Prescription Drug Abuse Hits Hospitals Hard
Tighter Federal Steps Aim to Deflate Crisis

Stephen Barlas

“P
rescription drug abuse affects hospital practice in
ways you wouldn’t have predicted five years ago,” says
David W. Jungst, RPh, PharmD, BCPS, Director of
Pharmaceutical Care Services at Sarasota Memorial Hospital
in Florida. His comment underlines the fact that hospitals and
their pharmacy departments are, in many ways, at the epicenter
of the prescription drug-abuse tsunami. Drug abusers arriving
in the hospital’s emergency department (ED) with an overdose
and others with infections from needles must be admitted as
inpatients. As a result, he writes in an e-mail, his
hospital faces challenges it never faced before:

A lot of people come in dying in front of us, not from
the drug but from the infection. They have great pain
and nasty wounds that require surgery. You have to
find something to treat the pain, but you must also find
a way to get them off the drugs so we can send them
home safely. It then becomes problematic as to how to
handle the discharge plan.

Sarasota Memorial has a “pain team” composed of repre-
sentatives from the nursing and pharmacy staffs. It meets
each day to discuss problematic patients. A medical director
oversees the team.

“The challenge is to give these patients enough medication
to manage their pain—but not enough to feed their addiction,”
Dr. Jungst says. A component of that effort is an unwritten
agreement between the physician and the patient that lays
out the “end game.”

He adds, “Sometimes there is not a good answer. Some
[doses] are titrated down to zero. Others will never get off
narcotics because their ongoing pain issues are quite amazing.”

The growing influx of prescription drug abusers creates a
burden not only for Sarasota Memorial but also for hospitals
everywhere, particularly in urban areas. David Seaver, RPh,
JD, Risk Manager at Brigham & Women’s Hospital in Boston,
says, “I believe all hospitals with emergency departments are
wary of drug-seeking patients who describe pain complaints
in hopes of being prescribed pain meds. We do worry about
abuse and diversion.”

Earlier this year, New York City Mayor Michael Bloomberg
announced that the city’s 11 public hospitals would no longer
provide more than 3 days’ worth of narcotic painkillers such
as hydrocodone/acetaminophen (Vicodin, Abbott) and oxyco-
done/acetaminophen (Percocet, Endo) to patients arriving in
the ED. Oxycodone (OxyContin, Purdue Pharma) and fentanyl
would no longer be dispensed, period.

The conundrum for hospitals and their pharmacists, of
course, is that they are at the back end of the prescription
drug-abuse epidemic. The problem doesn’t start with them, but
it most often ends with them. It is the physicians at pain clinics,
or sometimes the pharmacists at retail pharmacies, who often
unintentionally put patients on the road to an ED crash or to
an inpatient stay after the patient is laid low with cellulitis or a
heart-valve infection. That is the genesis—apart from the black
market—of the oversupply of Class II and Class III opioids,
particularly oxycodone and hydrocodone.

In June, Tom Frieden, MD, Director of the Centers for
Disease Control and Prevention (CDC), decried the widespread
treatment of aches and pains with narcotics. In an interview, he said:

These are dangerous medications, and they should be
reserved for situations like severe cancer pain. In many
other situations, the risks far outweigh the benefits. Prescribing an
opiate may be condemning a patient to lifelong addiction and life-threatening complications.

It is not surprising, then, that the Obama adminis-
tration, which issued a drug-abuse action plan in 2011, is using
regulatory agencies to attempt to crack down on physician-
owned and physician-run “pill mills” and the pharmacies that
support them. The Drug Enforcement Administration (DEA),
the FDA, and the Centers for Medicare & Medicaid Services
(CMS) are all in the process of either implementing or con-
considering changes in policy meant to retard prescription drug
abuse. Some past efforts have borne fruit, but there is still
plenty of work to do.

That was evident from testimony and questioning from repre-
sentatives and senators in two congressional hearings in June,
one in the House and the other in the Senate. Representative Joe
Pitts (R-Pa.), Chairman of the House Subcommittee on Health,
emphasized: “It is abundantly clear that the prescription drug
abuse epidemic is a crisis in the U.S.”

Opioid pain relievers, such as Vicodin and OxyContin, are
members of the largest class of abused prescription drugs, fol-
lowed by stimulants for treating attention-deficit/hyperactivity
disorder (ADHD), such as amphetamines (e.g., Adderall, Shire)
and methylphenidate (Ritalin, Novartis; Concerta, McNeil) and
by central nervous system depressants for relieving anxiety, such as
diazepam (Valium, Roche) and alprazolam (Xanax, Pfizer).

