PATIENTS IN PAIN:
HOW U.S. DRUG ENFORCEMENT ADMINISTRATION RULES HARM PATIENTS IN NURSING FACILITIES
A SURVEY OF CLINICIANS
The Quality Care Coalition for Patients in Pain (QCCPP)

The Quality Care Coalition for Patients in Pain (QCCPP) is a multi-stakeholder coalition of health care professionals who provide care and treatment to patients in nursing facilities, including patients receiving hospice services in such facilities. QCCPP members include physicians, nurse practitioners, nurses, pharmacists, and professional administrators, non-profit organizations and providers serving frail, elderly nursing facility and hospice patients, patients with chronic illness, and post-acute patients with skilled nursing and/or rehabilitation needs. QCCPP seeks to ensure that nursing facility residents and others have access to appropriate and timely pain medication by (1) advocating to eliminate barriers to access resulting from laws, regulations and policies governing the prescribing and dispensing of controlled substances; and (2) promoting compliance and best practices by educating providers, prescribers, consumers and their caregivers about appropriate prescribing and dispensing practices.

For more information about QCCPP, please call Claudia Schlosberg, J.D., at 703-739-1316 ext. 128, or email qccpp@ascp.com. Information about QCCPP and its membership is also available at www.qccpp.org.
Current U.S. Drug Enforcement Administration (DEA) rules are creating obstacles to the effective, appropriate, and timely administration of medication to frail, chronically ill and dying patients in nursing facilities, including those receiving hospice care in such facilities. These rules are in conflict with current treatment guidelines and standards of practice and leave vulnerable, frail patients to struggle through unimaginable pain for hours and even days, while physicians, nurses and pharmacists struggle to collect required DEA paperwork. There is an urgent need to change DEA rules to avoid unnecessary pain and suffering among nursing facility patients.
EXECUTIVE SUMMARY

In 2009, the U.S. Drug Enforcement Administration (DEA) began auditing a number of long-term care pharmacies and nursing facilities to determine compliance with Controlled Substances Act (CSA) rules for prescribing and dispensing controlled substances to nursing facility patients. These audits identified differences between the standards for practice in long-term care – designed to ensure that patients receive timely and appropriate access to needed medications – and DEA rules intended to minimize the risk of diversion.

Nursing homes are required to meet federal standards for quality of care
The U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), regulates over 16,000 facilities that provide skilled nursing care to approximately 1.5 million frail, elderly and disabled Americans each year. Under these federal regulations, nursing facilities are required to provide patients with appropriate routine and emergency pharmaceutical care, based upon the prescriber’s order, in a timely manner. Further, every patient’s medical care must be supervised by a physician. Physicians visit their patients who reside in nursing facilities on a routine and as-needed basis, but are not always physically present in these facilities. As a result, medication and other treatment orders are frequently communicated to facility nursing staff by telephone. Further, few nursing facilities have on-site pharmacies; most contract with an outside pharmacy that specializes in serving long-term care facilities (LTC pharmacy).

Current practice and documentation
When a nurse receives a physician’s medication order over the telephone, she acts as the prescriber’s agent by documenting the order in the patient’s medical record and then transmitting it to the LTC pharmacy, most often by facsimile. The LTC pharmacy then dispenses the medication and delivers it, usually within a few hours, depending on the distance between the facility and the pharmacy. Nurses then administer the medication based upon the prescriber’s orders. Typically, LTC pharmacies also provide facilities with a small emergency supply of medications – including antibiotics and certain controlled drugs such as those used to treat pain, anxiety or seizures – that can be accessed in emergency situations. These emergency supplies are stored in a locked box or cabinet often referred to as an emergency kit or box (“E-box”) or contingency box (“C-box”). In an emergency situation
when the patient has an urgent need for medication, the nurse will consult a physician, usually by telephone, to obtain the prescriber’s orders, and based upon those orders, will secure the drug from the E-box and administer it to the patient. In this situation, the nurse again serves as the prescriber’s agent by carrying out the prescriber’s orders and ensuring that the patient receives the ordered treatment. This system is designed to meet patients’ needs and satisfy CMS quality of care standards.

DEA rules can leave sick and dying patients without effective treatment for pain

Existing DEA rules categorize nursing facility patients as outpatients (ambulatory care) even though nursing facilities are more like hospitals than doctors’ offices with respect to operations and oversight. Consequently, DEA requires physicians, nurses and pharmacists to take extra steps and produce additional documentation before a pharmacist is permitted to dispense a controlled drug for administration to a patient. This is because DEA does not recognize the critical role that nurses play in long-term care as the prescriber’s agent. Therefore, in an emergency situation, if the physician has given the nurse a verbal order for a controlled substance, the nurse is not permitted to remove the drug from the E-box until the doctor personally has either called or faxed a prescription order to the pharmacy and the nurse has called the pharmacy to confirm that the pharmacy has in fact received the doctor’s order. These additional steps can significantly delay and even deny patients needed treatment, leaving sick and dying patients without adequate symptom relief to treat pain, seizures, psychiatric conditions, and end-of-life symptoms, among others. Some reports indicate that patients have been left suffering for hours and even days as their caregivers struggle to comply with these and other DEA requirements.

Measuring the impact of DEA rules

To understand how and to what extent DEA rules are affecting patients in nursing facilities, the Quality Care Coalition for Patients in Pain (QCCPP) conducted a survey of physicians, nurse practitioners, nurses, pharmacists and other clinicians providing care to nursing facility patients. The survey questions focused on pain management because of the prevalence of pain in post-acute and chronic patients in long-term care and patients at the end of life, including those receiving hospice services, and because many medications used to treat pain are controlled substances.
Nearly 900 clinicians – 896 physicians, nurse practitioners, pharmacists, nurses and other clinicians from 46 states – participated in the QCCPP survey, which was conducted during September and October of 2009. Key findings include:

1. On the key question of whether clinicians are experiencing delays in getting controlled drugs to their patients, 65.4% of respondents answered in the affirmative. In Ohio, where DEA has been most active, 86% of respondents indicated that treatment was being delayed.

