requiring medication treatment. The fragility of these residents requires the timely administration of medications. A resident's need for medications, including those used to treat severe pain, can arise at any time. The DEA has decided that Schedule III-V controlled substance prescriptions require a call between the pharmacist and the physician for a verbal order, while Schedule II controlled substances require a hard-copy prescription from the prescriber or, more often, a faxed copy thereof.

As a result, when the resident needs a pain medication in the middle of the night or on the weekend, two pathways are currently available under the law: 1) the nursing staff can contact the treating physician and ask the physician to authorize an emergency verbal prescription with the pharmacist for a Schedule II medication; or 2) the nursing staff can contact the treating physician who can then fax in an order for a new prescription to the pharmacy.

In the former case, once the nurse receives confirmation from the pharmacist that the physician phoned in the emergency order, she may remove the authorized medication from an emergency kit (if available) which contains non-patient specific medications and is stored at the long-term care facility. The burden then falls on the pharmacist to track down the prescribing physician to request a written prescription in order to fulfill the recordkeeping requirements of the DEA.

In effect, this creates a system in which pharmacists are reduced to threatening prescribers with DEA notification for noncompliance. On one hand, pharmacists risk damaging vital collaborative relationships if they report a physician to the DEA for failing to write the required prescriptions; on the other, they risk losing their right to practice pharmacy if they don't report noncompliant prescribers. This system is not in line with long-established practices in long-term care facilities and creates burdens that have the effect of limiting timely access to needed pain relief medications as well as straining the relationship between practitioners.

Importance of Chart Orders

Similar to the hospital environment, medical charts in the long-term care setting are used to record, monitor, and make necessary changes to a patient's medication therapy. "Chart orders" currently used in both the hospital and long-term care settings are an abbreviated form of prescriptions that are used to communicate the physician's directions for the patient to be carried out by the nursing staff. The nurse may record the physician's verbal order in the patient's clinical record, creating what is known as a "chart order", and makes sure that the physician's orders are acted upon.

Under current practice, if a physician orders a new drug or makes any change in a patient's drug regimen, it is the nurse's responsibility to create and fax the chart orders to the pharmacy so that the pharmacy can dispense the medication. Through this process, nurses ensure that medications are acquired in a timely manner to meet residents' changing and emergent medical needs.

However, in 2001, the DEA stated in a Federal Register notice that, "...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 long-term care facility nurse and the physician, this widely-used system is not in compliance with legal requirements."

DEA provided little notice and inadequate education for this change in policy, which does not easily flow from the traditional definition and use of the term "agency" in the healthcare context.

Further, this interpretation is not carried over to the hospital environment where nurses routinely practice as agents of the physician. Under 21 U.S.C. § 802(3): "The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser..." On its face, this definition, as used by the Controlled Substances Act, does not preclude the use of nurses not directly employed by physicians from acting as their agents (nurses acting as agents in hospitals are also not employed by the physicians with whom they work).

Conclusion

In the practice of long-term care pharmacy, any delay in providing a resident with needed pain medication places the resident in unnecessary discomfort and violates quality of care standards. The pharmacist thus faces the ethical and legal dilemma of not filling a prescription for a resident in pain and violating practice standards or violating DEA's interpretation of the Controlled Substances Act.

NCPA strongly urges that DEA immediately suspend actions against pharmacies that are trying to serve the legitimate needs of their long-term care residents. Then solutions such as registering facilities with the DEA, providing a comprehensive physician education program, and e-prescribing should be weighed. We cannot wait for a legislative or regulatory fix – which could take years. While we would want to work with Congress and the DEA on a permanent fix, an immediate solution is needed now.

NCPA stands ready to work with the DEA as well as our partners in the Quality Care Coalition for Patients in Pain on a solution. If DEA doesn't take action, Congress must ensure patients have access to needed medications via legislation to amend the Controlled Substances Act. Time is of the essence as current policies and DEA activity has caused needless instances of patient harm. DEA must act quickly to implement interim guidance addressing the "nurse as agent" issue until such time permanent changes can be achieved.

Thank you for the opportunity to submit this statement for the record.

