

# COVID-19 pandemic sparks regulatory changes for Rx

By Shannon Cox and Stephen Cummings

The rapid spread of the COVID-19 virus has placed an enormous strain on the U.S. health care system, and we can expect that the pandemic will continue to impact retail pharmacies for the foreseeable future. In addition to the wide range of operational challenges facing retail pharmacies, the COVID-19 virus has sparked a number of regulatory changes. This article is not intended to address all of the changes that are occurring, but focuses on key actions that federal and state regulatory authorities have taken to ensure that consumers have access to necessary medications during the COVID-19 pandemic.

## The crisis may expand the role of pharmacists.

### Federal Changes Relating to Telemedicine and Controlled Substance Prescriptions

On January 31, 2020, the Department of Health and Human Services declared a nationwide public health emergency. This decision triggered an exception to the requirement in the Controlled Substances Act for an in-person medical evaluation. As a result, practitioners can now prescribe Schedule II through Schedule V controlled substances pursuant to a patient encounter conducted by telemedicine, even for patients who have not had an in-person exam conducted by a practitioner.

The requirements under the public health emergency telemedicine exception are that the prescription be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice; the telemedicine communication be conducted using an audio-visual, real-time, two-way interactive communication system; and the practitioner be acting in accordance with applicable federal and state laws. Provided these requirements are met, the practitioner may issue the prescription using any of the methods of prescribing currently available and in the manner set forth in the Drug Enforcement Administration regulations. Thus, the practitioner may issue a prescription electronically (for Schedules II to V), by calling in an emergency Schedule II prescription to the pharmacy, or by calling in a Schedule III to V prescription to the pharmacy.

This means that pharmacies are likely to receive an influx of new controlled substance prescriptions that have been issued by practitioners via telemedicine for patients they have

never examined in person. And although there is a declared health emergency, pharmacists continue to have a "corresponding responsibility" under the Controlled Substances Act to identify, prevent and avoid the abuse or diversion of controlled substances. This means that pharmacists are going to have to be especially vigilant in looking for potential abuse and diversion. A complicating factor, however, is that in most cases the pharmacists are unlikely to be able to distinguish which customers have had an in-person exam from those that have not had an in-person exam.

Additionally, DEA has granted an exception for the duration of the public health emergency with respect to the ordering of Schedule II controlled substances using a DEA Form 222. DEA regulations usually require a purchaser to submit the original to the supplier. But under this exception, purchasers are allowed to now fax or email a scanned copy of the DEA Form 222 to suppliers. And suppliers are allowed to treat the faxed or scanned DEA Form 222 as the original. Pharmacies utilizing this option will need to ensure that the operational change does not interfere with their recordkeeping.

### State Law Changes Regarding Prescription Refills

States are also enacting various exceptions to existing pharmacy laws and regulations as a result of the COVID-19 virus. Most states have taken some action with regard to refill requirements to allow patients to continue to receive medications even if their health care provider is not available. The scope of the exemptions to refill rules varies significantly from state to state, so retailers with operations in multiple states will need to ensure that the requirements of each jurisdiction are being satisfied and may have to make adjustments to various system blocks.

For example, in Georgia, the governor issued an emergency order on March 20, 2020, that modified several requirements for dispensing prescription drugs. The emergency order granted pharmacists the authority to dispense a 90-day supply when the patient's prescription does not have any remaining refills if the pharmacist is unable to contact the practitioner to obtain refill approval. The order specified that it did not apply to Schedule II controlled substances, but did not address Schedule III to V drugs, which has caused confusion with some pharmacies and customers. The Georgia Board of Pharmacy subsequently issued guidance clarifying that the emergency order does not apply to any controlled substance. The emergency order also per-



Shannon Cox



Stephen Cummings

mitted pharmacists to dispense early refills for medications, including Schedule III through Schedule V drugs that have refills remaining.

Individual states have also granted numerous other exceptions designed to allow pharmacies to adapt their operations to meet the needs of the public and to focus all available resources on patient care. On March 27, 2020, the Wisconsin Pharmacy Examining Board granted a rule variance to allow pharmacists to dispense in locations that are not licensed pharmacies. Ohio and Oregon are allowing pharmacies to employ pharmacists and technicians licensed in other states. Texas and many other states have temporarily

suspended various administrative requirements and extended deadlines to accommodate the increased demands being placed on pharmacists by the COVID-19 response.

### Pharmacist Authority

In recent years, there has been significant momentum toward the expansion of pharmacists' authority to dispense medications with a prescription from a physician in order to increase consumer access to medical care, and the COVID-19 epidemic may lead to further expansion of the role of pharmacists.

The concept of leveraging pharmacists and retail pharmacies gained significant traction as a result of efforts to prevent opioid overdose deaths. All 50 states and the District of Columbia have taken some action to expand the authority of pharmacists to dispense naloxone in recent years. As these laws took effect, retail pharmacy dispensing of naloxone increased dramatically, and the expansion of naloxone dispensing has been a public health victory. A recent study demonstrated that states with operational pharmacist naloxone dispensing programs had 30% fewer opioid overdose deaths compared to states that had not yet implemented pharmacist dispensing.

There is also a growing acceptance of so-called "test and treat" authority, under which pharmacists can administer rapid diagnostic tests and dispense appropriate medications based on the results. In March, Florida became the latest state to grant this kind of authority to pharmacists. The new law, which will take effect on July 1, will allow a pharmacist, acting under a written protocol with a supervising physician, to test or

screen for and then treat a list of "minor, nonchronic health conditions" including flu, strep throat, lice, certain skin conditions and minor infections.

Given the recent spread of the COVID-19 virus, it is likely that there will be additional developments in this area. Retail pharmacies and pharmacists have the potential to provide invaluable support as the nation's health care system works to address the pandemic. Because of the accessibility of retail pharmacies, there have been a number of proposals to utilize retail pharmacies as test sites, and several drive-through test sites are operational at retail pharmacy locations. As COVID-19 testing programs are rolled out more widely, it is likely that retail pharmacies will play a major role. And pharmacists may play a significant role in the prevention and treatment of the virus. If a vaccine is developed, pharmacists can be leveraged to rapidly inoculate large numbers of people. And, if treatment options are developed, pharmacists might be granted "test and treat" authority in order to efficiently treat the potentially large number of patients.

As a result of the COVID-19 epidemic, the retail pharmacy industry is having to rapidly adapt to a changing legal and regulatory environment, which is likely to continue to evolve throughout 2020. Some of these changes may become permanent, and the COVID-19 virus may lead to long-term changes in the role of pharmacists and retail pharmacies in the health care system.

Shannon Cox and Stephen Cummings are counsels at King & Spalding's Atlanta office. They can be contacted at [scox@kslaw.com](mailto:scox@kslaw.com) and [scummings@kslaw.com](mailto:scummings@kslaw.com).