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May 2016

About VSHP
VSHP is the professional society that represents pharmacists who serve patients in Virginia across the continuum of care in integrated health care systems. VSHP has over 900 members practicing in organized healthcare settings.

Vision Statement
The Virginia Society of Health-System Pharmacists vision is that medication use will be optimal, safe and effective for all people all the time.

Mission Statement
The mission of the Virginia Society of Health-System Pharmacists is to inspire innovative pharmacy practice by promoting education, advocacy and collaboration to help
accept for return a previously dispensed drug for the purpose of destruction once authorized by Drug Enforcement Administration (DEA) as a collector. Drugs may be collected from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent’s property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility. The process used to collect and destroy drugs, along with any required record keeping, shall comply with applicable federal and state law.

Pharmacies that are already registered with DEA as an authorized collector are now listed on the Board’s website at www.dhp.virginia.gov/pharmacy/news_consumer.htm. The list of authorized collectors is intended to assist the public in identifying a location where persons may dispose of unwanted medications. Pharmacists who want to participate in drug collection efforts should first register with DEA and then submit the “Registration For A Facility To Be An Authorized Collector For Drug Disposal” form found on the Board’s website at www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm#Pharmacies. The Board will then add the location’s information to its online listing of authorized collectors. If an authorized collector chooses to cease acting as a collector, the pharmacist-in-charge (PIC) or medical director shall notify the Board within 30 days.

To review Regulation 18VAC110-20-211 within the Regulations Governing the Practice of Pharmacy, visit http://www.dhp.virginia.gov/pharmacy/pharmacy_laws_regs.htm.

From the Virginia BOP-New Pharmacy Exam

New Law Exam for Pharmacist Licensure

The Virginia Board of Pharmacy has historically administered its own jurisprudence examination, the Virginia Federal and State Drug Law Examination (FSDLE). However, as a result of the increasing number of complex issues facing the Board and its limited resources, it was determined that resources used to administer the FSDLE would be better utilized in addressing other issues. Therefore, the Board will cease administering the FSDLE on June 30, 2016. Beginning July 1, 2016, Virginia will become the 49th jurisdiction to require examination candidates seeking pharmacist licensure to successfully pass the Multistate Pharmacy Jurisprudence Examination® (MPJE®) administered by the National Association of Boards of Pharmacy® (NABP®). As of May 1, 2016, candidates will have the option of scheduling to take the FSDLE prior to July 1, 2016, or registering with NABP to take the MPJE on or after July 1, 2016. Those wishing to take the MPJE may register online by visiting www.nabp.net; click on Programs, then scroll down and click MPJE, and click Registering for the MPJE on the sidebar. Those who register for the MPJE will not be able to schedule their exam until July 1, 2016.

Additional information on the transition to the MPJE may be found at www.dhp.virginia.gov/pharmacy/news/MPJE_transition.pdf.

From the Virginia BOP-PIC Responsibilities

PIC Responsibilities

The PIC of a pharmacy is responsible for providing safeguards against diversion of controlled substances (CS) as well as ensuring that the practice of pharmacy is in overall compliance with the laws and regulations. Highlighted here are a few reminders for those serving in the role of PIC:

Regulation 18VAC110-20-190 states that the prescription department of each
pharmacy shall be provided with enclosures that meet certain requirements to protect the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty. Please ensure the enclosure is locked and alarmed at all times when a pharmacist is not on duty. “On duty” is defined in 18VAC110-20-10 to mean that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed. Simply locking the front door to the business does not sufficiently comply with the requirement to lock the enclosure to the prescription department.

Regulation 18VAC110-20-190(D) states that a “PIC or pharmacist on duty shall not permit access to the prescription department or [CS] by a pharmacist, pharmacy intern, or pharmacy technician whose license or registration is currently suspended or revoked.” The current status of a license or registration may be verified using the License Lookup feature on the Board’s website at https://dhp.virginiainteractive.org/Lookup/Index.

Changes to Guidance Document 110-27, PIC Responsibilities, were approved at the December 2015 full Board meeting. The amendments clarified when an incoming PIC inventory should be taken and the designation of the effective date for the change in PIC that is recorded on the application. Guidance Document 110-27 also offers Board suggestions for best practices to safeguard against diversion of CS and summarizes actions to take when leaving the PIC position.