The words “epidemic” and “crisis” get thrown around quite
a bit in this debate on Capitol Hill and elsewhere. However,
some voices are seizing on occasionally malleable statistics and
argue that the crisis may be abating.

H. Westley Clark, MD, JD, MPH, Director of the Center for
Substance Abuse Treatment, testified before the House health
subcommittee hearing on June 14:

“Recent data indicate that the rate of nonmedical use (of
prescription drugs) declined slightly between 2010 and 2011
and suggest that national, state, and local efforts to reduce

Mr. Barlas, a freelance writer based in Washington, D.C., covers
topics inside the Beltway.
prescription drug misuse may be beginning to have an impact."2

Dr. Clark’s center is part of the Substance Abuse and Mental Health Services Administration (SAMHSA), which is the keeper of statistics on nonmedical use of prescription drugs by individuals 12 years of age and older who either do not have a prescription in their own name or do have a prescription, obtained fraudulently, so they can get “high.” SAMHSA conducts the National Survey on Drug Use and Health (NSDUH). According to 2011 survey data, nonmedical prescription drug use ranked as the second most common class of illicit drug use in the U.S. The survey found that 1.9 million people 12 years of age or older had initiated nonmedical use of prescription pain relievers in the preceding year. Dr. Clark, however, did concede that with an average of about 5.7 million people age 12 or older, having misused prescription drugs between 2005 and 2011, “there is still much work left to be done.”

No one would disagree with him. For example, according to the latest estimates from the CDC, prescription opioid drugs were involved in 16,650 overdose deaths in 2010; this represents a 31.3% increase over the previous decade. CDC Director Frieden, in his June press conference, presented some of the latest CDC findings: fatal prescription painkiller overdoses among women have increased 400% since 1999 and are rapidly closing the drug death gender gap. (The increasing rates of opioid dependence in women are discussed in this month’s closing the drug death gender gap. (The increasing rates of opioid dependence in women are discussed in this month’s...)

The House health subcommittee hearings focused on what more the federal government could be doing to stem the tide. In 2011, the Obama administration released the Prescription Drug Abuse Prevention Plan. It focuses on four major pillars, each designed to intervene at a critical juncture in the process of diversion and abuse:

- education for prescribers, patients, and parents
- prescription drug–monitoring programs (PDMPs)
- proper medication disposal
- effective enforcement

But all those pillars have cracks, to a greater or lesser extent. The state-based, mostly voluntary PDMPs have numerous limitations, including flagging federal funding, a refusal of physicians and pharmacists to use them, and data shortfalls. The National All-Schedules Prescription Electronic Reporting Act of 2005 (NASPERS) created a grant program administered by SAMHSA for states to implement or enhance PDMPs. SAMHSA received NASPERS funding from Congress in fiscal years (FYs) 2009 and 2010 and provided 26 grants to 14 states. In FYs 2011, 2012, and 2013, Congress did not appropriate funding for NASPERS. However, SAMHSA did fund PDMPs in FYs 2012 and 2013 to the tune of $3.5 million per year by using funds from other programs.

State PDMPs collect, monitor, and analyze scheduled or controlled prescription drugs, with the goal of preventing prescription drug misuse and abuse and illegal diversion. Forty-six states operate PDMPs. Three states (Georgia, New Hampshire, and Maryland) have enacted legislation to establish PDMPs but do not yet operate them, and one state (Missouri) and the District of Columbia have not enacted legislation. Unfortunately, these PDMPs are not connected to the electronic health record (EHR) systems that are used by physicians (which undermines their effectiveness), nor is one state’s PDMP connected to another state’s PDMP. Therefore, it is possible for physicians and pharmacies to move across borders and restart illicit businesses without being detected, at least initially.

Massachusetts has an interactive PDMP. Brigham & Women’s David Seaver reports: “A clinician has to complete a form, and the state will enter you into the system. The Board of Medicine is entering all MDs into the system passively when they renew their licenses. That is new. The Board of Pharmacy is not doing the same service for pharmacists.”

Physician and pharmacist registration with the Florida PDMP is only voluntary, complains Representative Kathy Castor (R-Fla.), who described some of the holes in that state’s system at the House health subcommittee hearings. Florida, of course, has been home to all sorts of illegal pain clinics, some of which are connected to illicit and even legitimate pharmacies.

