Health Law Daily Wrap Up, STRATEGIC PERSPECTIVES: States fail to fully use telemedicine to fight public health crises, (Sept. 28, 2018)

Health Law Daily Wrap Up

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The opioid epidemic has been on the public's radar for years, and health care providers, payers, and policymakers are furiously playing catch-up to find solutions for prevention, diagnosis, and treatment. In 2017, the Trump Administration declared the epidemic a public health emergency, and the President directed agencies to use "every appropriate emergency authority to fight the opioid crisis." Telemedicine's inherent flexibility allows it to provide unprecedented access to health care services, and should be an obvious solution for agencies to tap into as they explore what "appropriate emergency authority" options they have. Yet regulatory burdens limit its implementation for providing care for patients with substance use disorders (SUDs) and mental health diagnoses, which often exist hand-in-hand. This Strategic Perspective will explore how telemedicine is being used for the public good, and what areas need significant development to ensure that barriers to treatment are overcome as quickly as possible while maintaining quality of care.

Telemedicine's Vital Role in Public Health

Telemedicine, a descriptor commonly used interchangeably with the term "telehealth," involves the use of technology in delivering remote health care services in various ways. The American Telemedicine Association (ATA) calls it that "natural evolution of healthcare in the digital world." Telemedicine services are delivered through many types of devices, from telephone consultations and doctor appointments held via video conferencing to remote cardiac monitoring. Telemedicine overall drastically improves access to health care services by allowing patients with limited mobility or who live in rural areas to connect with providers more easily, expanding the reach of specialized consulting, and reducing wait times for busy patients and doctors.

Due to its flexibility, telemedicine is a valuable tool for providing what the Centers for Disease Control and Prevention (CDC) has determined are 10 essential public health services. According to the CDC, some of the efforts all communities should take include monitoring the local population's health status to solve community health problems, investigating health hazards, informing the public of existing health issues, working to combine and mobilize resources to improve health efforts, and helping people find the health services they need. Although these are certainly important goals, communities—especially those in medically underserved areas—are often stretched thin and in need of additional resources and manpower. Telemedicine closes the gap between those in need and those who can provide assistance, and allows for significant data collection and analysis as remote health care monitoring and patient self-reporting through mobile health applications increase. Such benefits allow communities to better provide essential public services with fewer resources. However, legal and regulatory concerns spanning from privacy to payment complicate the use and usefulness of telemedicine, hampering implementation.

The Ryan Haight Act—A Major Federal Roadblock

In 2008, following the death of an 18-year-old who overdosed on a narcotic pain medication he received from an online pharmacy, the Ryan Haight Online Pharmacy Consumer Protection Act (Ryan Haight Act) (P.L. 110-425) was enacted. This act is enforced by the Drug Enforcement Administration (DEA), and prohibits dispensing a controlled substance via the internet without a valid prescription; for purposes of the Ryan Haight Act, a valid prescription can only be issued for a legitimate medical purpose by a practitioner who has evaluated the patient in person at least once.

Treatment for SUD generally involves a broad approach, including treatment for mental health issues, behavioral counseling, and medication-assisted treatment (MAT). For opioid addiction, the medications methadone, naltrexone, and buprenorphine are used to treat SUD in various ways, by blocking the effects of narcotics and/or reducing withdrawal risk or symptoms. MAT is somewhat controversial, because individuals who are not opioid users may experience euphoria when using these drugs. However, the National Institutes of Health (NIH) states that those who have developed a high tolerance for opioids do not experience the same effect, and that these drugs are necessary because patients are able to function normally and participate in other forms of treatment.

While the Ryan Haight Act was enacted to block internet prescriptions for medications that were not medically necessary, it has had the effect of blocking treatment for those with SUD. MAT treatments themselves are controlled substances, and therefore subject to the Act. This means that patients who are unable or unlikely to be seen in person to initiate SUD treatment will not receive prescriptions for MAT.

Francesca Ozinal, an associate from Epstein Becker & Green, P.C., believes that this act has "significantly hampered" providers' ability to treat SUD via telemedicine. She pointed out that physicians often lack expertise in opioid-use treatment, and may be deterred from working with such patients due to a stigma—as well as the DEA's scrutiny in this area of medicine. Such deterrents are multiplied by the lack of behavioral health care providers, especially in rural areas. Access barriers like these result in untreated patients and overworked providers, highlighting the need for telemedicine.

Jayme Matchinski, an officer at Greensfelder, Hemker & Gale, PC, believes that an in-person evaluation before prescribing controlled substances, particularly Schedule II narcotics, is imperative. She told Wolters Kluwer that an in-person appointment is in the patient's best interest because it will result in a more comprehensive evaluation and an opportunity for the patient to better communicate health concerns. She sees benefits for providers, too, in a better ability to assess potential issues and health risks the patient is experiencing, reduce liability, and protect state licensure.

