United States Pharmacopoeia (USP) (Rev. 12/19)

At the October 22, 2019 Pennsylvania State Board of Pharmacy (Board) Meeting, the Board discussed issues related to USP's decision to delay implementation of the revisions to chapters 795 and 797 pending resolution of appeals. The following decisions were approved by the Board and placed on record:

1. The Board is enforcing USP 795 and 797 as *currently* written. Board Regulation Section 27.601 was finalized on June 22, 2019 and requires compliance with section 503a of the federal Food, Drug and Cosmetic Act, federal regulations promulgated thereunder and the *current* version of the USP chapters governing compounding.
2. The Board is delaying the enforcement of USP 800 until the appeals of certain provisions of the revised USP 795 and 797 are resolved. While enforcement of USP 800 is being delayed, pharmacies should do their best to comply with the requirements of USP 800, including the sections related to the handling of hazardous medications, as these requirements will be enforced at some time in the future, dependent on resolution of the appeals of the revised USP 795 and 797.
3. The Board voted to adopt the following position and will be amending its regulations to reflect this information:
   The definition of "compounding" does not include the unencumbered flavoring of conventionally manufactured medications provided that the flavors used are inert, tested and do not alter a medication's concentration beyond USP's accepted level of variance.

Note: Please refer to the following links for additional information on USP 800 and its scope (i.e. it would be applicable only when a practitioner is engaged in compounding):

https://www.usp.org/sites/default/files/usp/document/our-work/compounding/usp-800-context-for-implementation-fs.pdf

https://www.usp.org/sites/default/files/usp/document/our-work/compounding/faqs-usp-800.pdf

Electronic Prescribing in Pennsylvania:

For Pharmacists The More Things Change, The More They Stay The Same

Ray J. Michalowski, Esq, Senior Prosecutor to the Pennsylvania State Board of Pharmacy

Mandatory electronic prescribing of controlled substances became effective and enforceable in Pennsylvania on October 24, 2019, exactly one year after the date that the law, Act 96 of 2018, was signed into law. For many prescribers this date will mark a sea change in the way they must issue prescriptions for controlled substances for their patients. The current DEA standards for secure electronic prescribing for controlled substances (EPCS) are nearly a decade old, yet as recently as 2017 EPCS prescriptions accounted for less than 25% of controlled substance prescriptions written nationally. (see Surescripts 2017 National Progress Report)

New York State instituted mandatory EPCS subscribing for all controlled substances in 2016, and the most recent available data shows that greater than 92% of all controlled substance prescriptions written in New York are prescribed via EPCS. Act 96 is quite similar to the EPCS law in New York and a comparable statistical progression from paper to EPCS prescribing over the next few years in Pennsylvania is reasonable to expect. The year that passed between the enactment of Act 96 and the law becoming enforceable enabled prescribers and the facilities that employ or contract with prescribers to take the necessary steps to develop, acquire and implement the required policies, procedures and EPCS compliant infrastructure necessary to comply with the requirements of the law.

Act 96 ushered in a new paradigm for prescribers to adapt and adjust to, but what about dispensers of controlled substances, i.e. pharmacists and pharmacies? How are dispensers affected by Act 96 becoming enforceable and what does the Pennsylvania State Board of Pharmacy (SBOP) expect of its licensees in regards to Act 96 and the new era of mandatory EPCS prescribing of controlled substances? First and foremost, the SBOP expects its licensees to know and understand Act 96 and its requirements, exceptions and exemptions. Act 96 did not amend the Pharmacy Act or the regulations of the SBOP directly, however the Act did amend the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act (the "Drug Act"). The Drug Act is incorporated by reference into the regulations of the SBOP, and hence does have a direct bearing on the practice of pharmacy, even if it is an indirect one. The Pennsylvania Department of Health is required to publish regulations to further implement Act 96, and while those regulations are not yet fully promulgated, you will find links at the bottom of this article with FAQ's and other useful information about Act 96 that have been published by the Department of Health.

It is important to know that Act 96 makes EPCS prescribing of controlled substances mandatory. Except when it doesn't. The mandates in Act 96 come with a list of exceptions to those mandates and a method for obtaining an exemption, each of which allow for non-EPCS prescribing of controlled substances in certain situations. Dealing with those in reverse order, a prescriber may request an exemption from the Pennsylvania Department of Health to continue to issue paper prescriptions for controlled substances. Exemptions must be requested on a case by case basis, last for one calendar year if granted, and may be renewed on a yearly basis. It is common sense to presume that the largest number of exemptions will be granted in this first year of Act 96 being enforceable and that over time they will significantly decrease in number.