Denise A. Barter, RPh, MBA, FASCP
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Operating a long-term care pharmacy as though we are serving the general public *for controlled substances* is creating an arena for mass confusion. History has proven that honoring a telephone order for a controlled substance, dispensing a short-term supply followed by a request to the physician for a prescription has worked well for all involved. The patient received medication that was intended by the physician in a timely manner and the order was verified through a signed prescription. In 27 years as a pharmacist I am not aware of even one incidence of diversion resulting from a nurse in a long-term care facility creating a false order for a controlled substance.

AHCA and Senior advocacy groups need to stand up for the rights of our elderly and disabled and put a stop to the dictatorship created by the DEA. There has been no intent in long-term care to create a situation for diversion, there has been no evidence presented to support this allegation from the DEA and there have been multiple cases where patient harm is documented.

The following are just a few cases that have actually occurred in the facilities I am associated with:

- A 12 year old developmentally disabled boy experienced a seizure. The physician instructed the nurse, via phone, to administer a rectal form of diazepam that was available in an emergency kit in the facility. The physician was told by the nurse that she could not access the medication unless he called the pharmacy to give permission based on the recent statements and fines levied by the DEA. The delay in medication administration resulted in a call to emergency services to transport the child to the hospital.
- A 72 year old female discharged from a hospital after having surgery for a broken hip, waited for 36 hours to receive pain medication because there was no order to access the emergency kit and no written prescription had been received.
- An 84 year old male with chronic bone pain was released from the hospital eight hours after his dose of pain medication was last administered. There was another 17 hours delay in getting his pain medication verified and a written prescription obtained. In the mean time the gentleman became combative and was given two doses of haloperidol injection. This is an antipsychotic medication with significant side effects. Once the patients' pain was treated there were no repeated combative episodes (followed for four weeks).

Long term care pharmacy procedures for controlled substances evolved in the 1980's based on the need and the desire for quality patient care: The patient was admitted to the facility, the primary care doctor verified the orders and the pharmacy dispensed a small supply of any CII narcotics and sent two prescriptions to the physician – one for the emergency supply and one to continue the order if so desired.

The situation that has been created through 1)the DEA's proclamation that the LTC facility nurse is NOT an agent of the physician, 2)that the physician must have verbal contact with the pharmacist before an 'emergency kit' can be accessed at the facility and 3)that the pharmacist must receive a verbal or written prescription from the physician prior to dispensing has created situations where the following has occurred:
1)Medication for pain management is delayed
2)re-hospitalization as a direct result of medication delay
3)Patient pain and suffering

4)Complete disregard and undermining of the responsibilities bestowed upon individuals licensed as nurses and pharmacists
5)Physicians must be personally available 24/7 (which is physically impossible due to the human requirement for sleep)
6)Extra expenses resulting from increased man hours and special deliveries
7)Multiple prescriptions being generated (which creates a situation for EASY diversion)
8)Multiple directions given due to the physician giving the order once to the nurse and then again to the pharmacist.
9)Large quantities of drugs being dispensed based on what the physician orders without regard to dispensing systems or patient needs. This creates an increased potential for diversion and increased expenses for medications which end up being destroyed.

The DEA has made a HUGE ethical error in the way they have approached the dilemma presented to them in LTC with total disregard to the human element and with no faith or trust in health care providers.

Respectfully submitted,

Denise A. Barter, RPh, MBA, FASCP
Consultant Pharmacist
Licensed in 1982

"Leading Our Profession in a Changing Health Care Environment"

March 22, 2010

Senator Herb Kohl
Chair, Senate Special Committee on Aging
G31 Dirksen Senate Office Building
Washington, DC 20510

Testimony from the Pharmacy Society of Wisconsin

The War on Drugs Meets the War on Pain: Nursing Home Residents Caught in the Crossfire
Hearing scheduled for March 24, 2010

Chairman Kohl and members of the Committee, thank you for conducting this hearing and for providing the Pharmacy Society of Wisconsin the opportunity to provide written testimony.

The Pharmacy Society of Wisconsin (PSW) is Wisconsin's professional association for pharmacists and pharmacy practices. PSW has over 2,000 members throughout the state. These pharmacy professionals work in a variety of practice settings; community pharmacies, health-system clinic pharmacies, hospitals, and long term care pharmacies among others.

To begin, PSW would like to thank Senator Kohl and the Committee staff, in particular Kristine Blackwood, for their attention to this issue. Recent enforcement action by the Drug Enforcement Administration (DEA) has greatly affected the practice of long term care pharmacy in the State of Wisconsin and our members have reported significant challenges in serving the needs of their patients living in skilled nursing facilities and other long term care settings.

