Pharmacists Step Up Efforts to Combat Opioid Abuse

The CDC and Congress Are Trying to Pitch In

Stephen Barlas

This year, every one of the 8,004 pharmacists with a current active license and an address of record in Virginia will have to complete one hour of continuing education (CE) on opioid addiction prevention. That is a new requirement imposed by the Virginia Board of Pharmacy: one hour out of the total 15-hour annual CE requirement. It may be a onetime requirement, according to Caroline D. Juran, RPh, Executive Director of the Virginia Board of Pharmacy. The board may or may not continue it in 2016.

On the one hand, one has to give the Virginia board credit. Even pharmacists not involved in dispensing opioids who work at free-clinic pharmacies, where only Schedule VI drugs are dispensed, and pharmacists working in consulting must complete the one-hour requirement. On the other hand, the board had the authority to make that a two-hour requirement but did not, and it may ditch the one-hour requirement next year.

Virginia pharmacies were already required to enter controlled-substance prescriptions into the state’s Prescription Monitoring Program (PMP) database weekly. That database, like those in other states, is supposed to help prevent opioid abuse.

The main reason for querying the database is to learn the drug-dispensing history for a specific patient during a specific period in an effort to determine the validity of a prescription or to see if the patient appears to be doctor shopping to obtain drugs for illicit reasons. A new Virginia law requires physicians to check the database before writing a prescription for painkillers. Pharmacists are not required by law to check the database when dispensing the prescription.

That said, Ralph Orr, Director of the Virginia PMP, notes that pharmacists are increasingly querying the database, in part because the PMP implemented 24/7 access and auto-response capabilities in 2009 for prescribers and pharmacists. “Submitting a request is fast, since a pharmacist is required to type in just three pieces of information,” Orr explains. “For over 99% of requests, the user can barely glance away from the screen before the report is returned for them to view. It is that fast.” More than 5,700 pharmacists are registered to use the PMP; in the first quarter of 2015, they made more than 24% of all requests processed by the program. In 2012, this percentage was 8%, with approximately 2,000 pharmacists registered to use the program.

The Virginia legislature and the state’s professional and regulatory bodies are not unique among states in upgrading requirements for pharmacists as bulwarks against opioid drug abuse in the U.S. National organizations, too, are ramping up their attention to what many have referred to as an epidemic.

In March, the National Association of Boards of Pharmacy, the American Pharmacists Association (APhA), and the American Society of Health-System Pharmacists were among the groups releasing a consensus document highlighting the challenges and “red-flag” warning signs related to prescribing and dispensing controlled substances.1 The goal of the document is to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flags warrant further scrutiny.

Leading physicians groups signed on to the consensus document, and that was important, according to Anne Burns, RPh, APhA’s Vice President for Professional Affairs. She explains that one of the big challenges pharmacists face is communication with physicians, who like pharmacists are busy. So it is now not always easy or quick to get messages back and forth regarding a particular customer who presents a prescription for a painkiller. “There is a tension in the marketplace between physicians and pharmacists,” Burns says. “Pharmacists are becoming more engaged than in [the] past, because of the legal responsibility to ensure a prescription for a controlled substance is legitimate.” This increased focus has much to do with escalating enforcement actions by the Drug Enforcement Administration (DEA).

The APhA, at its annual meeting this year in March, adopted a number of policy statements that bear on opioid abuse, including supporting:

1. Pharmacist involvement in the development of uniform standards for an integrated nationwide prescription-drug monitoring program (PDMP) that includes the definition of authorized registered users, documentation, reporting requirements, system response time, security of information, minimum reporting data sets, and standard transaction format.
2. Mandatory PDMP enrollment by all health care providers, mandatory reporting by all those who dispense controlled substances, and appropriate system queries by registrants during the patient-care process related to controlled substances.
3. Development of seamless workflow integration systems that would enable consistent use of a nationwide PDMP by registrants to facilitate prospective drug review as part of the patient-care process related to controlled substances.

The extent of these recommendations underlines the gap between what states require and what they could and should require. That gap helps explain the persistence, and even the expansion, of the opioid drug-abuse problem in the U.S. “Something is desperately wrong with our nation’s response to the opioid epidemic, and it is quite literally a matter of life and death that we get honest answers and not remain misguided.

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The Federal Response to Opioid Abuse

It isn’t as if the federal government is sitting on its hands. Remedial efforts are afoot, some of which will affect pharmacists and pharmacies. In late March, Sylvia Burwell, Secretary of the Department of Health and Human Services (HHS), announced a $133 million initiative,4 one prong of which involves providing training and educational resources, including updated prescriber guidelines, to help health professionals make informed prescribing decisions and address the overprescribing of opioids.