The same is true of the exceptions found in Act 96. Exceptions are based on circumstances that might apply to the location of the prescriber issuing the prescription, the nature of the prescription, the type of patient care being provided and so forth. The point of this article is not to set forth Act 96 in full or to replace your reading of Act 96 and the excellent materials already available from the Department of Health and linked below, but rather to remind Pennsylvania pharmacists that when a paper prescription for a controlled substance is received, it may be filled if the prescriber is exempt or the prescription fits the allowable exceptions.

Pharmacists and pharmacies are NOT charged with enforcing mandatory EPCS prescribing under Act 96, nor is the SBOP or the State Boards of Medicine, Osteopathic Medicine, Dentistry or any other Pennsylvania professional licensing board. Act 96 as it applies to prescribers is enforced solely by the Department of Health. Who enforces Act 96 for pharmacists and pharmacies then? Seems like a reasonable question, doesn't it? Reasonable it may be, and while the answer is the SBOP, the follow up question is, what exactly can the SBOP enforce? After all, Act 96 plainly states:

"A pharmacist who receives a written, oral or faxed prescription **shall not be required to verify** that the prescription properly falls under one of the exceptions provided in subsections (a) and (b) from the requirement to electronically prescribe. A pharmacist may continue to dispense medications from the otherwise valid written, oral or faxed prescriptions that are consistent with current laws and regulations." (emphasis added)

The mandatory use of EPCS transmitted prescriptions is a regulatory system designed to reduce prescription related medication errors, and to reduce or eliminate common means of prescription forgery and theft that fuels the illicit diversion of drugs, especially controlled substances. Act 96 is not a law designed to limit access to medically necessary controlled drugs and treatments for those patients who need them. That is why Act 96 was modeled upon laws in other states that have proven workable in achieving a diminution of prescription related diversion and medication errors, without unduly diminishing access to care for those who need it. The exemption provision in Act 96 recognizes that it will take time for some prescribers to fully adapt to the new law and the regulations which are being promulgated by the Department of Health to more fully implement the Act. The exceptions in the law recognize and allow for those instances where EPCS prescribing is impossible or highly impractical, and as seen in the statistics from New York that were shared above, the exceptions clearly do not swallow the rule. Instead, they make it workable.

Act 96 places no specific new statutory requirements on pharmacists because the legislature recognized that pharmacists have always played an integral role in doing the very things, i.e., preventing medication errors and drug diversion, that the new law seeks to enhance. Act 96 contains additional language that should be very familiar to pharmacists:

"If a pharmacist has a reasonable belief that a patient may be seeking a monitored prescription drug for a purpose other than the treatment of an existing medical condition, the pharmacist shall have the responsibility described in 21 CFR § 1306.04 (relating to purpose of issue of prescription)."

The inclusion of this language in Act 96 serves primarily as a reminder of the "Corresponding Responsibility" of pharmacists to ensure the validity of all prescriptions presented to them, no matter the form in which they are received. The rules and regulations of the SBOP that specifically allow a pharmacist to decline to fill any prescription that the pharmacist "knows or has reason to know that it is false, fraudulent or unlawful" or "in the pharmacist's professional

judgment exercised in the interest of the safety of the patient, the pharmacist believes the prescription should not be filled or refilled" have not changed.

Act 96 adds one more factor to consider along with all other indicators of whether a prescription is valid. A non-EPCS prescription for a controlled substance may be presented with enough information on the face of the prescription and/or based on prior knowledge of the prescriber or patient, that you will immediately understand and reasonably believe that an exemption or exception to the law applies. Other times you may see reasons to question whether the prescription is valid in general and will make further efforts to confirm the overall validity of the prescription, with its reason for being written on paper instead of transmitted via EPCS being only one of those factors to inquire about further.

The 'Red Flags' program that the National Association of Boards of Pharmacy promotes is still excellent guidance to augment your own professional judgment. A prescription for a controlled substance that is received in paper form is not, of itself, a red flag. But just as your knowledge and experience with a patient, the prescriber and your analysis of the prescription itself might make an exception or exemption obvious, at times they may raise points of concern. Is the paper prescription from a prescriber that has been sending your pharmacy EPCS prescriptions for months? That might be a cause for further inquiry. If the patient claims the prescription was written by an emergency room physician, yet the type, dosage and number of doses written on the prescription seems unlikely for such a physician to write, then inquire further. Confirm the validity of every prescription in ways you always have.