PSW, on behalf of our members, would like to share with you four major areas of concern.

- Recent DEA enforcement action has resulted in additional "hoops" for healthcare providers to jump through in order to provide adequate pain control for patients.
- The DEA does not recognize the nurse working closely with patients in a skilled nursing facility as an "agent" of the physician.
- The DEA has failed to provide guidance to pharmacists and other healthcare providers about how to comply with their interpretation of the Controlled Substances Act (CSA) when serving the needs of patients in long term care facilities.
- Healthcare providers working in long term care are working to serve the needs of a more acutely ill population and recent DEA enforcement action has challenged long-standing best practices.

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- **Recent DEA enforcement action has resulted in additional "hoops" for healthcare providers to jump through in order to provide adequate pain control for patients.**

Healthcare providers working with patients in long term care facilities are caring for the needs of a diverse patient population, including patients recently discharged from the hospital post-surgical procedures. In addition, patient acuity can change in the middle of the night, creating an immediate need for pain or symptom control. The use of emergency kits or contingency supplies is essential in assisting patients whose acuity has changed or who are recently admitted. These patients do not have a supply of medication on hand to address their pain and symptom management needs and patient pharmacies can be closed or at a distance when medication is needed.

It seems unfair to patients to have to have all of our "ducks in a row" or all of the paperwork completed prior to providing adequate symptom relieve with a Schedule II – V medication. Shouldn't we treat the needs of the patient and follow this with paperwork? Current DEA enforcement emphasis seems to care more about the paperwork than the person.

PSW urges the DEA to engage in discussion with the Quality Care Coalition for Patients in Pain (QCCPP) to determine best practices to provide adequate symptom management to patients around the clock in long term care facilities while recognizing staffing concerns in various settings. PSW believes that adequate symptom control through the use of Schedule II – V medications can prevent expensive hospitalizations.

- **The DEA does not recognize the nurse working closely with patients in a skilled nursing facility as an "agent" of the physician.**

In the State of Wisconsin, physicians, through their medical practice act, are able to delegate patient care duties to trained staff through the use of a collaborative practice protocol. Under this delegation, nurses in clinics and hospitals routinely make assessments of patients and provide recommendations to physicians for their clinical evaluation. In addition, when ordered in a chart by a physician in a clinic setting, nurses routinely call or fax new medication orders to pharmacies. When controlled substances are prescribed in a clinic setting, nurses routinely call or fax Schedule III – V prescription orders to a pharmacist who will then prepare the prescription medication for the patient. Based upon our understanding, the DEA will allow this practice because the nurse, in this case, is in an employment relationship with the physician or clinic where the physician practices.

The practice of nurses faxing or calling in prescription orders for medications including Schedule III – V controlled substances not only occurs in clinic and hospital settings, but also occurs in long term care facilities. With recent DEA action in Wisconsin and other states, the DEA has indicated to healthcare providers that this is an illegal practice and constitutes nurse prescribing. Our understanding is that the DEA does not recognize the nurse as an "agent" of the presciber because the nurse at the long term care facility, in most cases, is not employed by the physician.

By requiring an arbitrary employment relationship to exist in order to serve as an agent of the prescriber/physician, the DEA is indicating that a secretary or custodian at a physician clinic is more qualified to transmit the orders of a physician to a pharmacy than a trained and licensed registered nurse, caring for a patient five days a week. We disagree with this policy.

PSW strongly supports the recognition of long term care facility nurses acting based upon a physician's or another prescriber's orders as agents of the physician/prescriber.

- **The DEA has failed to provide guidance to pharmacists and other healthcare providers about how to comply with their interpretation of the Controlled Substances Act (CSA) when serving the needs of patients in long term care facilities.**

Due to the lack of education and guidance from the DEA, pharmacists serving long term care facilities have had to spend countless hours educating and re-educating facility staff on the DEA's interpretation of current rules and regulations related to narcotic use and dispensing. In addition to educating facility staff, pharmacists are serving a role in educating other healthcare professionals discharging patients from hospitals to long term care facilities and other healthcare professionals caring for the long term care facility residents.

This task has proved particularly challenging due to a lack of communication from the DEA.

In their roles as educators and patient advocates, pharmacists have had to deflect anger, tension, and misunderstanding from other members of the healthcare team, including physicians, directors of nursing, medical directors and others.