2. Delays in treatment vary in length. Among respondents who identified a timeframe, just 8% reported delays of up to one hour, while 40% reported delays of up to one day, another 40% reported delays of up to two days, and 12% reported delays of two or more days.

3. Thirty-one percent (31%) of all respondents and 43% of Ohio respondents indicated that there “has been a change in prescribing patterns for patients newly admitted to long-term care settings.” For existing patients, 26.1% of all respondents reported a change in prescribing patterns. Among Ohio respondents, 39% reported that prescribing patterns for existing patients had changed.

4. Reported changes in prescribing patterns include the use of less effective, non-narcotic drugs. Such drugs are often insufficient to control pain and increase the risk of adverse side effects in elderly patients.

5. Delays in treatment caused by DEA rules are forcing nursing facilities to send some patients back to the hospital for treatment and readmission. These practices are costly, difficult for the patients and completely avoidable.

6. Patients’ ability to participate in post-surgical rehabilitation is impeded, delaying their recovery and extending the need for skilled care.

7. Physicians, nurses, pharmacists and other clinicians working in long-term care report increased stress and tensions due to the inability to secure adequate and timely pain medications for their patients. These professionals report that they cannot comply with DEA rules and meet their professional obligations to patients or practice based upon established treatment guidelines.

8. Physicians, nurses, pharmacists and other clinicians also find that the DEA rules put them squarely in conflict with federal and state requirements establishing quality standards for nursing facility care. Some are questioning whether they can continue to practice in an environment where they are unable to provide appropriate care to their patients.

The survey results confirm that DEA rules are having a significant impact on the ability of practitioners to provide timely and appropriate treatment for their frail, elderly patients. The needless suffering of these patients calls for immediate action. Specifically, DEA must change its rules to recognize the essential role of nurses as agents of the prescriber in long-term care. As in hospitals, DEA also must acknowledge “chart orders” that represent the prescriber’s valid prescription drug orders. Steps must be taken to reach a more balanced regulatory framework that addresses the legitimate needs of law enforcement without causing harm to patients. Until then, the DEA must use its enforcement discretion to ensure that patients who need medications that are regulated by DEA are not denied adequate, appropriate and timely access to these drugs.
Under the Controlled Substances Act (CSA), the U.S. Drug Enforcement Administration (DEA) is responsible for enforcing the laws governing the prescribing and dispensing of narcotic and other controlled substances such as stimulants, depressants, hallucinogens and anabolic steroids. DEA rules, however, were written over 40 years ago and were designed to address ambulatory care environments where the prescriber sees the patient, writes a prescription and gives it to the patient to hand-carry to the pharmacy. The patient then gives the written prescription to the pharmacist who prepares and dispenses the drug. Existing DEA rules categorize nursing facility patients as outpatients (ambulatory care), even though nursing facilities are more like hospitals than doctors’ offices with respect to operations and oversight. Thus, DEA requires physicians and nurses to produce additional documentation before a pharmacist is permitted to dispense a controlled drug that can then be administered to a patient. For years, DEA did not actively enforce its regulations and acknowledged that its regulations are incongruent with the realities of long-term care prescribing and dispensing. In 2009, however, DEA changed its enforcement focus and began inspecting long-term care pharmacies and facilities, first in Ohio and later in Michigan, Wisconsin and Virginia. These pharmacies face potential penalties and millions of dollars in fines for practices that have been the standard of care in long-term care practice for decades. Growing concern among practitioners and clinicians in long-term care primarily stems from two issues:

DEA does not recognize the critical role of nurses in long-term care

Nurses play a vital role in long-term care by communicating patient information to practitioners, documenting all of the practitioner’s orders (e.g., orders for treatments, tests, medications, etc.) in the patient’s medical record and ensuring that the practitioner’s orders are implemented. When orders involve medications, it is the nurse’s responsibility to document the medication in the patient’s chart and transmit the “chart order” to the long-term care pharmacy for dispensing. These chart orders are most often transmitted to the pharmacy via facsimile.

For years, DEA did not actively enforce its regulations and acknowledged that its regulations are incongruent with the realities of long-term care prescribing and dispensing.
Although DEA rules explicitly permit a practitioner to rely on an “agent” to prepare and transmit prescription drug orders, DEA does not recognize any “agency” relationship between a practitioner and a long-term care facility nurse. In contrast to hospital settings, where DEA does recognize the nurse as the agent of the prescriber, or situations involving non-controlled drugs, this means that practitioners cannot rely on nurses in these long-term care settings to document their orders and transmit them to the pharmacy based upon their direct verbal orders. Pharmacists, in turn, may not dispense controlled drugs based on communications from the long-term care nurse in the nursing facility, but rather must receive all their orders directly from the physician. Unless an exception applies, these direct orders must always be in writing, and while they can be faxed to the pharmacy, only the prescriber or someone employed by the prescriber may do so. In emergency situations where verbal orders are permitted,¹ again only the prescriber or someone who is employed by the prescriber can communicate such orders to the pharmacy.

Outside of hospitals, DEA does not recognize chart orders

In long-term care, orders for all non-controlled medications are written into the patient’s medical record or chart, either by the prescriber or by the nurse acting on orders from the prescriber, usually on forms that allow the nursing facility to fax a copy directly to the vendor pharmacy. Once received by the vendor pharmacy, these orders are reviewed and the medications are dispensed and prepared for delivery to the facility. Notably, DEA permits hospital pharmacies to dispense controlled drugs based upon chart orders, but does not recognize chart orders when they originate from a nursing facility. Instead, in addition to the order that is on the patient’s chart, prescribers must prepare and sign paper prescriptions that may be faxed to the pharmacy. However, under DEA rules, only the prescriber himself or the prescriber’s agent (defined by DEA only as someone in the direct employment of the prescriber, such as the prescriber’s secretary, office assistant or nurse) can fax the prescription to the vendor pharmacy.