The new law leaves in place existing pharmacy laws, rules and best practices, all of which place great importance upon each pharmacist's use of their own professional training, judgment and experience in evaluating the validity and accuracy of all prescriptions they receive. A lot of things have changed under Act 96, especially for prescribers and their patients, but for pharmacists your role remains the same. Your diligence, devotion and professionalism as a pharmacist are the reasons that the new law did not need to significantly change what you do, and the State Board of Pharmacy expects that you will continue to exemplify those traits in your professional practices, and in the way you treat others, as the entire healthcare system adapts to the challenges we are sure to face in making mandatory EPCS a success.

Links:

Department of Health – EPCS page with links to Act 96 and FAQS:
https://www.health.pa.gov/topics/programs/Pages/Electronic%20Prescribing.aspx

DEA Pharmacist's Manual Section IX-XIV:
https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_content.htm#9

SBOP Act and regulations:
https://www.dos.pa.gov/ProfessionalLicensing/BoardsCommissions/Pharmacy/Pages/Board-Laws-and-Regulations.aspx

FILL YOUR CONTROLLED SUBSTANCE PRESCRIPTIONS

WITH COMPASSION AND UNDERSTANDING

Working in a community pharmacy nowadays has become very complicated. Pharmacists and technicians have so much to watch out for: proper regulations and requirements for the prescription, State Board of Pharmacy requirements, Department of Health requirements, federal DEA requirements, PBM requirements and rules, corporate policies we must adhere to, the opioid crisis, Prescription Drug Monitoring Program (PDMP) requirements, and more. And now we have the requirements for controlled substance prescriptions to be transmitted electronically. Wow, that's a lot.

With all of these rules to follow, sometimes we lose sight of the compassion needed to take care of the patient, and to look at the process from the patient's point of view. With this article, I'd like to focus on controlled substances and the patient's needs.

Clearly, with the opioid crisis upon us, and the requirements of lookup on the PDMP, pharmacists are jittery when filling pain meds. Large quantities, early refills, and patterns of doctor and pharmacy shopping are all things we must look out for. However, sometimes there is a legitimate reason for a prescription fill that falls outside our comfort zone.

For example, let's look at the early refill request by a few days for buprenorphine. At first glance, we know that this patient is in recovery and being treated for addiction. By definition, these patients have a track record of abuse, and we might even have on their files, from a year ago, a strong pattern of fills for oxycodone. The early refill request could be for reasons of abuse or diversion, or it might be because the patient claims to have lost some pills. Or the reason might even be because the patient "shared" some pills. However, if this patient is truly out of meds, and we deny the fill, then there is a good chance that patient will seek drugs on the street, acquire heroin, and possibly die from an overdose. The lesson here is to TALK to the patient. Try to get an honest reason for the early refill and, without judgement, have a compassionate conversation. If necessary, call the prescriber and discuss the issue. Document your conversation and act accordingly. In my experience, in this scenario, the prescriber will almost always authorize a few days of a fill to avoid a crisis and possible overdose on a street drug.

Another example would be an out-of-state prescription for hydrocodone, written by a dentist we do not know, on a paper prescription, on a Saturday afternoon, for someone about 20 years old. My guess is that many pharmacists will deny filling the prescription. We can't reach the dentist, and this patient rarely, if ever, has had a prescription filled at this pharmacy. However, this may be for a student in a nearby college who had a recent dental procedure. Have a conversation with the patient and get some of your questions answered. There are other ways to verify a prescription without reaching the dentist. For example, ask the patient to produce evidence of the dental visit, like a card for the follow-up appointment.

Regarding the recent requirement that controlled substance prescriptions be issued electronically, we would like to stress that it is NOT the pharmacist's responsibility to police the prescriber for compliance with this new requirement. This is a law that will be policed by the Department of Health. There are many exemptions to this law, including out-of-state prescriptions, lack of electronic health record compatibility by the prescriber, the ability for the prescriber to apply for an exemption and more.

Our oath as a pharmacist is to get the right medicine to the right patient at the right time. In today's complicated pharmacy environment, sometimes it is necessary to go the extra mile and have a compassionate conversation with the patient to get this done.