Various agencies within HHS are involved in the full-court press on opioid addiction. The Centers for Medicare and Medicaid Services (CMS) just announced new requirements for P&T committees at Medicare Advantage (Part C) and Prescription Drug (Part D) plans to develop the specifications for opioid “edits” at the point of sale (i.e., the pharmacy or mail-order level) that would prevent opioid overutilization while minimizing false positives.5

Meanwhile, Congress is likely to pass legislation giving Medicare the authority to establish “lock-in” programs that require recipients thought likely to abuse opioids to go to particular physicians and pharmacies. Many state Medicaid programs use this “lock-in” authority, but the CMS has argued that the 2003 Medicare Modernization Act, which established the Part D outpatient drug program, does not give it the authority to allow lock-in programs within Medicare.

The Centers for Disease Control and Prevention (CDC) has announced a new $55 million grant program that will allow 16 states to upgrade their PDMPs.6 The Food and Drug Administration (FDA) just published final guidance in April telling drug manufacturers what they need to do to get quicker approval of abuse-deterrent formulations of opioids.7

Opioid Lock-In Versus Lock-Out

The lock-in provision in H.R. 10218 has support from Democrats and Republicans and has passed two House committees. The legislation appears to allow a member of a Medicare prescription drug plan, deemed “at risk” by the plan, to select which pharmacy to use for opioid prescriptions. The pharmacy has to have some sort of drug management plan in place. However, the National Community Pharmacists Association (NCPA) has serious concerns about granting plan sponsors what it says is the “unilateral authority” in the bill to require certain Medicare beneficiaries to use a particular pharmacy for their prescribed controlled substances. The NCPA fears that drug-plan sponsors may simply assign beneficiaries to pharmacies that the sponsor owns or in which it has a financial interest. Kevin Schweers, spokesman for the NCPA, adds:

The language stated would give the beneficiary the opportunity to express their ‘preferences,’ although ultimately under our interpretation the plan sponsor would have the ultimate authority as to the ‘chosen’ pharmacy and provider—overall the language is not definitive enough. The sponsor could bypass beneficiary preference and therefore a pharmacy could still be locked out.

The CMS had long argued that besides it lacking the authority to mandate lock-in pharmacy programs, those programs also raise concerns about restricting beneficiaries’ access to services. The CMS also felt that opioid abuse wasn’t a big problem among Medicare recipients. In a 2012 study, the CMS analyzed Part D data to identify beneficiaries receiving potentially unsafe doses of prescription opioids for 90 or more consecutive days, excluding beneficiaries with cancer or in hospice care. The CMS concluded that 0.71% of all Part D beneficiaries were at high risk for potential adverse effects and had a high likelihood of inappropriate opioid use.9 At the time, that didn’t seem to be enough of a stimulus to countenance a lock-in program. But when the HHS Office of Inspector General recommended in August 2014 that the CMS consider lock-in programs,10 the agency finally concurred. However, Congress must still provide statutory authority—hence the provision in H.R. 1021, a bill that contains numerous other changes to Medicare’s authorities.

State PDMPs Vary in Nature and Funding

What pharmacies and pharmacists should be “locked in” on are state PDMPs, which vary from state to state. They are based on electronic databases that are supposed to include controlled-substance prescriptions ordered by a physician in that state and filled by a pharmacist in that state. By checking with these databases prior to filling a controlled-substance prescription, a pharmacist can get an idea about whether the person standing at the counter has a legitimate need for painkillers. If that is not the case, the pharmacist can explore a couple of avenues, including providing the prescription-holder’s name to local law enforcement. But very few states, if any, require pharmacists to check a customer’s bona fides.

A Congressional Research Service report published in March 2014 laid out the major reasons pharmacists and others don’t use their state PDMPs.11 The most common reason given was the time required to access it (73%); two other reasons—difficult navigation of the Web portal (29%) and forgetting the password (28%)—may contribute to the amount of time required to obtain PDMP information. More than a third of survey respondents (39%) felt that accessing PDMP information would not change their practice for that patient, although research suggests PDMP information changes prescribing behavior. Relatively small numbers of respondents reported that lack of computer availability (9%) or never having applied for access (11%) were barriers to using a PDMP.

Each state determines which controlled substances must be reported, which types of dispensers are required to submit data, how often data are collected, who may access information in the...
PDMP database, the circumstances under which the information may (or must) be accessed, and what enforcement mechanisms are in place for noncompliance. Oklahoma was the first state to impose an immediate entry requirement on pharmacists in 2012, according to Sheryll Brown, Director of the Injury Prevention Service at the Oklahoma Department of Health.

In Virginia, for example, the state legislature just passed a law requiring pharmacists to register with that state’s PMP each year when they renew their pharmacist license. Virginia law requires pharmacies to input prescriptions weekly. However, many pharmacies do so daily, for the most part voluntarily, says Sarah T. Melton, PharmD, Associate Professor of Pharmacy Practice at the Gatton College of Pharmacy of East Tennessee State University and Chair of the Board of Directors of OneCare Southwest Virginia. But besides inputting information about controlled-substance prescriptions, pharmacists should access a patient’s controlled-substance history to make sure he or she isn’t doctor or pharmacist shopping and to provide the best patient care. A pharmacist who identifies doctor or pharmacy shopping may have a legal responsibility to notify diversion officers in law enforcement. Virginia law does not require accessing a patient’s prior controlled-substance history. “But it is a professional obligation in providing the best patient care that we are trying to get pharmacists to recognize,” Dr. Melton says.