¹For controlled drugs listed as Schedule II substances, verbal orders are permitted only in “emergency situations.” Schedule III-V substances may be dispensed based upon the written, verbal or faxed order of the prescriber.
Changes in long-term care pharmacy practice in response to DEA

To comply with DEA rules and interpretations, long-term care pharmacies, nursing facilities and prescribers have to take additional steps to secure, prescribe, transmit and dispense a controlled drug for a patient in need in a nursing facility. For example, if a new patient is admitted to a nursing facility or a nursing facility patient has a change in condition, the nursing facility nurse cannot rely on the verbal telephone orders of the admitting physician to order pain medications from the pharmacy. Instead, regardless of the time of day or night, the physician also must prepare a written prescription drug order, find a fax machine and fax the prescription to the pharmacy.²

In emergency situations, where time is of the essence, nurses can no longer access medications stored in the nursing facility in the emergency drug box (“E-box”) based solely upon the physician’s verbal order. Rather, according to DEA, the nurse must contact the pharmacy to confirm that the pharmacy has received a valid written or verbal authorization from the physician. These additional steps can significantly delay and even deny patients needed treatment that has been ordered by the physician. If the nurse removes a controlled drug from the E-box to treat a patient experiencing pain based solely upon the physician’s direct verbal orders before confirming that the pharmacy has received the prescriber’s valid verbal or written prescription order, then according to DEA, she has taken the drugs without proper authority and is guilty of theft or drug diversion.

²According to the American Medical Directors Association (AMDA), which represents more than 8,000 medical directors, 40 percent of their members who are treating patients in nursing facilities do not have an office-based practice. Even those with offices are “on the run” most days, going from setting to setting. This means that in most instances, when a newly admitted patient requires pain medication, or when there is a change in a patient’s condition necessitating an adjustment to pain medications, the practitioner will not be near or have access to a fax machine.
INTRODUCTION

In 2009, the U.S. Drug Enforcement Administration (DEA) began auditing a number of long-term care pharmacies and nursing facilities to determine compliance with Controlled Substances Act (CSA) requirements for prescribing and dispensing controlled substances to nursing facility patients. The audits began in Ohio and as of December 2009, have expanded to include pharmacies and facilities in Michigan, Wisconsin and Virginia. These audits have identified differences between the standards for practice in long-term care – designed to ensure that patients receive timely and appropriate access to needed medications – and DEA rules, which are intended to minimize the risk of drug diversion.

CMS regulations and standards for quality of care

Nursing facilities are regulated by the Centers for Medicare & Medicaid Services (CMS), which establishes standards for quality of care for patients in nursing facilities. Under these federal regulations, nursing facilities are required to provide patients with appropriate routine and emergency pharmaceutical care, based upon the prescriber’s order, in a timely manner, and every patient’s medical treatment must be supervised by a physician. Physicians visit their patients who reside in nursing facilities on a routine and as-needed basis, but are not always physically present in these facilities. As a result, medication and other treatment orders are frequently communicated to facility nursing staff by telephone. Further, few nursing facilities have on-site pharmacies; most contract with an outside pharmacy that specializes in serving long-term care facilities (LTC pharmacy).

When a nurse receives a physician’s medication order over the telephone, she acts as the prescriber’s agent by documenting the order in the patient’s medical record and then transmitting it to the LTC pharmacy, most often by facsimile. The LTC pharmacy then dispenses the medication and delivers it, usually within a few hours, depending on the distance between the facility and the pharmacy. Nurses then administer the medication based upon the prescriber’s order. Typically, LTC pharmacies also provide facilities with a small emergency supply of medications – including antibiotics and certain controlled drugs such as those used to treat pain, anxiety or seizures – that can be accessed in emergency situations. These emergency pharmaceutical supplies are stored in a locked box or cabinet often referred to as an emergency kit or box (“E-box”) or a contingency box (“C-box”). In an emergency situation when the patient has an urgent need for medication, the nurse will consult a physician, usually by telephone, to obtain the prescriber’s orders, and based upon these orders, will secure the drug from the E-box and administer it to the patient.

3 Hereinafter, we will refer to an emergency supply of medications maintained in a nursing facility as an E-box.
DEA rules and delay of treatment for pain relief and other symptoms

The system as described is designed to meet patients’ needs and satisfy CMS standards for quality of care. However, DEA rules are different and require physicians, nurses and pharmacists to take extra steps and produce additional documentation. Generally, these additional steps must be completed before a controlled drug is dispensed and administered to the patient. For example, DEA does not recognize the critical role that nurses play in long-term care as the prescriber’s agent. Therefore, in an emergency situation, if the physician has given the nurse a verbal order for a controlled substance, the nurse is not permitted to remove the drug from the E-box until the doctor has either called or faxed a prescription order to the pharmacy and the nurse has called the pharmacy to confirm that the pharmacy has received the doctor’s order. These additional steps can significantly delay and even deny patients needed treatment, leaving sick and dying patients without adequate symptom relief to treat pain, seizures, or psychiatric conditions, and end-of-life symptoms, among others. Some reports indicate that patients have been left suffering for hours and even days as their caregivers struggle to comply with these and other DEA requirements.

To understand how and to what extent DEA rules are affecting pain management practices in nursing facilities, the Quality Care Coalition for Patients in Pain (QCCPP) surveyed practitioners and other health care professionals who care for nursing facility patients, from September 29, 2009 through October 27, 2009. The survey questions focused on pain management because of the prevalence of pain in post-acute and chronic patients in long-term care and patients at the 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. In hospice, pain management is a primary focus of care, and many patients require pain management throughout their course of hospice services.

As detailed in the following section, survey results show that DEA activities are significantly affecting the ability of these professionals to provide timely and appropriate pain treatment to their patients.

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OBJECTIVE AND METHODOLOGY

Given the enormous potential negative impact on nursing facility patients of delaying necessary pain medication, QCCPP wanted to document:

- how compliance with DEA rules is affecting patients’ access to medications
- if strict adherence to DEA rules is delaying treatment
- whether such delays are significant enough to adversely affect the quality of patient care
- how prescribers were responding to changes in workflow required by DEA rules and interpretations
- whether prescribers were changing their prescribing practices to avoid the use of controlled drugs for both new and existing patients

Finally, we were interested in collecting narrative information from nurses, pharmacists and prescribers to gain further insight into the impact of DEA rules on patient care.

