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September 3, 2019

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Rachel Levine, MD
Secretary of Health
625 Forster Street, 8th Floor West
Harrisburg, PA 17120

Re: Electronic Prescribing Exceptions under Act 96-2018

Dear Secretary Levine:

On behalf of the Pennsylvania Medical Society (PAMED), I am writing to you to voice our concerns about the Department of Health's (Department) recent guidance that it has issued concerning Act 96-2018. As you are aware, Act 96, introduced by Rep. Tedd Nesbit as HB 353, mandates practitioners to electronically prescribe all Schedule II-V controlled substances, subject to certain automatic statutory exceptions and other hardship exemptions that must be submitted to the Department for approval.

On July 30, your Department held a stakeholder conference call to discuss various issues relating to Act 96. One of the issues that both PAMED and the Pennsylvania Osteopathic Medical Association (POMA) raised was the Department's initial interpretation of one of the statutory exceptions contained in Act 96 regarding lack of Internet access or an electronic health record (EHR) system. Specifically, section 11(a)(4) contains a statutory exception to electronic prescribing that states:

The electronic prescription requirement under this subsection shall not apply if the prescription is issued:
(4) by a practitioner who or health care facility that does not have either of the following:

- (i) Internet access; or
- (ii) an electronic health record system.

A similar provision appears in section 11(b)(4). During the July 30 meeting, Department officials indicated that they were interpreting this exception to require a practitioner to lack both provisions, i.e. they needed to have no Internet access AND no EHR system, rather than simply needing to lack one or the other to be able to invoke the exception. PAMED and POMA representatives on this call expressed concern over the Department's interpretation, specifically highlighting that the exception says "either" and contains an "or" provision and not an "and" provision.

777 East Park Drive
PO Box 8820
Harrisburg, PA 17105-8820

Membership Inquiries
855-PAMED4U
(855-726-3348)

Tel: (717) 558-7750
Fax: (717) 558-7840
Email: KnowledgeCenter@pamedsoc.org
www.pamedsoc.org

In the Department's guidance document that was issued on August 23, the Department maintained its interpretation by publishing the following:

Q: If a practitioner does not have internet access and does not have an electronic health record system, do they meet the requirements for statutory exception?

A: The Pennsylvania Department of Health (the Department) considers the statutory exception in Section 11 (a)(4) and Section 11 (b)(4) of Act 96 to apply only if the practitioner or the health care facility is without both internet access and an electronic health record (EHR) system. If the practitioner or health care facility has at least one or the other, then compliance with the electronic prescribing of controlled substances is required. Providers who meet a statutory exception do not need to file for an exemption with the Department, nor do they need to notify the Department at this time.

PAMED played an integral role in the discussions relating to HB 353. The intent of this statutory exception was not to require both conditions; rather just one or the other.

During discussions regarding HB 353, PAMED, along with other stakeholders, expressed concerns that requiring practitioners who did not have EHR systems or Internet access to purchase such items could potentially put practitioners, and their patients, at risk, as practitioners would be forced to spend a significant amount of money to purchase EHR systems that have e-prescribing capabilities. As you are aware, many EHR systems do not automatically contain e-prescribing capabilities. Rather, e-prescribing is an add-on package that is cost-prohibitive for some practitioners.

The Department's interpretation will require many practitioners, particularly those in rural areas where Internet access is not readily available or reliable, or practitioners whose smaller practices could not sustain costs associated with implementing an EHR system, to face a no-win situation. Practitioners will either have to risk violating the Department's interpretation of Act 96, stop prescribing controlled substances, or close their practice. More importantly, patients with chronic pain, intractable cancer pain, or children with ADD, all of whom require a controlled substance, could lose access to those medications. None of these alternatives is desirable, as it will negatively affect patient care.

The Department's alternative, as referenced in the guidance document, is for practitioners to submit a hardship exemption. Setting aside our assertions that such an exemption is not required, a hardship exemption does not adequately assure that practitioners will not have to purchase EHR systems.

First, a hardship exemption is for circumstances where a statutory exception does not apply. PAMED believes such an exception already exists as explained above. Second, a hardship exemption is only valid for one year and at the discretion of the Department.

What is to prevent the Department from granting a hardship exemption for one year (or even several years) but informing a practitioner that further exemptions will not be granted, thus forcing a practicing to purchase an EHR system or risk violating the law? The Department's interpretation provides no assurances that this will not occur sometime in the future.

The Department's guidance indicates that it may take a minimum of ten business days for the Department to rule on a hardship exemption, though this timeframe may take longer depending on the volume of requests the Department receives. If the Department receives numerous hardship exemption requests prior to the effective date of the Act, yet the Department does not rule on them prior to October 24, what effect will that have on the practitioners who submitted the request? Will they now be in violation of the Act per the Department's interpretation of that statutory exception?

PAMED is requesting the Department to review its guidance document and reconsider its interpretation of the Internet access/EHR statutory exception to Act 96. This interpretation was not the intent of Act 96, nor is that how the exception is written. PAMED is cognizant of the Department's role in trying to stem the opioid crisis in the Commonwealth. However, the Department's interpretation of this statutory exception may jeopardize this goal and threaten the physician-patient relationship.

Thank you for your time and commitment to the citizens of this Commonwealth. We look forward to your response to our request.

Sincerely,

A handwritten signature in cursive script that reads "Danae M. Powers".

Danae M. Powers, MD
President, Board of Trustees

cc:

Hon. Tom Wolf, Governor
Rep. Mike Turzai, Speaker
Rep. Bryan Cutler, Majority Leader
Rep. Frank Dermody, Minority Leader
Rep. Tedd Nesbit, Prime Sponsor for HB 353
Sen. Joseph Scarnati, President Pro Tempore
Sen. Jake Corman, Senate Majority Leader
Sen. Jay Costa, Senate Minority Leader
Yvette Kostelac, Chief Counsel, Department of Health