PDMPs are funded by a variety of sources, different from state to state, and these sources sometimes include pharmacy licensing fees. Over the years, the federal government has established two grant programs aimed at supporting state PDMPs: the Harold Rogers PDMP grant, administered by the Department of Justice, and the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) grant, administered by HHS. The Harold Rogers PDMP received $7.0 million in appropriations for fiscal year 2014; NASPER last received appropriations (of $2.0 million) in fiscal year 2010.

**CDC Increases Funding for State PDMPs**

PDMP costs can challenge a state budget. A 2009 evaluation by the Maryland Advisory Council on Prescription Drug Monitoring found program startup costs ranging from $450,000 to more than $1.5 million. Further, based on available data from six operational PDMPs, the Maryland council estimated that annual operating costs range from $125,000 to nearly $1 million. Federal grants cover little of those costs. The Harold Rogers PDMP grant program is Lilliputian. It is dwarfed by the new CDC grant program, which will reach many more states with many more dollars. The CDC piloted the program in 2014 and called it Boost. Five states—Kentucky, Oklahoma, Tennessee, Utah, and West Virginia—received the first round of grants, $6 million over three years. The money goes for expenditures in three categories, one of which is maximizing PDMPs. Grant winners are supposed to expand interstate data-sharing among PDMPs, refine proactive PDMP reports to identify and address inappropriate prescribing patterns, shorten the PDMP reporting interval to make PDMP data more timely and useful, and leverage PDMPs as public health surveillance systems to better understand what drives overdose deaths.

Sheryll Brown says Oklahoma will use its Boost funds to (among other things) link the opioid user data with health outcomes data. This will allow the state, for instance, to get a clearer picture of people who have died from drug overdoses and develop some measures that will respond to those profiles.

The CDC is about to boost Boost. With $55 million from Congress, the agency has announced that it will award up to $1 million a year for each of four years to 16 states in a new “super-Boost” program called Prescription Drug Overdose Prevention for States (PFS) Prevention Boost.6 Courtney Lenard, a CDC spokeswoman, says that the while the new program is a follow-on to Boost, “There are some important distinctions in both scale and substance.” Both programs address the prescribing that fuels the epidemic and both prevent opioid addiction, abuse, and overdose before they happen, but PFS supports the implementation of larger, longer, and more ambitious state prevention programs. Boost grants are only $400,000 a year.

The larger grants require states to: 1) advance two activities to enhance and maximize PDMPs, and 2) implement community-level prevention in areas hit hard by the epidemic and/or implement health-system or insurer interventions to advance prevention. Under PFS, unlike Boost, there is built-in flexibility so that states can use the program to respond to new or emerging crises or opportunities, called “Rapid Response Projects.”

**Treatment Options for Opioid Abuse**

Of course, pharmacists play an active role on the “prevention” side of opioid addiction. They aren’t involved in treatment; that is done by physicians and counselors, mostly in treatment centers and physicians’ offices. Suboxone, the drug treatment of choice, contains a combination of buprenorphine and naloxone. Buprenorphine is an opioid medication; naloxone is a special narcotic that reverses the effects of other narcotics.

HHS’s Substance Abuse and Mental Health Services Administration (SAMHSA) regulates America’s 1,300 opioid maintenance treatment programs—formerly known as methadone clinics—and is responsible for certifying the 26,000 physicians who prescribe buprenorphine. But critics say use of buprenorphine by itself—without counseling, enrollment in a 12-step Alcoholics Anonymous-type program, blood and urine screening, and psychosocial counseling—is ineffective. Rep. Murphy called use of buprenorphine alone “addiction maintenance.”

Unfortunately, many SAMHSA grant-receiving clinics are too focused on providing buprenorphine alone. Private, physician-run clinics can, and have, turned into pill mills, with doctors prescribing willy-nilly because of the profit margin they earn from prescriptions of “bupe,” as it’s known on the street.

It is notable that the Burwell initiative focused in part on medication-assisted treatment (MAT), which research indicates is the most effective way to treat opioid addiction. Studies further demonstrate that MAT reduces the risk of drug overdoses, infectious disease transmission, and criminal activity. Despite this track record, in 2013, MAT was available in only 9% of substance-abuse treatment facilities nationwide.

“For example, right now there is a nationwide shortage of qualified substance-abuse providers, particularly people who can prescribe MATs,” says U.S. Rep. Diana DeGette (D-Connecticut). A physician must get a waiver from the special narcotic that reverses the effects of other narcotics.

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the doctor needs a special registration number from the DEA. To qualify for that number, the physician has to meet certain requirements, most of them regarding board and addiction certifications from groups such as the American Society of Addiction Medicine. To make matters worse, many health insurers don’t pay for MAT.

It is clear pharmacists can and want to do more to prevent opioid abuse, but they cannot do it alone. They need a more cooperative relationship with physicians, more advanced health information technology systems, and more funding of PDMPs. Pharmacists are only one piece of the solution, of course—but they are a critical one.

REFERENCES