

February 27, 2015

While New York healthcare practitioners with prescribing authority are waiting to see whether the deadline for compliance with electronic prescription requirements will be March 27, 2015, March 27, 2016, or some other date, questions about the content of the requirements remain. As described in a recent Pullano & Farrow Legal Briefing, in 2012, I-STOP was enacted. I-STOP is a law that, in part, requires any person in New York issuing a prescription for medications to do so electronically and as set forth by regulation.

One of the more frequent questions about e-prescribing concerns whether prescribing practitioners must comply with the e-prescribing requirement when they are not near a computer or where a computer is not available. The simple answer is not always. According to the New York State Department of Health (the "Department"), in such situations, the practitioner may use an Official New York State Prescription form as long as the circumstances meet a specific exception (the Department has assured practitioners that the Bureau of Narcotic Enforcement will continue to supply the forms). Otherwise, the prescribing practitioner must wait until he or she has access to a computer or other device with e-prescribing capability to issue the prescription.

One relevant exception to the e-prescribing requirement is where a practitioner seeks to issue a prescription when e-prescribing is not available due to temporary technological or electrical failure (the "failure exception"). Another exception is provided where a practitioner has received a waiver from the e-prescribing requirement due to economic hardship, technological limitations not reasonably within the practitioner's control, or other exceptional circumstances (the "waiver exception"). The law also excepts a situation where, regardless of the practitioner's ability to issue an electronic prescription, the practitioner reasonably determines that issuing an electronic prescription would make it impractical for the patient to obtain the medications in a timely manner and the delay would adversely impact the patient's medical condition (the "urgency exception"). The exact text of the law, including the exceptions above, is listed under Public Health Law § 281 and Education Law § 6810 and is available at the following site: <http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO>.

As for the failure exception, the regulations define a technological or electrical failure as:

- any failure of a computer system, application, or device;
- any loss of electrical power to a computer system, application, or device; or
- any other interruption in service for a computer system, application, or device.

To constitute a failure, the loss, failure, or interruption must prevent the practitioner from utilizing his or her e-prescribing application to transmit an electronic prescription. The regulations go on to state that the practitioner must seek to correct the cause of the failure without undue delay to the extent it is reasonably within his or her control. Although not listed by the Department, some examples of qualifying failures might include:

- a practitioner's office loses power,
- a software virus corrupts e-prescribing software, or
- the hard drive fails on the only device in the practitioner's office with e-prescribing capabilities.

It is worth noting that this exception, unlike the waiver exception, does not require that the cause of the practitioner's inability to access e-prescribing applications be beyond the practitioner's control (although the practitioner must cure the failure if it is later within his or her control). The exception appears reasonable, a welcome exception in healthcare law, by allowing an exception for mistakes and failures that were arguably avoidable. As a practical matter, at least one software provider is offering an e-prescribing application that is available on many different devices, including smart phones. For practitioners that adopt such technology, this situation could be rare.

The regulations require that practitioners seeking a waiver submit a sworn statement setting forth why the practitioner needs a waiver. The sworn statement must demonstrate an undue burden due to economic hardship, technological limitation beyond the practitioner's control, or other exceptional circumstances. The requirement of an undue burden is in the regulations, but not in the statute. Although hopefully not true, the addition of an undue burden requirement appears to reflect the degree of exceptionalism the Commissioner of Health will require before approving waiver. The sworn statement, according to the regulations, should also include any other information that might affect the Commissioner's determination, including information that could hurt the practitioner's application. Waivers are granted in increments less than or equal to one year, but they may be renewed.

The Department cautions that a waiver obtained for the Prescription Monitoring Program Registry does not include a waiver from the e-prescribing requirements. A separate application is required. As of the date of this Legal Briefing, the Department has not finalized its waiver granting process.

The urgency exception may prove to be the most difficult of the three exceptions for practitioners to navigate. Generally, for the failure exception, the practitioner's computer and e-prescribing software are working, or they are not. For the waiver exception, the practitioner has applied for and been granted a waiver by the Commissioner of Health, or it has not. The urgency exception, however, brings up many difficult questions and hypothetical situations

such as:

- How much does a practitioner have to know about the patient, accessible pharmacies, and the operations of such pharmacies before he or she can reasonably believe that it would be impractical for the patient to obtain the medications within the necessary time period?
- Are suspicions that it would be impractical sufficient under certain circumstances (what if a provider suspects the pharmacy is having issues processing e-prescriptions, but despite a phone call, has not received a confirmation of that fact)?
- What conditions would make it impractical for the patient to obtain the medication?
- Does a forecast of 6" of snow suffice? Does a history of mental illness that might affect the patient's ability to follow up on the prescription suffice? How about the scarcity of the drug?
- What constitutes adversely impacting a patient's medical condition? Is mental health included in the definition of medical conditions? What if the potential medical condition is a mild cold in an otherwise healthy adult (such that the patient's symptoms may endure longer if there is a delay, but the patient is still reasonably certain to recover quickly without lasting effect).
- Seeing as the purpose of the law was, at least in part, to prevent misuse of prescription drugs, is the practitioner also required to consider the potential for abuse if the prescription is not dispensed properly?

The number of close cases under the urgency exception is inestimable. We have labeled this exception the urgency exception for convenience, but there is no requirement of actual urgency in the statute or regulations. The law requires that a delay from using e-prescribing be harmful to the patient's medical condition, not actual urgency. The urgency exception is written with arguably deferential language – with deference to the practitioner's judgment. Hopefully, the Department will follow the intent inherent in the text of the exception and avoid judgments based on information not actually available to the practitioner.

The Department is in the process of issuing additional FAQ's which may address some of these issues. If the compliance date, March 27, 2015, is delayed by legislative action, however, this additional guidance may be delayed as well.

If you have any questions about any of these new developments, please contact any attorney of our Firm at 585-730-4773.

This Legal Briefing is intended for general informational and educational purposes only and should not be considered legal advice or counsel. The substance of this Legal Briefing is not intended to cover all legal issues or developments regarding the matter. Please consult with an attorney to ascertain how these new developments may relate to you or your business.

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