The QCCPP survey team developed survey questions (see Appendix) that were then disseminated through various professional associations to nurses, pharmacists, prescribers and other health care professionals practicing in long-term care facilities and hospice. The survey questionnaire was accessible from September 29, 2009 through October 27, 2009.

Figure 1
Respondents by Profession

<table>
<thead>
<tr>
<th>Professional Title</th>
<th>Percentage</th>
<th>Responses</th>
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</thead>
<tbody>
<tr>
<td>Director of Nursing</td>
<td>17.9%</td>
<td>160</td>
</tr>
<tr>
<td>Medical Director</td>
<td>17.4%</td>
<td>156</td>
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<tr>
<td>Pharmacist</td>
<td>17%</td>
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<tr>
<td>Nurse Practitioner</td>
<td>12.6%</td>
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<tr>
<td>Nurse (RN/LPN)</td>
<td>10.5%</td>
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<tr>
<td>Program Admin</td>
<td>10.3%</td>
<td>92</td>
</tr>
<tr>
<td>Other</td>
<td>14.3%</td>
<td>129</td>
</tr>
</tbody>
</table>

Please identify the professional title of the person completing the survey and the type of facility or services provided.

The vast majority (77.2%) of respondents to the survey were employed in or providing services to a nursing facility.

QCCPP received a total of 896 responses from 46 states. (See Figure 1 and Figure 2).

Figure 2
Respondents by State

<table>
<thead>
<tr>
<th>State</th>
<th>Responses</th>
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<td>WISCONSIN</td>
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<td>WYOMING</td>
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What state are you located in?
The largest number of respondents came from Ohio, the state in which DEA has been most active.
NATIONAL SURVEY RESULTS: NURSING FACILITY CLINICIANS SPEAK OUT

Over 65% of respondents reported that they are experiencing delays in getting controlled drugs to their patients. (See Figure 3). Major areas of concern for clinicians are new admissions from hospitals and situations in which existing patients experience a change in condition, especially during weekends and outside of regular business hours.

New admissions present challenges for nursing facilities because hospitals typically do not send hard copy prescription drug orders for patients who are being discharged to nursing facilities. Rather, the standard of practice is for the hospital to send a formalized transfer form that includes a comprehensive and up-to-date listing of orders for the patient’s care, including medications. Prior to DEA’s recent stepped-up enforcement activity, the facility nurse would verify the hospital orders with the patient’s physician, transcribe the physician’s orders, document them in the patient’s chart, and then fax a copy of the patient’s chart order to the pharmacy. Upon receipt of the faxed chart order, the pharmacy would dispense the medications to the facility for administration to the patient. Now when controlled substances are ordered, nursing facilities must either try to get the hospital to send hard copy prescriptions or contact the attending physician for emergency verbal orders.

Are you experiencing any delays in getting controlled drugs to your patients?

In Ohio, where DEA has been most active, 86% of respondents indicated that treatment was being delayed. Further, in Ohio, the length of reported delays ranged from 6 hours to four days, with the average reported delay being 24 hours.
Nurses within the facility report that obtaining hard copy prescription drug orders from a hospital for a newly admitted patient is not as simple as it sounds. Survey respondents write of “endless rounds of calls between nursing, office and provider/back-up pharmacy, all with potential for error.” A key reason is that doctors are not always available or able to immediately respond to pages, especially after hours and on weekends. For example, one respondent told of a situation involving a patient discharged from a hospital with orders for controlled drugs to treat both pain and anxiety. As is typical, the hospital physician did not write out paper prescriptions. When the nurse in the nursing facility tried to contact the hospital physician, she was told that he had left for the day. The nurse then contacted the facility’s “house” physician, but he declined to write the order, as he had never seen the patient and did not know her history. He suggested the nurse contact the hospital physician. Eventually, the nurse was able to obtain a written prescription for her patient, but by that time the pharmacy had already made its routine delivery to the nursing facility. As a result, the patient’s medication was delayed until the pharmacy was able to make a special delivery to the nursing home.

As the respondent reported, this was but one incident, but as is clear from the numbers of similar incidents reported, it is by no means isolated. Another respondent writes:

“\text{The time required to get the order, communicate to the pharmacy, have the physician called, have the pharmacy call back and give the OK for the E-box or stat drop the medication can be upwards of four (4) hours. That does not take into consideration [that] the last time [the patient] received pain control was three hours prior to leaving the hospital. That leaves the patient at risk for seven (7) plus hours.}”

Another respondent reports:

“We got a new admission at 6:30 pm and did not receive authorization to pull a pain pill from the E-box until 1:30 am. The [patient] waited 7 hours for a pain pill.”

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Even shorter delays are deeply troubling to staff and family members. In another case, the respondent reported that it took almost two hours to process the faxed paperwork to get authorization for the nurse to access a medication in the facility’s E-box for a new admission who had just had surgery to repair a hip fracture. The respondent reported, “the [patient] and his family were very upset with us for the delay but under the new [procedures] it was out of our control.”

Regarding the delay in obtaining signed prescriptions, another nurse writes:

“In the meantime, the patient is in pain and desperately looking to the nurse for treatment. We have standing orders for such pain relievers as Tylenol®, but for someone with cancer, bone pain, post surgical pain, Tylenol is not effective. There has to be a better way to serve those entrusted to our care.”

“There has to be a better way to serve those entrusted to our care.”

New orders for existing patients, especially after hours and on weekends and holidays, are also delayed because of the DEA mandates. “Our doctors respond quickly,” wrote one respondent, “but after hours, and on weekends and holidays, they are usually out of range of a fax machine.”

One doctor writes:

“As a physician who has only a long-term care practice and travels most days of the week, the office staff must track me down at various sites to fax the hard copy for signature. … This is all done, I believe, to prevent diversion of narcotics. The end is not achieved by this process and patient comfort and care is compromised.