“I’m concerned that physicians and pharmacists are not using the Florida database,” she said at the House hearings. “The state has not made a long-term commitment to make the database work.” She added that only 10% of the pharmacists in the state use the database.

Despite shortcomings in Florida’s PDMP, the state has seen improvements in its prescription drug-abuse record. For example, in 2010, the DEA’s Automation of Reports and Consolidated Orders System (ARCOS) reported that 90 of the top 100 physicians in the nation who purchase oxycodone were located in Florida. The number of Florida doctors appearing in that nationwide list dropped from 90 to only 13 in 2011. Today the DEA is happy to announce that no Florida doctors are on this list; this is a result of the DEA’s intensive enforcement efforts in that state, directed at both illicit physician-owned pain clinics and pharmacies, some of which might have been unwitting accomplices of these pain clinics.

In 2009, the DEA’s Miami Field Division introduced the Tactical Diversion Squad in Weston, Florida. Investigations by the squad are focused on rogue pharmacies, doctors, and pain clinics. Since then, the squad has expanded to Tampa, Orlando, and West Palm Beach.

The DEA’s efforts in Florida have embroiled CVS and Walgreens pharmacies as well as Cardinal Health. In June, Walgreens signed an $80 million civil settlement with the DEA—the largest in the agency’s history—regarding rules violations that allowed tens of thousands of units of powerful painkillers (such as oxycodone) to wind up illegally in the hands of drug addicts and dealers. Mark R. Trouville, Chief of the DEA’s Miami field office, said that Walgreens committed numerous record-keeping and dispensing violations of the Controlled Substances Act at a major East Coast distribution center in Jupiter, Florida, and at six retail pharmacies within the state. The drugs also included hydrocodone and alprazolam. The settlement further resolves similar open civil investigations in the District of Colorado, the Eastern District of Michigan, and the Eastern District of New York, as well as civil investigations by DEA field offices nationwide, pursuant to the Controlled Substances Act.
Whereas the DEA has achieved successes in enforcement, the CMS has had much less to brag about. That was clear from testimony presented in the Senate Homeland Security and Government Affairs Committee on June 24. Gary Cantrell, Deputy Inspector General for Investigations (OD) at the Department of Health and Human Services (DHHS), said:3

Prescription drug diversion is a complex crime that can involve many co-conspirators. Drug distributors and traffickers, health care professionals, drug-seeking patients, and pharmacies may all play a role, and criminal enterprises are becoming an increasing presence in prescription drug diversion.

Mr. Cantrell discussed a number of investigations that the Office of Inspector General (OIG) had conducted concerning Medicare Part D reimbursements; some of these focused on ineligible prescribers, such as massage therapists, athletic trainers, and dental hygienists. In an investigation of 10 states, the OIG found almost 350,000 scripts written by ineligible prescribers. Part D paid $26.2 million for these drugs. In addition, tens of thousands of drugs ordered by individuals without prescribing authority were controlled substances, Mr. Cantrell explained.

Jonathan Blum, Acting Principal Deputy Administrator and Director at the CMS, acknowledged at the Senate hearings:4

The growth of prescription drug abuse has touched providers, pharmacies, and beneficiaries in the Part D program. Part D plan sponsors can manage the benefit only at the beneficiary level, because they do not have access to Part D prescriber and pharmacy data beyond the transactions they manage for their own enrollees, which makes it more difficult to identify prescribers or pharmacies that are outliers in their prescribing patterns or are filling patterns relative to the entire Part D program.

A report published in 2011 by the Government Accountability Office (GAO) found 19 examples of potential egregious overutilization of medications by Part D beneficiaries who were obtaining opioid medications from multiple prescribers; the vast majority of these beneficiaries were receiving medications from five to 10 health care providers in 2008.5 Through discussions with the industry, the CMS determined that Prescription Drug Plan (PDP) sponsors need to adopt more effective concurrent and retrospective drug utilization review (DUR). The CMS, through its final calendar year 2013 Call Letter and subsequent guidance, outlined an approach to reduce potential opioid overutilization in the Part D program. Under this approach, Part D insurance plans would ensure that safe dosages are dispensed through the improved use of concurrent claim edits and formulary utilization management design. The CMS’s guidance clarified that sponsors should analyze cases of unsafe cumulative dosing that DUR programming has identified through patterns that suggest potential overutilization of drugs.

