Physician FAQs on Pennsylvania Law Concerning Electronic Prescribing of Controlled Substances

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A Pennsylvania bill on electronic prescribing of controlled substances was signed into law by Gov. Tom Wolf on Oct. 24, 2018. The law – Act 96 of 2018 – mandates that all Schedule II through V controlled substances, except when dispensed or administered directly to a patient by a practitioner or authorized agent, other than a pharmacist, to an ultimate user, shall be prescribed electronically. This law replaces the traditional method of prescribing controlled substances to a patient, i.e. paper prescription pads.

In this *Quick Consult*, PAMED answers physicians' frequently asked questions about the law.

1. *When does Act 96 take effect?*
   Act 96 takes effect on Oct. 24, 2019.

2. *Who does Act 96 apply to?*
   Act 96 applies to any health care practitioner that is authorized to prescribe Schedule II through V controlled substances.

3. *What does Act 96 change regarding the prescribing of controlled substances?*
   Except when dispensed or administered directly to the patient by a health care practitioner or an authorized agent (other than a pharmacist), to an ultimate user, Schedule II through V controlled substances must now be electronically prescribed as opposed to the traditional method of prescribing, i.e. prescription pads.

4. *Are there exceptions to electronic prescribing?*
   Yes. Electronic prescribing is not required if the prescription is issued:
   1. By a veterinarian;
   2. Under circumstances when an electronic prescription is not available to be issued or received due to a temporary technological or electrical failure;
   3. By a practitioner and dispensed by a pharmacy located outside this Commonwealth;

4. By a practitioner who, or health care facility that, does not have either of the following:
    a. Internet access; or
    b. An electronic health record system;
5. 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 a controlled substance would be impractical for the patient to obtain the controlled substance prescribed by electronic prescription or would cause an untimely delay resulting in an adverse impact on the patient's medical condition;
6. For a patient enrolled in a hospice program or for a patient residing in a nursing home or residential health care facility;
7. For controlled substance compounded prescriptions and prescriptions containing certain elements required by the Food and Drug Administration (FDA) or any other governmental agency that are not able to be accomplished with electronic prescribing;
8. For a prescription issued pursuant to an established valid collaborative practice agreement between a practitioner and a pharmacist, a standing order or a drug research protocol;
9. For a prescription issued in an emergency situation pursuant to federal or state law and regulations of the Department of Health;
10. Under circumstances where the pharmacy that receives the prescription is not set up to process electronic prescriptions;
11. For controlled substances that are not required to be reported to the prescription drug monitoring program system (PDMP) administered by the Department of Health; or
12. Any other situation as prescribed by the Secretary of Health by regulation.

5. What is a temporary technological or electrical failure?

A "temporary technological or electrical failure" is defined as "any failure of a computer system, application or device, or the loss of electrical power to that system, application or device, or any other service interruption to a computer system, application or device in a manner that reasonably prevents a practitioner from utilizing his or her certified electronic prescribing application to transmit an electronic prescription for a controlled substance in accordance with this act and federal requirements."

6. If I experience a temporary technological or electrical failure, what should I do?

Act 96 requires a practitioner to seek to correct any cause for the failure that is reasonably within the practitioner's control within 72 hours.

It is also recommended that during any time a practitioner is unable to electronically prescribe due to a temporary technological or electrical failure, the practitioner note any prescriptions issued to a patient via a prescription pad in the patient's medical record and the reasons for issuing the prescription via a prescription pad. Practitioners and health care facilities should also consider developing policies for tracking these instances and the steps taken to correct the temporary technological or electrical failure in the event that the Department of Health or other governmental entity investigates these instances.

7. *If I have Internet access but do not have an electronic health record system, or vice-versa, do I qualify for a statutory exception?*
On Oct. 21, 2019, the Department of Health responded to a letter from PAMED which asked for clarification on this issue. The Department of Health clarified in this letter that the Department will not take action against a practitioner if the practitioner has internet access but the practitioner does not have an electronic health record system (or vice-versa). The Department further opined that under these circumstances, a practitioner is not required to apply for a hardship exemption and is therefore not required to e-prescribe.

8. *I have patients who tell me they will be filling the prescription at a pharmacy located outside of this Commonwealth. Am I required to verify this since that is one of the exceptions to electronic prescribing?*
Act 96 does not mandate that a practitioner verify or follow-up with a pharmacy to ensure that the patient filled a prescription outside of this Commonwealth. If a practitioner issues a written prescription via a prescription pad due to this exception, the practitioner should note this reason in the patient's medical record and any other record that the practitioner is keeping to track when a prescription is issued via one of the exceptions to electronic prescribing.

9. *Is it correct that simply having a patient in the emergency department or a health care facility is not enough to invoke that exception to electronic prescribing?*
Correct. That exception has two parts. First, that the practitioner is treating a patient in an emergency department or a health care facility. Second, the practitioner must reasonably determine that electronically prescribing a controlled substance would be impractical for the patient to obtain the controlled substance prescribed by electronic prescription or would cause an untimely delay resulting in an adverse impact on the patient's medical condition.

