ROY SNELL

Sara Kay Wheeler Sheds Light on the Opioid Epidemic

Compliance Officers Need to Be Aware of the Risks in Their Organizations

Roy Snell is the chief executive officer (CEO), co-founder, and first president of the 9,000 member Society of Corporate Compliance and Ethics and Health Care Compliance Association. He has written over 100 articles, edited two manuals and three magazines, and published a book for compliance professionals. He is an outspoken advocate for compliance professionals and a fierce promoter of compliance programs. He is a former University of Wisconsin compliance officer, consultant for Deloitte and PricewaterhouseCoopers, and Mayo Clinic administrator. He has a Master degree from St. Mary's college. His email address is Roy.Snell@corporatecompliance.org.

Sara Kay Wheeler is a partner with King & Spalding. She practices exclusively in the area of health law where she advises a diverse array of organizations including health systems, academic medical centers, health plans, faculty practice plans, and entities involved in the drug delivery system, including retail pharmacies (chain pharmacies and large retailers with pharmacy operations), specialty pharmacies, pharmacy benefit managers, and retail clinics. She has extensive experience in the creation and implementation of corporate compliance programs and investigations, government contractor audits (including RACs, MACs, MICs, PSCs and ZPICs), Medicare regulation (including Medicare Part D issues), Medicaid regulation (including managed care, audit, and enforcement matters), fraud and abuse concerns, internal investigations, voluntary disclosure strategies, clinical research compliance, privacy matters, and managed care arrangements. Ms. Wheeler also works with King & Spalding's Special Matters Group to defend health care providers that are investigated by federal and state enforcement entities. She can be reached at SKWheeler@KSLAW.com.

Snell: Can you give us some statistics and other information about the opioid epidemic?

Wheeler: Here are a few worth noting:

- Based on information from the Centers for Disease Control and Prevention (CDC), drug overdose deaths from opioid drugs have almost tripled since 2002.
- Opioids are involved in over 60 percent of overdose deaths.
- More than 33,000 Americans died from an opioid-related overdose in 2015, the latest year for which the CDC has data.

- The most common drugs involved in prescription opioid overdose deaths include Methadone, Oxycodone, and Hydrocodone.
- There is also an established path from opioid abuse to heroin abuse because in many locations, heroin is actually cheaper than pharmaceutical opioids.

Snell: Please tell us a little about the State of Ohio suing big pharma over this issue.

Wheeler: The State of Ohio has filed suit against five pharmaceutical manufacturers alleging that the companies fraudulently marketed prescription pain medications, by misleading physicians and patients regarding the risks and benefits of prescription opioids. The state is seeking hundreds of millions of dollars in damages. In its complaint, the state alleges that:

- In 2012, 793 million doses of opioids were prescribed to Ohio patients — enough to supply every man, woman, and child in the state with 68 pills each.
- In 2016, 2.3 million Ohio patients, or approximately 20 percent of the state's population, were prescribed opioids.
- The number of people in Ohio who died from unintentional drug overdose deaths exceeded the number killed in motor vehicle accidents for the first time in 2007, and the number of overdose deaths has increased every year since then.

Several other entities have filed similar lawsuits recently, including the states of Missouri and Oklahoma, the Cherokee Nation, several counties in Tennessee, and cities such as Everett, Washington.

Snell: What advice would you give compliance officers in clinics and hospitals?

Wheeler: As we all recognize, compliance professionals in the health care industry are expected to be attentive to evolving areas of potential risk. In recent years, the enforcement community has emphasized that risk identification and mitigation efforts are critical components of well-functioning compliance programs. Accordingly, given the increased legislative, regulatory, and law enforcement focus on opioid abuse, this is likely to be a potential risk that should be factored into annual risk assessments pursued by hospital systems, clinics, and other health care providers.

While existing compliance efforts may touch on certain discreet risks relevant to the opioid crisis, many hospital systems are considering the need for additional proactive efforts to better understand the universe of potential risks from a more holistic perspective so that those potential risks can be better understood and more effectively mitigated.

- From a hospital system perspective, this need is even more elevated in systems with significant numbers of employed prescribers.
- Further, since many relevant authorities are state law based, systems operating in multiple states should be aware of state-specific requirements so that such standards can be factored into risk assessments and associated compliance strategies.

Areas to potentially consider (*not exhaustive*) include:

- Overall awareness of epidemic; development and articulation of organizational stance to combat opioid epidemic.
- Consideration of industry and community participation to better understand epidemic and facilitate networking with other industry stakeholders including the CDC, manufacturers, distributors, retail pharmacies, prescribers, first responders, community awareness groups, et cetera.
    - It is helpful to remember that some of these stakeholders have already experienced some of the increased legislative, regulatory, and law enforcement activity and may have already conquered certain analyses or developed effective strategies that could be

useful to the hospital system and other provider communities.
- Analyze existing prescription drug monitoring programs (PDMPs) to determine whether such programs can help to identify rogue prescribers or doctor-shopping behaviors.
- Identify particular departments that could be at heightened risk, such as pain management clinics, other outpatient clinics, and emergency rooms.
- Review existing drug diversion controls to determine whether enhancements would be prudent. Potentially relevant controls in this area could include:
  - controls around ordering, maintenance, and prescribing of controlled substances;
  - protocols for investigating and remediating potential diversion; and
  - technological enhancements including camera surveillance techniques.
- Work with prescribers and other clinicians to consider potential checklists to use with high-risk patients, including patients with chronic pain.
- Revisit associated training programs to ensure content is current and organizational expectations are clearly communicated.