Robert Frankil, RPh

Independent Community Pharmacy Representative, PA State Board of Pharmacy

Electronic Prescribing is Now Required (Sort of)[1]

On October 24th, 2018, Governor Wolf signed into law Act 96 of 2018, to become effective one year later. Act 96 amended Pennsylvania's Controlled Substance, Drug, Device and Cosmetic Act ("PA Drug Act") and, with several exceptions, provides that except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in Schedules II – V shall be dispensed without an electronic prescription of a practitioner.[2]

Exceptions

The many exceptions to the electronic prescription requirement include, among others, when the prescription is issued:

- by a veterinarian;

- when an electronic prescription is not available to be issued or received due to a temporary technological or electrical failure;

- by a practitioner and dispensed by a pharmacy located outside Pennsylvania;

[1] Any opinions expressed in this article are solely those of the author and do not necessarily reflect those of the Pennsylvania State Board of Pharmacy, the Pennsylvania Department of State or any other governmental body. The author, Kerry E. Maloney, Esq., is an attorney with the law firm of Post & Schell, P.C.

[2] The definition of "practitioner" in the PA Drug Act includes a physician, osteopath, dentist, veterinarian, pharmacist, podiatrist, nurse, scientific investigator, pharmacy, hospital, clinic or other person or institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance, other drug or device in the course of professional practice. Compare this to the definitions of "individual practitioner" and "institutional practitioner" under federal DEA regulations (21 C.F.R. § 1300.01), which explicitly do not include a pharmacist or a pharmacy.

- by a practitioner who, or health care facility that, does not have either internet access or an electronic health record system;

- by a practitioner treating a patient in an emergency department or a health care facility under circumstances when the practitioner reasonably determines that electronically prescribing would be impractical or would cause an untimely delay resulting in an adverse impact on the patient's medical condition;

- for a patient enrolled in a hospice program or for a patient residing in a nursing home or residential health care facility;

- pursuant to an established collaborative practice agreement between a practitioner and a pharmacist[3], a standing order or a drug research protocol; or

- under circumstances where the pharmacy that receives the prescription is not set up to process electronic prescriptions.

Pharmacists: The good news is that Act 96 provides that a pharmacist who receives a written, oral or faxed prescription[4] shall NOT be required to verify that the prescription properly falls under one of the exceptions. A pharmacist may continue to dispense medications from the otherwise valid written, oral or faxed prescriptions.

However, while the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescriber, pharmacists continue to have a corresponding responsibility under state and federal regulations.[5] Additionally, the State Board of Pharmacy's regulations[6] state that a pharmacist may not knowingly fill or refill a prescription for a controlled substance if the pharmacist knows or has reason to know it is for use by a person other than the one for whom the prescription is written, or will otherwise be diverted, abused or misused.

Petition for Exemption

When a practitioner, pharmacy or health care facility is unable to timely comply with the electronic prescribing requirements, and if they do not meet one of the exceptions, they may petition the Department of Health for an exemption based upon economic hardship, technical limitations or exceptional circumstances. The Department of Health may approve an exemption for a period of time not to exceed one year from the date of approval and may be renewed annually upon request, and subject to department approval. A temporary exemption form may be found on the Department of Health's website at

[3] See 49 Pa. Code §§ 27.301 and 27.302.

[4] Act 96 provides that a prescription generated on an electronic system and printed or transmitted via facsimile is NOT an electronic prescription. This is consistent with Pharmacy Board regulations at 49 Pa. Code § 27.201(a).

[5] 21 C.F.R. § 1306.04.

[6] 49 Pa. Code § 27.18(c).

https://expressforms.pa.gov/apps/pa/health/Act96-of-2018-Temporary-Exemption

Existing Electronic Prescription Regulations

The State Board of Pharmacy's regulations regarding electronically transmitted prescriptions remain intact and valid, to the extent they do not conflict with Act 96. For example, prescriptions on file must show the patient information, prescriber information, including the DEA number of the prescriber, the name and quantity of the drug prescribed and the name or initials of the dispensing pharmacist.[7]

Electronic transmission of prescriptions for controlled substances must comply with federal and state laws including the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act,[8] the Pennsylvania Department of Health regulations,[9] and DEA regulations relating to requirements for electronic orders and prescriptions.[10]

Act 96 directs the Pennsylvania Department of Health to promulgate regulations within one hundred and eighty (180) days of the effective date. While the department does not have any implementing regulations in place, it has provided guidance in Question and Answer format at https://www.health.pa.gov/topics/Documents/Programs/PA_EPCS_FAQ.pdf.

[7] 49 Pa. Code § 27.18(b)(1) and (2). See also 49 Pa. Code § 27.201 for detailed and specific requirements for electronically transmitted prescriptions.

[8] 35 P.S. §§ 780-101 *et seq.*

[9] 28 Pa. Code §§ 25.1 – 25.131.

[10] 21 C.F.R. Part 1311.