The time involved in obtaining signed prescription orders is complicated by the fact that patients may see more than one physician, especially if they are transitioning between care settings. Also, when a patient’s physician is unavailable, on-call physicians are reluctant to write prescriptions for controlled drugs for patients they do not know personally. As one respondent writes, “If the patient comes without a legal prescription, it is very difficult to get the required documentation, e.g., who do you contact? Some hospitalist at the transferring facility or the attending doctor who may not have even seen the patient yet? And good luck trying to get hold of either after 5 pm when most transfers get to the [nursing facility].”
Another respondent writes:

It has become more than bothersome for the attending physicians. When [the patient’s] “usual” physician is not the original “prescribing” doctor, that causes a problem, as is the case when the attending [physician] is not on call or off for the day – the doctor on call doesn’t want to attach their license and signature to a prescription for a [patient] that they have never met before. The weekends are a real issue because most physicians do not have a fax machine at their house and are not readily available for us to get their signatures on the weekends. …

Likewise, another respondent writes:

[Obtaining medications] is especially problematic with admissions/readmissions. Often [patients] do not come with prescriptions for such medications and if they do, the hospitalist, [physicians and nurse practitioners] do not provide scripts that meet all of the criteria for [the drugs] to be dispensed. We are reliant upon trying to get in touch with the already busy attending physician to get either a script or verbal authorization so that the patient’s needs may be met in as timely a manner as we can. Depending on the time of day and who is on call, this can add to the challenge.

Survey respondents consistently identified delays that were attributed to the need to comply with additional paperwork even when the physician’s intention clearly has been communicated to the nurse and the nurse has a valid physician order to administer the medication. One pharmacist writes:

[I] am unable to obtain properly completed written or faxed CII-V narcotic prescriptions in a timely manner and am unable to dispense needed pain medications although the intent of the prescribing physician is clear. It takes up to one hour for one pharmacist to contact a physician to write/fax a needed prescription for one medication for one patient. Meanwhile, the patient is suffering.
Physicians view the DEA rules as additional steps that are both unnecessary and time consuming, taking them away from caring for their patients. One physician notes:

Adding an additional step of direct communication between the prescriber/pharmacist in addition to the required communication between the prescriber and facility nurse is detrimental to patient care and the time required does cause delays in getting medications to the patients. This is time that the prescriber could be spending on patient care. … Verbal communication is not always possible since both individuals are dealing with other patients. This has added a lot of time to the workday of both the prescriber and the pharmacist.

Nurses, too, are spending more time securing the required paper documentation and verbal authorizations and less time on patient care. To secure the signed prescription orders for the pharmacist, one respondent reported that she is driving to the doctor’s office and personally picking them up. She writes:

This takes away the support I provide to my staff. Instead of assisting them and monitoring programs, I am now driving all over to pick up prescriptions. Instead of a nursing supervisor, I am turning into a delivery person. This is absurd and damaging to the facility and can be harmful to the [patient] if they cannot get the needed medication right away.

**Experiences of dying patients**

Dying patients have not been spared from the impact of the new procedures. One respondent identified 14 instances in which therapeutic medications to control pain were delayed 8 to 24 hours while efforts were made to contact physicians and obtain prescription orders that comply 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. One respondent noted:

[In] one case in particular, I watched a hospice [patient] suffer with respirations above 35 due to our inability to get her Roxanol™ to the facility on time. The medication got here one hour after she passed away.

Another respondent told of her experience:

One of my 101-year-old [patients] made the choice for comfort care and agreed to take a Duragesic® patch and Roxanol. But there was confusion between the nurse, pharmacist and covering physician in getting these meds in a timely
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manner. She ended up dying without any comfort medications. This really hurt me
a lot. I never encountered issues with the previous method, but these new [procedures]
are killing our time and contributing to
lapses in care.

Similarly, another nurse reports:
We had a [patient] dying and we
could not fill her prescription in a
timely frame. The [patient] died in fear,
gasping for air, crying and screaming, as were the family members and staff. [There is]
no excuse for anyone to have to die this way!

Another respondent expressed her concerns about dying patients as follows:
Patients and their families do not understand the regulations that we must follow
for controlled substances. All they know is that their loved one is dying, is in pain
and their medications aren't delivered yet. There has got to be a better way to care
for the patients without jeopardizing my license if I don't follow the letter of the law.

Another respondent writes:
[It is] unspeakable and inhumane that someone suffered in their last hours because
we could not give a verbally ordered medication that we had on-hand in our contingency box.

Patients needing controlled medications for non-pain-related symptoms
It is important to recognize that controlled drugs are used to treat symptoms other than pain.
Respondents identified patients with psychiatric symptoms and need for access to medications
to control seizures. In one case, the respondent reported:
We had a nurse try to delay giving Ativan® for a [patient] having an active seizure
for fear of DEA. She delayed giving the medication until the pharmacy relayed
that the physician had been spoken to and had given the O.K. This clearly
illustrates lack of understanding by DEA and other government agencies of the
level of care our patients require. Not to mention how quickly their status can change. …
Respondents’ anger and frustration is palpable:

God help the poor patient seizing uncontrollably, while the Valium® remains safely locked in that damn[ed] [E-box] until a properly authorized and signed [written] order arrives.

Impact on prescribing practices

To understand how the DEA rules are affecting prescribing practices, the survey asked two questions. First, we asked whether there has been a change in prescribing patterns for newly admitted patients, and second, whether there has been a change in prescribing practices for existing patients. (See Figure 4 and Figure 5). Responses to these questions indicate several disturbing trends.

First, doctors are hesitating to write prescriptions for controlled drugs. Second, patients are being prescribed non-controlled drugs that are not as safe and do not adequately control their symptoms. According to one commenter, “Many physicians have switched [to non-controlled drugs] so there is not a delay in the patient receiving medications.”

