

**STATEMENT  
Of**

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**On Behalf Of**



**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**

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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collective concerns, as well as some real world examples of the negative impact that recent, stepped up enforcement of outdated rules and regulations is having on the patients we care for in my hometown of Menasha, Wisconsin.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## ***Enforcing Outdated Rules & The Negative Impact on Patients***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.<sup>1</sup> 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 US. Drug Enforcement Administration Rules Harm Patients in Nursing Facilities*. The QCCPP report, which is being released in conjunction with this

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<sup>1</sup>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.dea diversion.usdoj.gov/prog\\_descrypt/index.html](http://www.dea diversion.usdoj.gov/prog_descrypt/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<sup>®</sup> patch along with Percocet<sup>®</sup> 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 interfered 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 for 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 care 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.<sup>2</sup> 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

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<sup>2</sup> 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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