In Ozinal's view, the determining factor for holding an in-person evaluation before prescribing controlled substances should not be the "necessity" of such a visit, but instead "whether the standard of care dictates an in-person evaluation." She believes that the Ryan Haight Act does not recognize that physicians are legally and ethically obligated to follow the standard of care, and that Congress should revise the law to reference the standard instead of requiring an in-person evaluation for each patient.

Congress is aware of the issue. Earlier this year, two discussion drafts, titled Improving Access to Remote Behavioral Health Treatment Act and Special Registration for Telemedicine Clarification Act, were put forth in the House for consideration. The Improving Access Act would have required the U.S. Attorney General to register community mental health or addiction treatment centers with the DEA under the Controlled Substances Act (21 U.S.C. §823(f)) as clinics, allowing providers to prescribe controlled substances via telemedicine to patients at those locations without an in-person examination. This Ryan Haight exemption would be restricted to DEA-registered hospitals and limited types of clinics. Similarly, the Special Registration Act (which was passed by the House) would require the DEA to create interim regulations allowing providers to obtain a special registration allowing prescribing without the in-person exam—an exception contained within the Ryan Haight Act that the DEA has never activated.

Although these discussion drafts did not proceed further, on September 28, 2018, the House and Senate have both passed the SUPPORT for Patients and Communities Act and were in the process of finalizing remaining details. This legislation was created by combining multiple of bills directed toward fighting the opioid epidemic, largely focused toward improving access to addiction treatment. If the bill becomes law, Sec. 1009 would require HHS to provide guidance to states on options for receiving federal Medicaid funding for SUD treatment delivered via telehealth, and Sec. 2001 would remove geographic requirements for the location of a Medicare-enrolled patient to receive reimbursable telemedicine services if the patient has a SUD diagnosis and the services provided are for treating SUD or co-occuring mental health disorder. Sections 3201-3204 would improve flexibility of delivering MAT by eliminating a time limitation for nurse practitioners and physician assistants to become qualifying practitioners for the purposes of prescribing MAT, and Sec. 3232 would require the DEA to

finally create regulations for special telemedicine registration, within one year of the passage of the SUPPORT Act. At *Health Law Daily*'s deadline, the House passed a resolution and the bill was awaiting final Senate approval. House Speaker Paul Ryan (R-Wisc) indicated that the President was likely to sign the bill into law.

State Efforts to Work Around Federal Requirements

In Ozinal's experience, states worry that passing regulations that violate the Ryan Haight Act could result in restricted or blocked funding for necessary programs. In an interview with Wolters Kluwer, Sean Sullivan, an associate with Alston & Bird LLC, noted that states are trying to gain traction where they can—particularly within the flexibility of their Medicaid programs.

He highlighted that in Georgia, an ambulance can be an eligible originating site for telemedicine and may bill the originating site fee to Medicaid—and that a rule was recently approved to permit payment for ambulance treatment without transport. Private payer parity laws, however, are slower to develop in states, and commercial insurers are often not required to implement coverage or payment parity for telemedicine versus in-person services. Finally, he noted that state medical boards are extremely resistant to change, and he believes that this stems from fear of losing control of prescribing and the "potentially misguided" fear that telemedicine allows patients to more easily obtain addictive drugs. In his view, telemedicine is "one of the strongest tools" available for combatting the opioid epidemic, providing access to both MAT and mental health treatment that patients would otherwise be unable to obtain, or would be required to go to great inconvenience to obtain.

State task forces. States are using task forces and telehealth councils to determine how to best implement telehealth services to serve their communities. The Texas Health and Human Services e-Health Advisory Committee has made several recommendations to the state, such as (1) requiring payer and public health information for Medicaid and Children's Health Insurance Program (CHIP) clients to be consolidated in an easily accessible, standard format; (2) reviewing the patient consent model to identify changes that would maximize clinical, payer, and public health information sharing, especially for the use of mental health treatment and emergency response; (3) repealing outdated, confusing language from state telemedicine regulations; (4) enabling pharmacists as reimbursable providers for teledelivered medication therapy management services and consultations; and (5) making home telemonitoring a permanent benefit, applicable to more conditions.

Similarly, the South Carolina Telehealth Alliance (SCTA), funded by the state legislature, is made up of various organizations working together to develop and implement strategies for broadening the use of telehealth services. The SCTA works to equip providers, especially those in rural and underserved areas, with technology and training for telehealth service provision, develop inpatient and specialty telehealth services that meet the needs of the community, and broaden access to care, especially mental health care.