Doctors responding to the survey confirmed that they are moving patients from controlled to non-controlled drugs to avoid a delay in treatment. One physician writes, “I feel that physicians are being ‘forced’ to order non-controlled drugs because they know the medication will be available much quicker for the patient.” Another explains, “I have to change patients to non-controlled drugs; otherwise they would have no pain medications.” A third physician writes, “Because of the need for writing out a new monthly prescription, there is clearly an

Figure 4
Change in Prescribing Patterns for Newly Admitted Patients – All Respondents Compared to Ohio

Has there been a change in prescribing patterns for newly admitted patients?

Among all respondents, 31% answered affirmatively, while 69% answered in the negative. Among Ohio respondents, 43% answered affirmatively, while 57% answered in the negative.
incentive to treat with non-narcotic medication. Some of the time that I would spend giving direct patient care is now taken up by completing paperwork for medications that I have already approved and prescribed in the [patient’s] physician order sheet.” A fourth physician admits, “I’m using more non-scheduled drugs for pain, probably pushing the limit on acetaminophen more frequently.”

The increased utilization of non-narcotic drugs to avoid the delays associated with prescribing controlled medications is leaving patients without adequate pain control. For example, one respondent writes:

I often see patients with chronic malignant and nonmalignant pain where opiates would normally be prescribed and where they had been switched to around-the-clock acetaminophen or PRN tramadol. Pain management suffers and the patient ultimately suffers suboptimal pain control, poor quality of life and avoidable consequences of immobility (bedsores) from lack of appropriate pain medication.

Another respondent adds, “Ibuprofen, tramadol, etc., are not sufficient to control pain for these patients. Therapy is delayed and recovery prolonged due to inadequate pain control that may take days to re-establish after getting the additional signed RX needed.”

Has there been a change in prescribing patterns for existing patients?

Among all respondents, 26% said yes, while 74% answered in the negative. In Ohio, 39% answered affirmatively, while 61% answered in the negative, suggesting that DEA’s focused efforts in Ohio are having a greater effect on providers, facilities and patients.

Responses to the survey indicate disturbing trends.
First, doctors are hesitating to write prescriptions for controlled drugs.
Second, patients are being prescribed non-controlled drugs that are not as safe and do not adequately control their symptoms.
Inadequate pain medication leaves patients in pain and severe discomfort. In one case, a respondent described a patient who was being treated with Vicodin® for pain as a result of a fracture. After leaving the hospital, the patient was able to receive only extra-strength Tylenol until a prescription could be obtained for stronger medication. The patient was reduced to tears for over an hour. The respondent writes, “For those of us having to watch a [patient] in pain unnecessarily, it is very frustrating.”

Several respondents reported that substituting tramadol or Tylenol for Vicodin or Percocet® is becoming common practice. One respondent reported that this is occurring in 75% of admissions. Another respondent reported that nine times out of 10, patients are being admitted to nursing facilities with inadequate pain control.

In addition to providing inadequate pain relief, increased use of tramadol and Tylenol can increase risks to elderly patients. For example, one respondent notes that many patients in nursing facilities are taking an SSRI antidepressant. Taking tramadol with an SSRI may increase the potential for an adverse drug interaction and result in “serotonin-syndrome (SS).” Another respondent noted the concern with increased use of NSAIDs in the elderly because of decreased renal function.

A case example reported by another respondent illustrates these concerns:

We had a patient discharged from the hospital where they were using IV morphine and changed to a weaker opioid with dangerous directions and possible acetaminophen toxicity. Patient had radiation burns and was in extreme pain when being rolled in bed by staff. As a result, she asked the staff not to move her. This could only lead to more problems with care, such as pressure ulcers. Something needs to be done soon to address this issue so that health care providers provide the care that we are all trained to do and know how to do.

Yet another respondent comments, “Many physicians are trying to use high doses of acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs) or tramadol or combinations instead of more potent scheduled agents. These drugs are often ineffective and increase risk of adverse effects including hepatic damage, renal failure and seizures.”

“Some of the time that I would spend giving direct patient care is now taken up by completing paperwork for medications that I have already approved and prescribed in the [patient’s] physician order sheet.”

“Nine times out of 10, patients are being admitted to nursing facilities with inadequate pain control.”
Increased hospital readmissions due to DEA rules

Without the ability to provide adequate pain control, a number of respondents reported that patients had to be readmitted to hospitals for pain management. Needless transitions to and from acute care settings can be difficult and even dangerous for frail, elderly patients. For example, an older female patient with cancer and a bone metastasis was being treated with morphine. However, when the nursing facility was unable to obtain morphine on a timely basis because of DEA rules, she was sent back to the hospital. The respondent notes that she was at the nursing home for less than eight hours. In another case, a gentleman with liver failure was transferred back to the hospital, again because the nursing facility was unable to obtain his pain medications on a timely basis.

Another respondent reports that a newly admitted patient, who was dying and in pain, could not receive her pain medication because the physician had been unable to return the pharmacy’s call seeking confirmation of his verbal orders. The patient was admitted at 2:00 pm and was in severe pain and without pain medication until 8:00 pm, when the family took the patient out of the facility. The respondent did not know if she was taken home or moved to another facility.

Negative impact on care providers

Healthcare professionals are deeply concerned about the impact of DEA rules on their ability to provide adequate care to patients. (See Figure 6). The need to comply with DEA rules...
for prescribing and dispensing controlled drugs and the resulting delays place nursing facilities and health care providers in conflict with their professional responsibilities and personal values. Respondents feel like they are being targeted for trying to provide good care to patients. For example, a nurse writes:

I think this has been taken to an extreme that is truly unfair to the [patients]. Many of these [patients] are waiting for pain medications for two and three days because of these rules. [These rules] need to be looked at more closely. The abusers of the system are the people who should be punished, not the elderly that need the medication for pain relief.

A pharmacist adds:

I have been a pharmacist for 25 years and [it] is killing me to see these patients suffer because of a misguided law. Fix the problem. We are all not drug dealers; we are trying to take care of the elderly we serve. They deserve better.

