Cutting-Edge Hospital Legal and Regulatory Issues Related to the Opioid Crisis

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Now, more than ever, hospitals are joining the front lines to help solve the opioid epidemic. Since 2000, the United States has seen a 200% surge in opioid-related deaths.[1] In 2016 alone, more than 63,000 people died from drug-related overdoses. More than 42,000 of these were attributed to the use of opioids, according to the National Center for Health Statistics.[2] In response, state and federal legislatures have taken the initiative to curb opiate prescribing practices and redesign hospital treatment and discharge processes, disrupting traditional modes of operation for hospitals and providers alike. This article provides an overview of some of the recent regulatory compliance issues faced by hospitals in light of the opioid crisis, as well as a few of the current and foreseeable legal and regulatory changes related to treatment of opioid use disorders.

Compliance with Federal Staffing Requirements

The sharp increase in the volume of patients in emergency departments because of opioid overdoses raises concerns over the ability of hospitals to comply with federal staffing requirements. Federal opioid treatment standards require providers working with opioid use disorders to have "sufficient education, training, and experience….to enable that person to perform the assigned function."[3] It is estimated that by 2025, there will be a shortage of approximately 250,000 providers in the fields of substance abuse and mental health treatment.[4] This issue may be exacerbated by the fact that reimbursement rates for these types of services, including for psychology and psychiatric nursing, remain relatively low.[5]

As such, hospitals may find themselves at risk for violating regulations related to the number, and adequacy, of staff engaged in the treatment of opioid use disorders. Medicare-participating hospitals may also find themselves at risk of violations of their Conditions of Participation (COPs) if at the time of survey, they do not have a sufficient number of physicians on staff qualified to handle issues and complications related to opioid overdoses.[6]

Staffing shortages may also raise compliance concerns with the federal Emergency Medical Treatment and Labor Act (EMTALA), which requires hospitals to stabilize patients and treat emergency medical conditions.[7] Generally speaking, stabilization requires emergency room staff to resolve the patient's acute symptoms so as to avoid serious jeopardy to the patient's health. As the rates of opioid-related emergency conditions increase, many hospital emergency rooms may lack sufficiently trained staff to diagnose opioid use disorders and provide the appropriate range of medically assisted treatment and psychosocial services to truly stabilize a patient.[8] Indeed, the President's Commission on Combating Drug Addiction and the Opioid Crisis specifically addressed this issue and recommended that the U.S. Department of Health and Human Services (HHS) provide the resources to incentivize hospitals to hire appropriate staff for their emergency rooms.[9]

Hospitals should also be mindful that if outpatient services are provided to the public, EMTALA mandates that those same services be available through on-call coverage of the emergency department.[10] The shortage of adequately trained and qualified providers thus raises the potential for violations of EMTALA's on-call responsibilities if physicians and staff who are well-versed in dealing with opioid overdoses and related emergency conditions, are not part of the hospital's on-call list.

State Legislation Limiting Opioid Prescriptions and Supporting Use of Prescription Drug Monitoring Programs

Legislation limiting opioid prescriptions gained traction in 2016, when Massachusetts passed the first law of its type and set a seven-day limit on initial opioid prescriptions.[11] Since then, several states have followed suit.[12] North Carolina imposed a five-day limitation on opioid prescriptions which went into effect on January 1, 2018,[13] and similar legislation is making its way through the Florida state legislature to impose a three-day limitation on opioid prescriptions.[14] Similarly, the Florida Agency for Health Care Administration limits narcotics prescriptions in the Medicaid program to a maximum seven-day supply.[15] Although there are no comparable federally-mandated limitations yet, such regulations are likely in the near future.

One issue with prescription-limiting laws, however, is that many do not impose a limitation on the prescribed dosage *amount*, which has allowed some providers to effectively avoid the prescription limitations. However, some states, like Maryland, limit opioid prescriptions to the lowest effective dose in a quantity no greater than what is needed for the expected level of pain.[16] Similarly, Arizona is proposing legislation that would both set a five- or 14-day limitation (depending on the circumstances) on prescriptions, *and* cap maximum prescription dosages.[17]

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States are also increasingly mandating the use of prescription drug monitoring programs by providers. These programs, also known as PDMPs, allow providers to analyze a particular patient's past and present prescription drug use before they write prescriptions for opioids or other drugs with high rates of addiction, such as Percocet, Vicodin, and Oxycontin. In fact, 47 states currently allow for inter-jurisdictional sharing of their PDMPs so that providers may reference the patient's PDMP status in nearby states.[18] That said, PDMP programs could benefit from increased electronic health record integration. The President's Commission also addressed this issue, recommending that the federal government work with the states to remove legal barriers preventing PDMPs from incorporating all available data, including data from the U.S. Department of Transportation's Emergency Medical Technician (EMT) overdose database.[19] The report found it necessary to have overdose data and naloxone deployment data in the PDMPs to ensure that PDMPs are of maximum use to providers.