To review Regulation 18VAC110-20-190 within the Regulations Governing the Practice of Pharmacy, visit www.dhp.virginia.gov/pharmacy/pharmacy_laws_regs.htm.


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Clinical Article

**Update on Antibiotics: Advances in Lipoglycopeptides**

Jeremy Rose, Pharm.D., BCPS & Hannah Morris, Pharm.D.

With the development of methicillin-resistant *Staphylococcus aureus* (MRSA) it became necessary to derive medications which could treat this pathogen, one such class of antibiotics is the glycopeptides. The original glycopeptide, vancomycin, was identified in the 1950s but its use was minimal until penicillin resistance became more predominant. Since then it has become the drug of choice for MRSA infections and for patients with severe β-lactam antibiotic allergies requiring intravenous (IV) antibiotics for treatment of gram-positive bacterial infections. Unfortunately, increased use has led to vancomycin-resistant *Staphylococcus aureus* (VRSA), resulting in a need for antibiotics to take the place of vancomycin. In response to increasing VRSA prevalence, three new lipoglycopeptide antibiotics were developed: telavancin, dalbavancin, and oritavancin.

Lipoglycopeptides inhibit cell wall synthesis in the same manner as vancomycin, via binding to the peptidoglycan precursor C-terminal D-Ala-D-Ala subunit, thereby preventing its inclusion in the peptidoglycan chain. In addition to the heptapeptide core and two sugar moieties that are characteristic of glycopeptides, lipoglycopeptides benefit from the addition of a lipophilic side chain, which anchors the drug molecules in the bacterial cellular membrane and enhances their antimicrobial activity. Other effects of the lipophilic side chain include extended half-life (dalbavancin and oritavancin) as well as increased distribution and clearance, resulting in decreased nephrotoxicity (telavancin). Similar to vancomycin, rapid intravenous infusions may cause a Red-man syndrome-like reaction including: flushing of the upper body, urticaria, pruritus, or rash. Slowing the infusion may result in termination of the infusion reaction.

Telavancin, marketed under the brand name Vibativ, was the first FDA approved lipoglycopeptide in 2009 for the treatment of complicated skin and skin structure infections. It later gained FDA approval for hospital-acquired and ventilator-associated bacterial pneumonia caused by susceptible isolates of...
S. aureus. Along with other agents in its class, telavancin is only active against gram-positive bacteria and is bactericidal against staphylococci, streptococci, and vancomycin-susceptible enterococci. It is only available as a reconstitutable powder for IV injection and not oral administration due to poor bioavailability. Dosing for both indications is 10 mg/kg administered intravenously over 60 minutes every 24 hours. The dose should be adjusted to 7.5 mg/kg every 24 hours for creatinine clearance (CrCl) from 30-50 mL/min and 10 mg/kg every 48 hours for CrCl from 10-29.9 mL/min; there is not enough information to adjust dosing for patients with end-stage renal disease, defined as CrCl less than 10 mL/min, or on hemodialysis. Telavancin penetrates blister fluid, pulmonary epithelial lining fluid, and alveolar macrophages well, but has low cerebrospinal fluid penetration. Its pharmacokinetic profile includes 93% protein binding, 70% renal elimination, and a 7-9 hour half-life; additionally it inhibits CYP3A4/5. All patients on telavancin should have their renal function monitored as the drug and solubilizing agent, hydroxypropyl-beta-cyclodextrin, can accumulate. Side effects include nausea, vomiting, altered taste sensation, prolonged QT interval, and nephrotoxicity.