In an effort to assist our members with understanding the DEA's current interpretation of the CSA and how pharmacists must work with other healthcare providers, PSW provided a two hour continuing education program at the PSW Senior Care Conference on March 17, 2010. This program included a panel presentation from national thought leaders on this issue. An invitation to the DEA to provide a presentation and serve as a resource on this panel was declined.

While pharmacists make every necessary step to work within the framework of the law, the added time and effort for the education, phone calls and prescription tracking takes away from their time to care for their patients. DEA must provide clarifications and education to assist healthcare providers in meeting the needs of their patients within the framework of the law.

- **Healthcare providers working in long term care are working to serve the needs of more acutely ill patients and recent DEA enforcement action has challenged long-standing best practices.**

Put simply, nursing homes are not what they used to be; they no longer care for a static population of elderly patients who are fairly stable. Nursing homes now are frequently admitting more acutely ill, frail elderly who have been transferred from the hospital still in need of considerable intensive care. Long term care facilities are caring for more patients only several days out from their knee and hip replacement surgery where good pain control is critical to participation in rehabilitation therapy. There are often times when facilities admit patients in need of immediate hospice services where prompt administration of pain medications provides significant comfort. Most people do not get sick during regular business hours and providing timely pain medications during the night and on weekends is difficult.

For these reasons, the practice of healthcare in long term care facilities has evolved along with patient need. Facilities have developed industry-wide best practices to provide prompt and high-quality care to this patient population.

The DEA's interpretation of the CSA has not evolved along with patient needs and is forcing pharmacists and other healthcare providers to operate using an "outpatient" model in an "inpatient" or institutional setting.

PSW strongly supports the use of best practices, similar to practices in hospital/inpatient/institutional settings to provide prompt and high quality pain and symptom management for skilled nursing facility patients.

Thank you again for providing the Pharmacy Society of Wisconsin the opportunity to provide written testimony for this important hearing. We would be happy to work with the Committee to further address questions about how recent DEA enforcement action is affecting the patients in our state. We also strongly encourage the Committee to continue to work closely with the Quality Care Coalition for Patients in Pain (QCCPP), of which PSW is a member, and Claudia Schlosberg on this issue.

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Senator Herb Kohl
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Dear Senator Kohl,
I would like to thank you for your work on advocacy to streamline the narcotic distribution process in nursing homes. As a pharmacist who has worked in long term care settings for over 7 years, I have personally dealt with the challenges the current regulation creates when trying to dispense medications efficiently and safely to patients in need.

Put simply, nursing homes are not what they used to be. We no longer care for a static population of elderly patients who are fairly stable. Nursing homes now are frequently admitting more acutely ill, frail elderly who have been transferred from the hospital still in need of considerable intensive care. We are seeing more patients only several days out from their knee and hip replacement surgery where good pain control is critical to participation in rehabilitation therapy. There are often times when we admit patients in need of immediate hospice services where prompt administration of pain medications provides significant comfort. Most people do not get sick during regular business hours and providing timely pain medications during the night and on weekends is difficult.

As the pharmacist at a long term care facility, I have spent countless hours educating staff at our facility on the DEA's interpretation of current rules and regulations related to narcotic use and dispensing; a task that has been challenging because of the DEA's lack of communication to pharmacies. There have been delays in providing pain medications to patients at our facility when prescriptions cannot be obtained from prescribers. As someone who truly wants to provide the best care possible for our patients, it is a very difficult decision to withhold pain medications in order to comply with current regulations. Because our facility accepts patients from many area clinics, hospitals and other facilities, I have educated social workers, nurses, physicians, pharmacists and other staff from those facilities as well. I have sent "Dear Physician" letters to doctors in four area cities at multiple clinics and hospitals to help facilitate understanding of DEA regulation. I have taken numerous phone calls and emails from others looking for my guidance on this issue; a role I believe the DEA should be playing. I am constantly working to keep colleagues informed on what the legal requirements are. While I take every necessary step to work within the framework of the law, the added time and effort for the education, phone calls and prescription tracking takes away from my time to care for the patients I am here to serve.

Again, I thank you for your continued attention to this issue and ask that you continue to advocate for a change in DEA policy. Thank you for the opportunity to share my experiences with you.

Sincerely,

Kristie Roller-Bauknecht

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