Grants. Ozinal and Matchinski both pointed to federal grants and other efforts that have allowed states to implement other strategies. For example, funding for rural states has come through the Agency for Healthcare Research and Quality (AHRQ) for MAT therapy. Project ECHO, a program that trains primary care clinicians on using telemedicine, has also received help from the AHRQ to provide treatment in several states. Rural states located in Appalachia have conducted studies on addiction and treatment, allowing them to receive distance learning and telemedicine grants.

State legislation. Despite the issues surrounding the Ryan Haight Act, states have begun to implement various laws to encourage the use of telemedicine to treat these public health concerns and improve access to care as they can.

- Connecticut Public Act 18-148. Connecticut has specified that a telehealth provider may not prescribe controlled substances through telehealth, except for controlled substances other than opioids to treat psychiatric disability or SUD, including MAT. The text specifically mentions that such prescribing must be fully consistent with the Ryan Haight Act.
- Del. Code Ann. Tit. 24 §1769D(g)). Delaware requires that telemedicine be used only within an established physician-patient relationship (except for consultations or during emergencies). However, it does allow for controlled substances to be prescribed through telemedicine if such a relationship exists.

- Delaware 1700 Board of Medical Licensure and Discipline, 19.0. Delaware's medical board has established that opioids can only be prescribed via telemedicine through addiction programs offering MAT with a special waiver obtained through the state. Other controlled substance prescribing through telemedicine is held to the same standards of care as for in-person visits.
- Ind. Code 25-1-9.5-8. Indiana allows a prescriber to issue a prescription for partial opioid agonists via telemedicine without the in-person examination, provided that the prescription is issued to treat opioid dependence and is within the prescriber's scope of practice. A prescriber may also, via telemedicine without the prior in-person exam, continue a controlled substance treatment plan established by a prior Indiana provider who had examined the patient in person, as long as the prescribing provider had reviewed the treatment plan.
- Maryland HB 983. Maryland now requires insurers to provide coverage for services "appropriately-delivered through telehealth," and specifies that counseling for substance use disorders is considered appropriately delivered.
- Maryland SB 1106. Maryland also created the subtitle "Teletherapy" under the Code of Maryland's Health Occupations article. The code specifies that a licensed provider may use telemedicine to deliver behavioral health services if he or she (1) establishes a patient-practitioner relationship; (2) provides for the privacy of teletherapy communications; and (3) addresses the need to maintain the patient's safety and well-being. The law also required the various relevant state boards to adopt uniform, nonclinical regulations for the use of teletherapy. Although the Maryland Board of Physicians evaluated drafted regulations in a January hearing, they were tabled for consideration and have not yet been finalized or implemented. The deadline for adoption of these regulations is October 1, 2018.
- Ohio Admin. Code 4731-11-09. Ohio's state board has, through an unwieldy and confusing rule, established a set of circumstances under which a physician may prescribe a controlled substance via telemedicine without a prior in-person examination. These circumstances include situations in which the patient is actively treated by an Ohio licensed physician or other provider who is a colleague of the prescribing physician, and the drugs are provided under an on-call or cross-coverage arrangement.
- Texas SB 922. Texas established that its Medicaid program would provide reimbursement for licensed counselors, therapists, or school psychologist specialists for teletherapy services provided through the school district or charter school.
- Utah HB 154. Utah classified communication by telemedicine as face-to-face contact for reimbursement purposes under the state's Medicaid program, including managed care. The state also requires a Medicaid program to reimburse for teletherapy services.
- W. Va. Code §30-14-12d(g)(1)-(2). In West Virginia, physicians are specifically prohibited from prescribing Schedule II controlled substances to patients with whom the physician only treats through the use of telemedicine (with exceptions). Physicians are also prohibited from prescribing pain-relieving controlled substances to treat chronic nonmalignant pain solely based on telemedicine encounters. The code does not otherwise limit the prescribing of controlled substances via telemedicine. The code also references that telemedicine technology treatment is subject to the same standard of care as traditional physician-patient encounters—similar to Ozinal's suggestion.

Conclusion

Telemedicine is a powerful tool that can help alleviate the pressure on providers to meet the needs of patients in medically underserved areas. The federal and state governments have failed to use telemedicine to its full potential to address the issues of opioid addiction and behavioral health needs facing their communities, due in part to the Ryan Haight Act, but states are finding ways to work in reimbursement for telehealth services in their Medicaid programs and encouraging providers to prescribe MAT as permitted by federal law via telehealth. To further expand permissible uses of telemedicine to address the opioid crisis, states will need to (1) encourage coverage and payment parity from private payers; (2) ensure that medical boards are providing the right guidance for physicians about the use of telehealth; and (3) work with the federal government to loosen the regulatory and statutory burdens that hamper efforts to address pressing public health crises.

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