State-Led Redesign of Hospital Treatment and Discharge Process

With the goal of changing the way hospitals treat and discharge patients with opioid use disorders, states are passing legislation to prescriptively redesign the treatment and discharge process. Recently, the New York State Department of Health gave notice of proposed rulemaking under Public Health Law 2803-u, which would require New York hospitals to implement and develop policies and procedures related to the treatment of patients with substance use disorders. Specifically, the new rule would require hospitals to develop policies and procedures to identify and refer individuals with substance use disorders to further treatment and stresses the importance of identifying individuals who may have a substance use disorder (or be at risk for developing one) at all stages of treatment, including discharge. The new rule would also mandate that hospital staff both refer patients to substance use treatment, and assist patients in coordinating appropriate services, such as by securing admission, helping patients set up an appointment with a community treatment program, or connecting patients to telehealth providers. Moreover, the regulations require hospital staff, as part of the discharge process, to provide patients with educational materials selected by the Office of Alcoholism and Substance Abuse Services and the New York Department of Health.

Nevada provides another example of a state initiative to redesign processes, where, starting January 1, 2018, an emergency law went into effect with the hope of strengthening the relationship between physicians and their patients, as well as increasing the ability of providers to identify patients presently struggling with, or at risk of developing, opioid use disorders.[20] A recent amendment to the Nevada Controlled Substance Abuse Prevention Act requires providers to seek continued medical education related to the misuse and abuse of controlled substances, mandates registry and use of a Prescription Monitoring Program, and sets forth new prescription requirements and prescribing guidelines.[21]

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In New Jersey, state law also oversees how providers interact with patients when prescribing opioids. Specifically, the law requires providers to explicitly discuss with patients the risks of addiction, physical or psychological dependence, and about the availability of alternative treatments.[22] A provider is required to have such a discussion prior to the initial prescription and again before issuing a third re-fill.[23] Moreover, providers must note the occurrence of such a discussion in the patient's permanent medical record.[24]

Agencies like the Arizona Department of Health have issued voluntary consensus guidelines that mimic many of the provisions seen in New York and Nevada. These guidelines seek to improve the discharge process and promote provider-patient engagement.[25] They require hospitals to, for example, check a patient's history with the Arizona Controlled Substance Monitoring Program, notify the patient's primary care provider about recent overdoses, and provide peer support and access to recovery treatment centers.[26]

Lack of Alignment of Payment Methodologies

An additional legal issue is the lack of alignment between current payment methodologies and the efforts necessary to address the opioid crisis. However, state-run innovation programs such the New York Delivery System Reform Incentive Payment (DSRIP) program are making funds available and providing payment flexibility to groups committed to redesigning and restructuring health care access, including for those individuals impacted by the opioid crisis.[27] Not only have these programs been extremely successful, but they have the potential to demonstrate the importance and benefits of community-based efforts to fighting the opioid crisis.

The Staten Island Performing Provider System (PPS) provides one example the use of DSRIP funds to not only expand upon the variety and availability of clinical and social services, but also to offer services that would not ordinarily be compensated under traditional Medicaid.[28] For example, recovery and resource centers are now open 24 hours a day and providers have the flexibility to engage with opioid patients even without appointments.[29] The PPS has also increased efforts to provide peer-recovery support services both to the public-at-large and to those within the criminal justice system, often through point of access diversion programs.[30]

Loosened Constraints on Information Sharing

HHS promulgated new regulations under 42 CFR Part 2, effective February 2, 2018, that loosened some Health Insurance Portability and Accountability Act (HIPAA)-imposed constraints on the ability to share patient information. Primarily, the new regulations make it easier for health care

providers to share patient substance use disorder records with a patient's family and caretakers following an opioid overdose. The regulations grant providers greater flexibility and autonomy in disclosing patient information in certain limited situations, including without the patient's consent. In support, the HHS Office for Civil Rights recently issued Guidance which clarifies the conditions and criteria under which the sharing of mental health information of patients in distress due to their substance use disorder is permissible.[31]

Conclusion

State and federal authorities are only just beginning to tackle the opioid crisis by enacting a variety of different laws and regulations. By imposing limitations on prescriptions and prescribing discharge practices, states are attempting to ensure that providers are in the best position to treat patients with opioid use disorders while also proactively contributing to the solution and continuing to combat pain. As such, hospitals should be mindful of state and federal legislative changes related to the treatment of patients with opioid use disorders and consistently review their compliance efforts to keep up with substantial changes in this space. C

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Endnotes

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