Dalbavancin was FDA approved in 2014 for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of gram-positive microorganisms, including MRSA. Also known by the brand name Dalvance™, it is available as a powder for reconstitution in a 500 mg vial. The first dose of 1,000 mg is given over a 30 minute IV infusion followed by a 500 mg infusion 7 days later. Dosing should be adjusted for patients with renal impairment and CrCl less than 30 mL/min, with a first dose of 750 mg and a second dose of 375 mg. Recently a study published in Clinical Infectious Diseases found that a single 1,500 mg dose of dalbavancin was noninferior to the current FDA approved weekly regimen and had a similar safety profile. Of note, dalbavancin should be diluted in 5% Dextrose Injection, USP, and the line should be flushed with 5% Dextrose Injection, USP, before and after administration of the infusion as saline solutions may cause precipitation. Its pharmacokinetic profile includes 93-98% protein binding, a half-life of 8.5 days, and it does not induce, inhibit, or serve as a substrate for CYP450 enzymes, unlike telavancin. No accumulation was noted in studies of patients with normal renal function. Side effects include nausea, vomiting, diarrhea, rash, and headache.

Oritavancin, brand name Orbactiv®, was FDA approved in 2014 for the treatment of ABSSSI caused by susceptible isolates of gram-positive microorganisms, including MRSA, Streptococcus species, and Enterococcus faecalis. Speed of bactericidal activity varies, with rapid activity (1 hour) against Streptococcus pyogenes, MRSA, and VRSA and slower activity (10-20 hours) against daptomycin-resistant Staphylococcus aureus, vancomycin-susceptible enterococci, and vancomycin-resistant enterococci (VRE). The regimen is a one-time 1,200 mg dose given as a 3 hour IV infusion, which must be diluted in 5% Dextrose Injection, USP, as normal saline may cause precipitation. There are no dose adjustments required for renal or hepatic impairment. Oritavancin has the lowest protein binding of the lipoglycopeptides at 85% and extensively distributes into tissues including liver, kidney, spleen, and lungs (Vd ~ 87.6 L). It is not metabolized and is excreted unchanged in the urine and feces. It also has the longest half-life at 393 ±73.5 hours. Although only approved as an IV formulation animal studies have suggested that oral oritavancin may have a role in treating Clostridium difficile infections, but this has yet to be confirmed in human studies.

The new lipoglycopeptides each have unique aspects which may make them a preferential choice for treatment of certain patients. Dalbavancin and oritavancin do not act on CYP450 enzymes and subsequently have minimal drug interactions, in comparison to telavancin. Oritavancin is the only agent which does not require renal or hepatic dose adjustment and is active against VRE. However, one of the largest hindrances to using the new lipoglycopeptides is cost. The newer agents especially have a higher cost, dalbavancin AWP is $1,788 per 500 mg vial and oritavancin AWP is $3,480 for three 400 mg vials. High cost may prevent these agents from being used for patients admitted to the hospital, in spite of their benefits. In summary, the lipoglycopeptides have advantages over vancomycin and as more research is...
conducted their use may expand to other disease states, including *C. difficile* infections.

References:


Kate Traynor

BETHESDA, MD 29 Apr 2016 - University of Southern California (USC) pharmacist Steven Chen is confident that data from a nearly completed multimillion-dollar project will definitively show that clinical pharmacy services are cost-effective and improve patient outcomes.

"It's practice-transforming," Chen, chair of the USC School of Pharmacy's Titus Family Department of Clinical Pharmacy and Pharmacoeconomics and Policy, said of the $12-million Centers for Medicare and Medicaid Services (CMS)-funded project's findings.

Read More

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**California Mulls Coverage of Comprehensive Medication Management**

[May 15, 2016, AJHP News]

Cheryl A. Thompson

BETHESDA, MD 29 Apr 2016 - A bill to have the nation's largest Medicaid program cover comprehensive medication management (CMM) services by pharmacists and primary care physicians emerged from a committee hearing on April 5 with a unanimous round of ayes by state legislators.

"In the past few years, we have added millions of Californians into Medi-Cal, making the effective management of the quality and cost of care an absolute necessity," Assemblyman Jim Wood told fellow members of the state Assembly Health Committee.

Read more

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**ASHP Urges Maine Legislators to Override Veto of Naloxone Bill**

4/29/2016

**UPDATE:** *The Maine legislature voted 132-5 to overturn the governor's veto.*

ASHP has asked Maine's legislative leaders to initiate a vote to override Governor Paul LePage's *veto* of LD 1547: *An Act to Provide Access to Affordable Naloxone Hydrochloride for First Responders.* The legislation, passed earlier this year, would allow the state's attorney general to negotiate for bulk purchase of naloxone for use by first responders. Maine is one of eight states that have not enacted legislation to increase access to naloxone.