10. *Where can I find more information concerning collaborative practice agreements between a practitioner and a pharmacist?*
The regulations concerning collaborative management of drug therapy went into effect in August 2015 and are discussed here. The pharmacy regulations may be accessed here. Specifically, sections 27.301 and 27.302 address management of drug therapy in institutional and non-institutional settings, respectively.

11. *I noticed that Act 96 references 21 CFR §§ 1306.04 (relating to purpose of issue of prescription), 1311.102 (relating to practitioner responsibilities) and 1311.120 (relating to electronic prescription application requirements). Where can I find a copy of these federal regulations?*
The regulations at 21 CFR Part 1306 can be accessed here.
The regulations at 21 CFR Part 1311 can be accessed here.

12. *Do facsimiles meet the requirements under Act 96 for electronic prescriptions?*
No. A prescription generated on an electronic system and printed or transmitted via facsimile is not an electronic prescription for purposes of Act 96.

13. *I do not meet one of the exceptions listed but I do not believe I will be able to comply with these requirements by the effective date. Is there anything I can do?*
Yes. A practitioner, pharmacy or health care facility that does not meet an exception to the electronic prescribing requirements under this act and is unable to timely comply with these requirements may petition the Department of Health for an exemption from the requirements.

14. *Are there requirements that must be met to apply for an exemption?*
Yes. An exemption must be based upon economic hardship, technical limitations or exceptional circumstances.

The Department of Health is authorized to grant additional exemptions beyond those provided for in the law by regulation.

15. *How do I apply for an exemption?*
Act 96 requires the Department of Health to adopt rules establishing the form and specific information to be included in a request for an exemption. The temporary exemption form is available online here.

16. *Who decides whether my exemption is approved?*
The Department of Health will determine whether an exemption is approved.

17. *How long will it take the Department of Health to rule on my hardship exemption?*
The Department of Health has stated that it may take a minimum of ten business days to render a decision on hardship exemption, though the Department cautions that this timeframe could take longer depending on the volume of requests it receives. It is important for any practitioner to file for a hardship exemption as soon as possible to ensure that the Department issues a decision prior to the law taking effect.

18. *How long may an exemption last?*
The Department of Health may approve an exemption for up to one year from the date of approval. The exemption may be renewed annually upon request by the practitioner and subject to the Department of Health's approval.

19. *Are pharmacists required to verify that one of the exceptions or a hardship exemption exists if they receive a non-electronically prescribed prescription?*
No. A pharmacist who receives a written, oral or faxed prescription is not required to verify that the prescription falls under one of the exceptions in Act 96. A pharmacist is authorized to continue to dispense medications from otherwise valid written, oral or faxed prescriptions.

Note, however, that separate from Act 96, pharmacy regulations do not require a pharmacist to fill a prescription if the pharmacist knows or has reason to know that it is false, fraudulent or unlawful, or that it is tendered by a patient served by a public or private third-party payor

who will not reimburse the pharmacist for that prescription. In addition, a pharmacist may decline to fill or refill a prescription if, 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.

The pharmacist is required to explain the decision to the patient, and if deemed necessary, the pharmacist shall attempt to discuss the decision with the prescriber. Therefore, nothing in Act 96 or the pharmacy regulations require a pharmacist to unequivocally honor a prescription, regardless of whether it is filed electronically or via a prescription pad.

20. What are the penalties under Act 96?

A practitioner who violates this act is subject to an administrative penalty as follows:

- First through tenth violations - $100 per violation.
- Eleventh and subsequent violations - $250 per violation.

The maximum cumulative fines in any calendar year cannot exceed $5,000.

21. Do violations carry over into subsequent calendar year?

No. Violations reset each calendar year. As an example, Practitioner A incurred ten violations in a calendar year. In the next calendar year, Practitioner A incurs another violation. This violation will count as Practitioner A's first violation and not an eleventh violation. Thus, Practitioner A will be fined $100 for a first violation instead of $250 for an eleventh violation.

22. Am I required to report Act 96 violations to my licensing board?

No. Act 96 specifically states that the assessment of an administrative penalty under Act 96 shall not be reported by the Department of Health to the practitioner's appropriate licensing board and shall not be considered disciplinary action. Thus, the practitioner is not required to report the violation to the practitioner's appropriate licensing board.

23. The Department of Health has cited me for a violation of Act 96, but I don't believe I have done anything wrong. Can I appeal this decision?

Yes. A practitioner may appeal the assessment of an administrative penalty. The Department of Health is required to provide you with information regarding your appeal rights.

24. Will the Department of Health issue regulations regarding Act 96?

Act 96 requires the Department of Health to promulgate regulations within 180 days of the effective date of the act. Therefore, the Department will be required to promulgate regulations by April 21, 2020.

25. Where can I read a copy of Act 96?

Act 96 can be accessed here.

26. Where can I obtain more guidance regarding Act 96?

The Department of Health recently issued interim guidance on Act 96 pending the release of formal regulations. You can access that frequently asked questions document here.

27. Should I make sure to keep accurate medical records when invoking an exception?

Yes. A practitioner issuing a paper prescription due to one of the exceptions should note the reason for issuing the paper prescription in the patient's medical record.

28. I want to contact the Department of Health myself. How can I do that?

You can contact the Department of Health at 1-877-PA-HEALTH or through its website here.