Besides requiring PDP’s operating within Part D to step up internal review of opioid use, the CMS also put in place a new requirement that forces Part D sponsors to submit Prescription Drug Event (PDE) Payment Reports with an active and valid individual prescriber national provider identifier (NPI) beginning January 1, 2013. Starting on May 6, 2013, the CMS began to deny all PDE claims without an active and valid individual NPI PDE Payment Reports detail for every prescription filled, as follows:

- the amount paid by the Part D sponsor
- the pharmacy’s and health care provider’s identification numbers
- the beneficiary
- a description of the drug, including the dosage and amount

Pharmacies also sometimes contribute to Medicare prescription drug abuse. In a 2009 study, the OIG pointed out that Medicare Part D inappropriately paid $25 million for Schedule II drugs billed as refills.6 Federal law prohibits the refilling of Schedule II controlled substances. A new prescription authorizing the pharmacy to provide the drug is required each time a Schedule II drug is dispensed.

That restriction is one of the reasons that the FDA is considering recategorizing hydrocodone-combination drugs (such as Vicodin) as Class II controlled substances instead of the current category of Class III. The DEA has the final decision, but the FDA’s recommendation is a necessary preliminary step. An FDA Advisory Committee voted 19–10 earlier this year to recommend rescheduling hydrocodone-combination products (containing an analgesics or an antitussive) from Schedule III to Schedule II. As defined by the DEA, Schedule II controlled substances are those that “have a high potential for abuse which may lead to severe psychological or physical dependence.” Representative Schedule II products include morphine, oxymorphone, methadone, meperidine (Demerol, Hospira), oxycodone, and fentanyl.

Schedule III controlled substances are those that “have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.” Examples of Schedule III narcotics include buprenorphine and combination products containing less than 15 mg of hydrocodone per dosage unit.

Opinion within the pharmacy industry differs on the wisdom of reclassifying hydrocodone-combination drugs as CII. Rescheduling the painkillers would add another layer of regulations for manufacturers and pharmacies, as well as more extensive recordkeeping and tighter security. Some organizations, such as the American Society of Consultant Pharmacists (ASCP), oppose the move.

“ASCP believes a schedule change may impede medication access, putting patient care at risk while increasing health care costs,” says ASCP President Sean M. Jeffery, PharmD, CGP.

The American Society of Health-System Pharmacists (ASHP) supports reclassification. Christopher J. Topoleski, ASHP Director of Federal Regulatory Affairs, says:7

ASHP recognizes that moving hydrocodone-containing products to Schedule II will make it more difficult for clinicians to prescribe and for patients to obtain these therapies. However, we believe that the current processes associated with dispensing these therapies as Schedule III controlled substances may be contributing to abuse due to the lack of accountability and other safeguards.

Of course, oxycodone products are already Schedule II drugs, and that designation has not prevented them from being

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abused. That is why the FDA has tried to encourage drug companies to come up with abuse-deterrent formulations of opioid pain medications. In January, the agency issued draft guidance about the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies will be evaluated by the FDA, and which labeling claims may be approved based on the study results. Public meetings are scheduled for September 30 and October 1, 2013.

The FDA also recently took regulatory actions regarding two opioid products, oxycodone (OxyContin) and oxymorphone (Opana ER). These drugs were reformulated to make them more difficult to manipulate for purposes of abuse.

On April 16, 2013, the FDA approved updated labeling for Purdue Pharma’s reformulated OxyContin describing its abuse-deterrent properties. The reformulated version was originally approved in April 2010. Four months later, Purdue Pharma took “original” OxyContin off the market. The FDA says that it will not approve any new generic versions of original OxyContin.

On May 10, 2013, the FDA determined that the original formulation of Opana ER had not been removed from the market for reasons of safety or effectiveness, because the available evidence was insufficient to conclude that the original formulation had an increased potential for abuse compared with reformulated Opana ER. Although reformulated Opana ER has the capability of being more crush-resistant than the original formulation, study data show that the reformulated version’s extended-release features can be compromised when it is subjected to other forms of manipulation, such as cutting, grinding, or chewing, followed by swallowing. As a result, the FDA says it will not take steps to remove existing generic versions of the original formulation from the market and will continue to approve such generics as long as they meet all applicable requirements. (In July, for instance, Actavis received the FDA’s approval of its Abbreviated New Drug Application for oxymorphone HCl ER, a generic equivalent to Opana ER)

At least one hospital executive claims that the FDA, DEA, and CMS have been slow to address prescription drug abuse. “The federal folks are late to the party,” says David Seaver.

It remains to be seen whether these recent federal regulatory efforts will be cause for celebration.

REFERENCES