Read more

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**ASHP Partner CSRxP Unveils Market-based Solutions to Address Soaring Drug Prices**

4/28/2016

This week, the Campaign for Sustainable Rx Pricing (CSRxP), of which ASHP is a member of the Steering Committee, announced the release of market-based policy solutions to curb rising drug prices. ASHP *joined* the Steering Committee in February as part of its continuing effort to address the impact of increasing drug costs on patients and its members.

Read more
How Hospital Pharmacists Improve Care Without Breaking the Bank
Hospitals & Health Networks (03/16) Aston, Geri

Health reform is motivating hospital pharmacies to improve care and expand services while curbing costs. At Lifespan, a Rhode Island health system, pharmacists visit patients who are at-risk of readmission while they are still in the hospital to discuss medications and how the drugs work in the body, says Christine Berard-Collins, director of pharmacy. A clinical pharmacist oversees the transitions-of-care program at Lifespan's Rhode Island Hospital and the Miriam Hospital, and three pharmacists make the patient visits that are followed-up by case-management nurses. Many hospitals are sending patients home with their outpatient medicines in hand to prevent the patient-provider disconnect that exists in the traditional model of hospital pharmacy services, Berard-Collins says. Mark Eastham at McKesson Pharmacy Optimization says rising interest in continuity of care into the outpatient setting is prompting more hospitals to create their own retail pharmacies. Access to patients' electronic health records means hospital retail pharmacists can check physicians' notes, what drugs a patient was on in the hospital, lab values, and the last time a patient visited a hospital clinic. Hospital-owned retail pharmacies also allow hospitals to capture revenue that otherwise would be lost to pharmacy chains. However, careful analysis needs to be done to determine whether a hospital-owned retail pharmacy is financially viable, such as by determining the baseline number of discharges and specialty services needed to cover expenses.

Hospitals See On-Site Pharmacies as Revenue Generators as Medication Management Pays Off
Healthcare Finance News (03/16/16) Lagasse, Jeff

More hospital systems consider on-site pharmacy services revenue generators as they seek more efficient and controllable medication delivery to patients. There are two benefits to this approach: the hospital collects more revenue from patients by letting them fill their prescriptions on-site, and it can reduce readmissions and help health systems save even more. "A lot of the initiative is more along the lines of hospitals making sure that patients can access and adhere to their medications," says Penn Medicine's Rick Demers. A key impediment for patients who want to fill prescriptions via a third-party vendor is that those pharmacies may not carry the desired medication, and this problem has grown with the pharmaceutical industry's increasing complexity. Stanford Health Care's John Cunningham says the current situation differs from the early 2000s, when hospitals with on-site pharmacies were beginning to close those operations due to medications being less costly and complicated, and there being little momentum in ambulatory care. The passage of the Affordable Care Act, which penalized hospitals for escalating readmission rates, was a driving factor in the reversal of this trend. On-site pharmacies permit more control on the hospital side, says the Medicines Company's Fred Pane. Such facilities give clinicians direct access to information such as who's prescribing which medications to whom.

Do Armed Guards Make Health-System Pharmacies Safer?
Pharmacy Times (02/29/16) Ross, Meghan

Slightly more than half (52%) of hospital security guards currently carry handguns, according to a 2014 International Healthcare Security and Safety Foundation report. This is an increase from a 2011 Hospital Security Survey that found 22% of respondents who were hospital officials in charge of security had their security officers carry a firearm or were considering the use of firearms. Back then, 78% of respondents said they had "no plans to use firearms." For some pharmacists, the question of safety in relation to armed guards depends on the hospital setting. Craig Cocchio, PharmD, BCPS, an emergency medicine clinical pharmacist at Trinity Mother Frances Hospital, has also worked in hospitals both with and without armed guards. He currently works in a health system that allows security guards to carry guns. He noted that the emergency department frequently has law enforcement officers present for a variety of reasons, in addition to the armed security. "Personally,
I never thought of my safety being any different with or without armed security guards," Dr. Cocchio said. Beth Lofgren, PharmD, BCPS, who has practiced in home health, long-term care, and hospital pharmacy, said she currently works in a hospital that has security guards whose guns are in plain view. "I feel much safer knowing that armed guards are located on our campus," Dr. Lofgren said. A 2015 Healthcare Crime Report released by the International Healthcare Security and Safety Foundation suggested that violent crime in hospitals is on the rise. According to the report, the violent crime rate per 100 hospital beds increased from 2 in 2012 to 2.8 in 2014.