Snell: What about collaboration with compliance officers in pharmaceutical companies?

Wheeler: Hospital systems, clinics, and other providers can certainly consider reaching out proactively to pharmacies, PBMs, distributors, and manufactures to ensure there is a flow of information relating potential abuse or diversion. Specifically, it may be helpful to develop contacts at such entities in the event that potential abuse or diversion is detected at a hospital system or clinic so that information sharing and investigational efforts are more efficient. Further, pharmacies, PBMs, distributors, and manufactures often have sophisticated diligence operations and data mining that are used to identify potential abuse diversion, so there also may be opportunities to network and learn about programs and other strategies that have been effective with these stakeholders.

Snell: Are there any other compliance officers in other segments of health care that should be concerned about this?

Wheeler: The opioid epidemic is viewed by many as a public health issue that requires collaboration across the industry. Given the statistics, we expect the CDC, research institutions, trade associations, insurers, and others to continue to analyze the problem and pose innovative strategies for decreasing access and use, and for more effectively combating overdose scenarios. For example:
- There are studies under way in the pain management arena to facilitate the development of alternate treatment regimens and to further the clinical debate about whether opioids are an effective treatment option for long-term pain management.
- In New York, law enforcement officers have access to naloxone (which helps to combat the effects of an opioid overdose) and are trained on how to administer the drug.
- Also, there is a suspected co-relation between opioid abuse and Medicaid participants, which calls into question when the Centers for Medicare & Medicaid Services (CMS) will increase its review of reimbursement for opioid prescriptions.

Snell: What laws could be broken here? Is there a specific law that you think will be at issue?

Wheeler: With respect to hospital systems, there are a myriad of federal and state controlled substance statutes and regulations that apply. Failure to comply with these statutes and regulations can result in criminal and/or civil penalties and loss or suspensions of licenses. Individual practitioners similarly are subject to these same federal and state laws and face the same penalties. Moreover,

physicians who team with physician extenders, such as nurse practitioners, have additional oversight responsibilities. Hospital pharmacies and pharmacists are subject to the same federal and state laws and face the same penalties. For organizations operating in multiple states, each state seems to approach the issue uniquely, so there can be jurisdictional differences that are highly relevant. Reimbursement requirements along with provider participation rules can also be critical to opioid compliance regimens.

Snell: Some feel this situation might be similar to the big tobacco incident years ago. Tell us what the comparison is.

Wheeler: According to comments made in a recent news conference, Ohio Attorney General Mike DeWine suggests that the pharmaceutical manufacturers downplayed the risks of using opioids, thereby contributing to the epidemic. In the Complaint, the State of Ohio specifically states, "Borrowing a page from Big Tobacco's playbook, Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as key opinion leaders (KOLs) and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as Front Groups)." The State of Ohio further states "to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain." Like the tobacco wars, these contentions will play out in multiple forums, including but in no way limited to the judicial system.

Snell: Society is mad. They don't seem like they are going to stop until someone is blamed and pays dearly. However, everyone is blaming everyone else for the problem. Are you concerned that all segments of health care think this risk belongs to some other segment of health care and that no one will do anything about the risks?

Wheeler: Because all aspects of the health care industry are at risk, there is the danger that not all segments realize the danger and assume that someone else is implementing and utilizing safeguards to identify and avoid abuse and diversion. The situation also demonstrates the critical importance of various aspects of the health care system — prescribers, dispensers, distributors, and manufacturers — working together and sharing information to address the situation.

Snell: What more do you think the compliance profession could be doing to help make sure that the right segments of health care are doing the right thing? What more can the health care compliance profession be doing to help their peers with this?

Wheeler: Here are a few suggestions:

- Understand that health care systems play an important role in combating the epidemic.
- Stay abreast of trends in your area. Not every city or state has the same problem.
- Carefully consider where effort is needed in terms of awareness and community participation.
- Revisit and update (as warranted) proactive controls to better mitigate potential risks.
- Collaborate with important stakeholders both inside and outside of your organization.
- Consider adding specific opioid-related risks to annual risk assessments.

Snell: What is the logic behind those who say that doctors are at fault? What are doctors doing that needs to be changed?

Wheeler: Opioids are valuable drugs, but doctors are facing increasing pressure to balance the health and safety of their patients with regulatory or law enforcement scrutiny. Regulators and law enforcement expect practitioners and institutions to use all of the tools available to them

to identify potential abuse or diversion, including but not limited to prescription drug monitoring programs. Regulators and law enforcement will be looking for rogue prescribers and prescribers who may not be adequately vigilant in terms of doctor shopping and other signs of opioid abuse. Regulators and law enforcement expect practitioners to err on the side of not prescribing or administering if there is any doubt about the patient, and this may go against a doctor's training.

Snell: Is anyone else being blamed or a potential target for prosecution?

Wheeler: All aspects of the health care industry are at risk. But there is increased risk for hospitals and clinics because drug abusers have identified them as potential targets as law enforcement cracks down on pill mills and retail pharmacies. Emergency rooms are very busy, and the practitioners may not have access to all patient records. Hospital pharmacies and pharmacists are not as accustomed to looking for drug abuse and diversion as are retail pharmacies. Any practitioner of a facility that is prescribing or dispensing opioids should be alert to the threat and attempt to identify and minimize abuse and diversion.

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