Telepharmacy and the Law

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Telepharmacy and the Law

Abstract
Recently, an "Advisory Notice" was placed on the website of the New York State Board of Pharmacy entitled "Automated Dispensing Machines" that provide "drugs for sale to customers outside of their respective registered pharmacy areas", and that it "considers this to be a violation of state law"\(^1\). In support, the Notice cited the Education Law relating to the profession of pharmacy\(^2\) and Regulations of the Commissioner of Education\(^3\). Finally, ownership of the pharmacy and the Supervising Pharmacist are responsible for compliance and "may be subject to disciplinary and unprofessional conduct action". The Notice did not name specific pharmacies. The Board described a form of "telepharmacy" that is arguably covered by a legislative proposal before the New York State legislature.

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Telepharmacy and the Law
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Recently, an “Advisory Notice” was placed on the website of the New York State Board of Pharmacy entitled “Automated Dispensing Machines” that provide "drugs for sale to customers outside of their respective registered pharmacy areas", and that it “considers this to be a violation of state law”¹. In support, the Notice cited the Education Law relating to the profession of pharmacy² and Regulations of the Commissioner of Education³. Finally, ownership of the pharmacy and the Supervising Pharmacist are responsible for compliance and "may be subject to disciplinary and unprofessional conduct action". The Notice did not name specific pharmacies. The Board described a form of "telepharmacy" that is arguably covered by a legislative proposal before the New York State legislature.

The National Association of Boards of Pharmacy recognized and defined telepharmacy as "the Practice of Pharmacy by registered Pharmacists and Pharmacists located within US jurisdictions through the use of telepharmacy technologies between a licensee and patients or their agents at distances that are located within US jurisdictions."⁴ On February 3rd 2017, Assembly Bill 4553 was filed amending the education law in relation to establishing the practice of telepharmacy⁵.

The telepharmacy legislation was inspired by the North Dakota program that provided both products and counseling to patients in localities that have lost pharmacy services. The goal here is to provide access in rural areas while maintaining "the same standard of care and would still receive consultation by a pharmacist" via "cutting edge technology"⁶. First proposed in 2007, the legislation has been reintroduced in the current session of the legislature. There is no companion bill in the NYS Senate at this time.

By creation of a new section (6832) in the Education Law, the bill proposes use of telepharmacy in three distinct ways. The first of these, in 6832(1) is the use of a "remote site". In this system, a pharmacist would work at a central pharmacy and could oversee up to four remote sites connected by "computer link, video link, and audio link". The remote site would have a technician licensed by the Board of Pharmacy present at all times of operation. The prescription could be received at either the central or the remote site and before a medication is dispensed the pharmacist would need to check the physical prescription, the stock bottle that the technician filled from, the contents that are in the bottle to be dispensed and the label. The pharmacist would also be required to counsel on every prescription that is picked up from the remote site. The pharmacist would be responsible for inventory, record keeping and all other operations at the central and remote site. The pharmacist would need to make inspections of the remote facility at least once a month and to prepare a report of each inspection. Note that the proposal excludes controlled substances.

Section 6832(11) establishes the second style of remote dispensing: the "telepharmacy satellite". The satellite system allows a pharmacist to prepare and fill a prescription at a central site and then a patient can pick it up from a satellite location. The satellite location does not require a pharmacy technician, just personnel trained on how to use the telecommunication equipment. The satellite location would not maintain a prescription inventory. Filled prescriptions would be kept in a locked drawer or cabinet until a patient picks them up. The supportive staff can receive requests for refills or written original prescriptions that can be sent on to the central location⁷.

The third style of community telepharmacy involves the use of a dispensing machine (6832(13)). The dispensing machine would contain filled prescriptions for individualized patients in a secure fashion. A pharmacist would verify the prescriptions before release from the machine, and counseling would still occur via an audio or telephone link. Note that this appears to be the area of concern addressed by the Board of Pharmacy on its website.

The current New York State bill also discusses the use of telepharmacy in hospitals (6832(12)). The use that the bill sets forth is to require that a pharmacist verify medications via an audio, video, or computer link. This portion of the proposal lacks the detail associated with the community context, perhaps tacitly acknowledging that telepharmacy has been utilized hospital practice for many years now. Indeed, remote care and service by a pharmacist is utilized by virtually every New York hospital that is not open around the clock.
The concept of a pharmacist being able to perform their duties in a way that is safe and effective from a remote location began to spread out of just the community sector of pharmacy and make its way into the clinical realm. Physicians in hospitals frequently rely on pharmacist consultation for medication adjustments. Some companies have realized the benefit of the pharmacist consultation and have made pharmacists available via telecommunication pathways to doctors. This is beneficial when a hospital doesn’t have a pharmacist on duty. Other companies have made pharmacists available to telecommunicate with patients during a transition of care. The pharmacist is able to check in on the patient and adjust medications accordingly and check adherence to ensure the best possible results for the patient.

Hospitals using pharmacists to monitor transition of care through a telecommunication pathway have reduced 30-day readmission rates by 20-40%

A valid concern that may also arise is that of job security for pharmacists. With remote pharmacies a single pharmacist can control multiple sites and there may be a lesser need. Many states that have implemented telepharmacy have included provisions that do not allow a remote telepharmacy within a certain distance of a fully functioning standard pharmacy. In Montana a telepharmacy cannot be located within 20 miles of any other pharmacy. It has also been suggested that the use of telepharmacy in hospitals will not eliminate jobs but just expand resources and give the pharmacists directly employed by the hospital more face to face time with the patient as they will be spending less time answering doctor’s questions

While many other states have been using telepharmacy for the better part of two decades, it may be the ideal time for New York to establish their own system. Telepharmacy has developed greatly since its introduction in North Dakota in 2011, but in this time of constant technological advances, there is no doubt more improvements will be made.

References:
2. Education Law §§6802(1) and 6808(1), the definition of pharmacy, and pharmacy registration requirements, respectively.
3. 8 NYCRR §53.6 stating that pharmacies “located in New York must meet all requirements outlined” in the Regulation.
5. 4053, “Justification” section.

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