Bridging Pharmacy Automation and EMRs

*Drug Topics (03/10/16) Vecchione, Anthony*

Amid rising consolidation of hospitals and health systems, hospital pharmacy directors must now address interoperability between pharmacy automation and electronic medical records (EMRs). Challenges facing pharmacy directors include connectivity and standardization issues, a shortage of resources, and funding problems. At Southampton Hospital in South Hampton, N.Y., for instance, the hospital's old legacy computer system was not able to transfer information to a new EMR, according to Jerard West, PharmD, director of Pharmacy. As a result, predefined common orders had to be built from scratch using a 1,600-medicine item master. West adds that the pharmacy department also had to design its system to incorporate current workflow practices, perform a Pyxis conversion to the new EMR, implement bar-coding technology, and assist with order set development for the medical staff. Dave Swenson at CareFusion says the company's enterprise approach is to allow health systems to standardize using a single formulary and to manage users across a health system instead of on a hospital-specific basis. Rich Berner at Allscripts' Sunrise business unit says medication management is crucial because it can help reduce errors, provide savings, and prevent fraud. Aesynt's Kraig McEwen estimates that when multiple hospitals merge, "most health systems need to take 20 percent of their cost structure out over the next several years just to remain solvent, so standardization is one of the mechanisms they use to help become more efficient."

Local Pharmacy Partnership to Prevent Pediatric Asthma Reutilization in a Satellite Hospital

*Pediatrics (03/16/16) Sauers-Ford, Hadley S.; Moore, Jennifer L.; Guiot, Amy B.*

A recent study investigated whether a partnership with community pharmacies could help reduce pediatric asthma reutilization (readmissions and emergency revisits) when hospital resources are limited. In this case, the satellite hospital lacked an outpatient pharmacy on site, so the researchers teamed up with community pharmacies, aiming to reduce asthma reutilization by providing medications in-hand at discharge. The median percentage of asthma patients who received medications in-hand rose from 0% to 82% during the study period. Expanding the medication in-hand program to all patients was a key factor, the researchers note, but other changes include expanding the team to evening stakeholders, narrowing the number of community partners, and developing electronic tools to help key processes. Following the intervention, the mean percentage of asthma patients who were discharged from the satellite hospital who had a readmission or emergency department revisit within 90 days dropped to 11% from 18%. The authors report, "When hospital resources are limited, community pharmacies are a potential partner, and providing access to medications in-hand at hospital discharge can reduce asthma reutilization."

IU to Offer One of the First Data Science Courses to Use Real Clinical Trial Data

*IU Newsroom (03/24/16)*

Indiana University (IU) will partner with Eli Lilly to offer one of the first data
sciences courses in the U.S. to use real-world clinical trial data. "Our goal is for students to gain a better understanding of the overall drug development process, and specifically the human clinical trial phases," says Eli Lilly clinical data associate Sara Bigelow. "This includes gaining knowledge on the data side of the process—where the data comes from, where it goes, how it's used, and why it's so important not only to clinical trial research but also the pharmaceutical industry as a whole. Another key takeaway will be awareness about the privacy process involved in working with patient data." The IU course will be offered as a four-week summer class starting May 2 via the data science master's degree program at the IU School of Informatics and Computing. The trial data will employ anonymized information collected from human subjects during the safe testing of potential new pharmaceuticals. Students enrolled in the new course will have an opportunity to gain hands-on instruction in understanding, refining, and analyzing real-world data of the type used by drug companies in making major business decisions on drug development.