For some, the inability to provide adequate treatment may drive them away from treating patients in long-term care. This is especially concerning given the already serious shortage of physicians willing to practice in this setting. As one doctor emphasizes:

This has to change. Even after doing this for a month the system is cumbersome, slow and patient-unfriendly. I will continue to practice in LTC but the more regulations that [are] added on, the more of my colleagues who drop out. Currently, for the four LTC facilities in our area (approx. 375 beds total) we have less than a half-dozen providers willing to follow patients. This will never be a full-time practice for me, but I can’t keep up an office practice, have a life and follow 375 LTC patients. I currently am the medical director for 2 facilities: one close to my office and one at the other end of the county. I love this work but I can’t continue to spend time doing work which adds no value to patients’ quality of life and is eating up all of my time.

“I have been a pharmacist for 25 years and [it] is killing me to see these patients suffer because of a misguided law. ... They deserve better.”
Delay in dispensing and administering pain medications also is increasing stress and tensions among already strained health care professionals. In addition to the pain and suffering of the patient, one respondent writes that there is increased animosity toward the pharmacy “as the facilities believe that we are causing the problem.” Another wrote about the stress of dealing with angry family members and feeling helpless to relieve her patients’ pain:

Families and [patients] become upset when their loved one is not provided pain medication in a timely manner. Some [patients] have voiced complaints that it takes too long to get their pain medication. But I also do not like my nurses feeling helpless in relieving the pain and suffering of their [patients]. Some of these [patients] have serious diagnoses and need their pain medication [on a] timely [basis]. We cannot be sure they were given medication prior to their discharge from the hospital. So when they say they are in pain, we believe them.

Another respondent wrote:

During the weekend that I worked recently, I was informed of a patient who had gone without pain medication for four days because we, in the pharmacy, could not send it without a written prescription. That patient had a decubitus ulcer the size of an adult hand on his buttocks and screamed in pain while wound care was done. For four days, he did without pain relief that a pain medication could have provided.

The need to comply with DEA requirements for prescribing and dispensing controlled drugs and the resulting delays placed on nursing facilities and health care providers also places them at risk for violating quality of care standards established under federal and state law.

Wrightes one respondent:

Our facilities are required by federal and state governments to adequately control our [patients’] pain. How can we possibly do this with the stringent requirements by the DEA on narcotics? We aren’t like hospitals that have doctors and pharmacies at their
disposal 24/7. Our doctors don’t [perform] round[s] daily or even weekly. … Then the requirement is that they sign extra scripts at their offices when they don’t even have the [patients’] charts in front of them. The [patients’] charts are in the nursing facilities. … This is just another example of paper pushing that impedes our ability to take care of our [patients] adequately.

Another respondent writes:

Unlike a hospital with a pharmacy available 24/7, we are reliant upon delivery from a pharmacy 2 hours away. After the last delivery in the evening, we are unable to obtain meds if not in the [E-box]. I am responsible to the state to provide pain control that is effective and this regulation seems to be in direct conflict with the regulation I must follow as a Nursing Home Administrator. We are in a Catch 22 and the patients are the ones who suffer.

Another respondent simply wrote, “We as care providers cannot stand by and watch our [patients] suffer needlessly.” Finally, one respondent summed up the situation this way:

So really it comes down to which federal law or mandate we violate. It is a no-win situation for pharmacy providers and SNFs. Whether it is violating federal DEA law about the technicalities of processing a legitimate controlled substance order from a prescriber or violating CMS Survey Guidelines by being noncompliant with the timely delivery of an emergent medication for pain that directly results in patient hardship and discomfort. We cannot hope to comply with them both under the current manifestations of the laws and mandates involved. Federal law regarding controlled substances needs to change to reflect the year 2009 and the information age we live in.
DISCUSSION: DEA'S IMPACT ON PATIENT CARE

These QCCPP survey results clearly identify that DEA rules are causing harm to frail, chronically ill and dying nursing facility patients who require narcotic medication for pain and other symptoms. The survey results illustrate that attempts by physicians, pharmacists and nurses to strictly adhere to DEA rules are impeding the timely administration of narcotic medications to treat patients who are in pain or who are experiencing other symptoms in nursing facility settings. Patients are being left undertreated or untreated for hours and even days, while health care providers struggle to contact physicians and obtain paperwork to confirm the prescriber’s verbal orders. The survey also shows an increase in the inappropriate substitution of non-narcotic drugs, leaving patients with inadequate pain relief and increasing their risk of adverse drug events. The inability of physicians, nurses and pharmacists to provide patients with appropriate pain relief in long-term care settings also is leading to increased hospital readmissions. Physicians, nurses and pharmacists, unable to meet their patients’ needs, are increasingly frustrated and angry. The need to comply strictly with DEA rules is resulting in suboptimum care and places providers in conflict with their obligations to their patients. Some are openly questioning their ability to continue to practice in an environment in which they are unable to provide their patients with timely, appropriate treatment.

Today’s nursing home population: older, sicker, frailer

The impact of the DEA rules is especially disturbing given the patient population in long-term care today. Over the years, the role of nursing facilities has changed significantly. Today, the nursing facility population is older, sicker and significantly frailer than historically was the case. The major patient groups populating today’s nursing facilities include post-acute patients admitted after a relatively brief hospital stay, long-term residential patients who have multiple chronic medical conditions and serious limitations in functional capacity, and hospice patients who, by definition, have less than six months to live.

Regardless of length of stay or reason for admission, the majority of nursing facility patients experience medical instability, multiple complications, fluctuating conditions, and diverse co-morbidities (coexisting diseases and risk factors), and many experience pain.
Within the nursing facility setting, over a quarter of all patients are receiving pain medication, and medications for pain management are the second most commonly prescribed products. For hospice patients, pain management is a primary focus of care, and many patients require pain management throughout their course of hospice services.

