AMERICAN SOCIETY OF CONSULTANT PHARMACISTS

QCCPP the quality care coalition for patients in pain

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.

---

[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

[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

---

[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

---

[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

---

[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,

[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

[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

---

[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.

---

[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

[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

---

[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

---

[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

---

[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

[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)

**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. *

UNITED STATES DEPARTMENT OF JUSTICE
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, 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?