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**EHR 'Gaps' Hinder Patient Medication Adherence**

*FierceEMR (03/24/16) Hirsch, Marla Durben*

Electronic health records (EHRs) and health IT are not improving patient medication adherence, according to a new report in *JMIR Medical Informatics.* Non-adherence can cost the health care industry large amounts of money, and EHRs have been considered as a possible solution. They can use certain tools to help improve adherence and better engage patients. But the report indicated four "gaps" that are stymieing efforts. First, interoperability is underdeveloped and does not allow patients to connect self-monitoring data to a doctor's EHR. Second, inconsistencies in data definitions make it difficult to determine the validity and efficiency of data sources. Third, National Drug Codes are not yet standardized in EHRs. And fourth, medication management therapy is not handled particularly well by EHRs. To fix the issues, the report outlined a system-based view of medication use, management, and patient adherence. Interoperability should be improved and data definitions should be standardized. Doing so can create a collaborative environment that would benefit patients, physicians, pharmacists, and all others involved in the adherence process.

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**Hospitals Dealing With Drug Price Increases**

*Washington Post (03/14/16) Dennis, Brady*

Hospitals nationwide are being forced to address higher drug costs. The increases often involved brand-name drugs with little or no competition as well as commonly used generics around for decades. "There's been a huge consolidation of these generic companies ... everybody is buying everybody else," says Gerard Anderson, a professor at the Johns Hopkins Bloomberg School of Public Health. "If there's no competition, the prices go up. We are seeing a lot of [drug] shortages, and also price increases. That shouldn't happen, but it is." Jeff Rosner, senior director of pharmacy sourcing and purchasing at the Cleveland Clinic, says the "challenge is, you don't have a crystal ball." His organization last year faced an unexpected increase of more than $8 million after the prices of two heart therapies surged. Rosner says it is increasingly difficult to anticipate how much the institution will spend on the myriad drugs it buys annually. Hospital officials insist that even when sudden price increases occur, patients receive access to the medicines they need. However, the unpredictable increases wedge their institutions financially, as they cannot immediately pass on the cost if a drug gets more expensive because reimbursement rates for certain procedures already have been set by Medicare and private insurers. That means sharply higher prices can lead to losses.

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**New Naloxone Training Program for Pharmacists Takes Aim at Opioid Epidemic**
Newswise (03/29/16)

The University at Buffalo School of Pharmacy and Pharmaceutical Sciences (SPPS) has partnered with the Erie County Department of Health and the Harm Reduction Coalition to create an online education program for dispensing naloxone. The free course trains community pharmacists about dispensing naloxone without a prescription to the public, including those at risk for opioid abuse, their friends, and families. "This program is a mechanism for getting the antidote out to reduce the number of deaths," says Edward Bednarczyk, PharmD, chair of the SPPS Department of Pharmacy Practice. "Rather than distributing the medication through police stations, schools, and hospitals, pharmacies provide the community with an instant, ready-made network for distributing medicine."

Mississippi Database Tracks Prescription Drug Abusers

Jackson Clarion-Ledger (Mississippi) (02/29/16) Fitzgerald, Robin

In Mississippi, the Prescription Drug Monitoring Program (PMP) is helping pharmacists, physicians, and law enforcement to combat the abuse of legal narcotics. Pharmacists were first to begin using the database of prescription drug records in 2005 and are the only profession legally obligated to enter information into it. At least once daily, they input details about prescriptions they have filled—data that can then help identify anyone who may be fraudulently obtaining drugs to feed an addiction or to sell on the street. Gulfport pharmacist Larry Knox, for example, contacts prescribing doctors if the PMP indicates that a person is already receiving the same medication from other providers or from multiple pharmacies. Doctors, similarly, will see the same data when mining the system themselves to check a new patient's prescription history. Prescription orders originating from outside of Mississippi also raise red flags, but the database can access records from most neighboring states. While a valuable resource for nabbing violators of prescription drug laws, the PMP also takes steps to avoid misuse of the system. Pharmacists who reach out to prescribers about suspicious orders or customers must take care not to trip federal privacy laws, and criminal investigators are prohibited from running checks unless the target is a person of interest in an active case.