**Current guidelines for pain relief**

Current practice guidelines for treatment of persistent pain in older adults, published by the American Geriatrics Society (AGS), recommend the use of opioids for moderate to severe pain to avoid the risks associated with NSAIDs. NSAIDs, especially in higher doses and long-term use, are strongly discouraged in the elderly due to the high risk of GI bleeding, as well as kidney toxicity and liver dysfunction that can have permanent effects. In the elderly, NSAIDs are responsible for more than 107,000 hospitalizations and 16,500 deaths annually.\(^5\)

For the treatment of post-operative pain, best practice and evidence-based practice recommendations include low-dose narcotics, specifically oxycodone, to mobilize patients as soon as possible to avoid adverse effects associated with immobilization and to reduce mortality and morbidity. Transitioning to rehabilitative care or sub-acute care without the continuation of these scheduled medications can lead to increased mortality in six months and permanent loss of function, leading to long-term nursing facility placement.\(^6\) Thus, DEA rules that discourage the use of opioids in older patients are in conflict with current treatment guidelines.

It is also well documented that the failure to adequately treat chronic and acute pain leads to further health complications, behavioral problems, social isolation, depression, poor nutrition, increased mortality and morbidity and higher health costs. Further, because pain is easier to control when it is mild than when it is severe, any delay in treatment can lead to further complications. According to a recent Mayday Fund report, “A Call to Revolutionize Chronic Pain Care in America: An Opportunity in Health Care Reform,” chronic pain affects an estimated 70 million people and is a greater health problem and burden than diabetes, heart disease and cancer combined.


IMPACT ON PATIENT CARE

Failure to treat chronic pain is also inhumane. The Joint Commission (formerly JCAHO) has now officially recognized that pain is a major health problem and “patients have the right to appropriate assessment and management of pain.” (JCAHO, 2000)

DEA rules that discourage the use of opioids in older patients are in conflict with current treatment guidelines. So important is pain management for older adults that recent federal guidelines defining quality of care standards for long-term care facilities make clear that the failure to provide timely and appropriate pain management to patients constitutes substandard quality of care. In January 2009, the Centers for Medicare & Medicaid Services (CMS) released revised interpretive guidelines and investigative protocols for pain management. One of the most significant additions to the interpretive guidelines includes new pain management guidelines that focus on the facility’s recognition, evaluation, and management of pain in patients who have pain, are being treated for pain, or have the potential to have pain symptoms. If a pain management concern is identified, surveyors are encouraged to evaluate other related F-Tags, including F-Tag 425 to determine if the medications required to manage a patient’s pain were available and administered as indicated and ordered at admission and throughout the stay. A facility’s failure to provide adequate and timely pain relief can result in substantial fines and penalties and can lead to de-certification as a Medicare and Medicaid provider.

Failure to treat chronic pain is inhumane. The Joint Commission (formerly JCAHO) recognizes that “patients have the right to appropriate assessment and management of pain.”

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7 F-Tag 309 in Appendix PP of the State Operations Manual (SOM)

CONCLUSION: NOW IS THE TIME FOR ACTION

The survey results demonstrate that DEA rules create insurmountable obstacles to the effective, appropriate, and timely administration of medication to frail, elderly, chronically ill and dying patients and are in conflict with current treatment guidelines and standards of practice. DEA neither recognizes the long-term care nurse as the agent of the prescriber nor acknowledges the validity of a physician’s order reduced to writing in the patient’s chart. As a result, vulnerable patients struggle through unimaginable pain for hours and even days, while physicians, nurses and pharmacists struggle to collect the required DEA paperwork.

We must find a way to achieve a more balanced regulatory framework that addresses the legitimate needs of law enforcement without causing harm to patients.

The needless suffering of these patients calls for immediate action. Specifically, DEA must change its rules to recognize the essential role of nurses as agents of the prescriber in long-term care. As in hospitals, DEA also must acknowledge “chart orders” that represent the prescriber’s valid prescription drug orders. We must find a way to achieve a more balanced regulatory framework that addresses the legitimate needs of law enforcement without causing harm to patients. Until this more balanced framework is established, the DEA must use its enforcement discretion to ensure that patients who need medications that are regulated by the DEA are not denied adequate, appropriate and timely access to these drugs.

Until this more balanced framework is established, the DEA must use its enforcement discretion to ensure that patients who need medications that are regulated by the DEA are not denied adequate, appropriate and timely access to these drugs.
1. Please identify the professional title of the person who is completing this survey.

- Pharmacist
- Medical Director
- Director of Nursing
- Attending Physician
- Nurse Practitioner
- Physician Assistant
- Nurse (RN)
- Nurse (LPN)
- Facility or Program Administrator
- Social Worker
- Discharge Planner
- Other (please specify)

2. Please identify the type of facility or services being provided.

- Hospital
- Hospice (in-patient)
- Hospice (in the home)
- Home Infusion
- Pharmacy (dispensing)
- Pharmacy (consulting)
- Home Health
- Skilled Rehabilitation Services
- Skilled Nursing Facility/Nursing Facility
- Other (please specify)

3. What state are you located in?

4. Are you experiencing any delays in getting controlled drugs to your patients?  
(If yes, please detail specific situations in the text box below.)

- Yes
- No

5. Has there been a change in prescribing patterns for newly admitted patients (for example, patients being admitted with Tylenol® or tramadol instead of a controlled drug that they were taking up until discharge)?  
(If yes, please detail specific situations in the text box below.)

- Yes
- No

6. Has there been a change in prescribing patterns for existing patients (e.g., resident who was in pain was being managed on a controlled drug but has been changed to a less effective non-controlled drug)?

- Yes
- No
7. Are you concerned about your ability to ensure that patients are able to receive timely, adequate pain relief or other symptom control (e.g., seizures, psychiatric, end of life, etc)?
   Please provide additional details below if needed.
   Yes  No

8. Please use this space to provide additional information about actual patient experiences or any other comments you wish to share.

9. Name and telephone number of contact person (Optional)
   Please note that we are asking each survey respondent to voluntarily identify a contact person to allow us to follow up in case we have any questions regarding the survey responses or need additional information. However, providing the name and telephone number of a contact person is entirely optional. All answers to this survey will be aggregated with the results of other respondents and no information will be released or made available that would identify a particular facility, its residents or the identity of the contact.
QCCPP’s membership has grown to over 120 member organizations and individuals representing pharmacists, physicians, nurse practitioners, long-term care nurses and others. To join QCCPP or to obtain more information, go to www.qccpp.org.