HOSPITALS' ROLE IN COMBATTING THE OPIOID CRISIS

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Hospitals and health systems play a central role in helping to address the opioid crisis. Even before increased national attention, hospitals were developing policies, protocols, and procedures for opioid prescribing best practices, as well as model programs aimed at diversion detection and prevention. Comprehensive hospital guidance is critical for departments and practitioners who regularly treat patients requiring pain relief or struggling with an opioid disorder, especially in light of recent and increased legislative, regulatory and litigation activity.

The importance of these hospital initiatives is further heightened by federal and state legal developments and opioid-related litigation and enforcement actions. Indeed, recent reports that find the federal Food and Drug Administration ("FDA"), manufacturers, and prescribers mishandled distribution of fentanyl are likely to spur an uptick in legislative, regulatory, and litigation activity. [1] This client alert focuses on certain legal developments most applicable to hospitals and identifies and discusses national trends in hospital policymaking related to opioid prescribing and diversion control, as well as certain tools available and forthcoming to support these efforts.

FEDERAL DEVELOPMENTS

Many provisions within recent federal opioid legislation and implementing regulations are particularly relevant to hospitals and health systems, including provisions within the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the "SUPPORT Act"), [2] implementing regulations under the earlier Comprehensive Addiction and Recovery Act [3] ("CARA"), and proposed changes to regulations under the Health Insurance and Portability and Accountability Act ("HIPAA"). [4]

SUPPORT Act Sections Most Relevant to Hospitals

On October 24, 2018, the SUPPORT Act was signed into law as comprehensive opioid legislation in response to the opioid crisis. There are a number of provisions in the SUPPORT Act that hospitals should be aware of in the context of their opioid-related policy development efforts.

Section 6092 of the SUPPORT Act requires the Secretary of Health and Human Services ("HHS") to develop guidance on pain management and opioid use disorder prevention for hospitals receiving Medicare Part A payments. [5] This provision requires HHS to develop a toolkit by July 1, 2019, that provides best practices to Medicare-participating hospitals for reducing opioid use and to post the toolkit and related guidance on the Centers for Medicare & Medicaid Services ("CMS") website. [6] HHS is required to develop this guidance in consultation with medical professional organizations and other providers, health care consumers, and additional stakeholder organizations identified by the Secretary of HHS. [7] Section 6094 creates a similar obligation for HHS to publish recommendations for reducing opioid use in pain management specifically in surgical settings.

[8] Relatedly, Section 7091 establishes a demonstration program designed to test alternative pain management protocols that limit the use of opioids in hospital emergency departments. [9] This provision also makes available technical assistance for hospital emergency departments and other acute care settings regarding best practices for opioid-alternative pain management. [10]

Section 7081 of the SUPPORT Act provides resources for hospitals to develop protocols on discharging patients who have presented with an opioid overdose and on continuation of care for drug overdose patients. [11] Protocols develop with this support are intended to address (i) the provision of an overdose reversal medication upon discharge, (ii) connection with peer-support specialists, and (iii) referral to treatment and other services that best fit the patient's needs. [12]

Lastly, Section 6072 of the SUPPORT Act requires the Medicare Payment Advisory Commission ("MedPAC") to evaluate and report on areas of Medicare payment and policy that may affect how practitioners behave with respect to opioid prescribing and treatment. [13] Specifically, this provision requires MedPAC to submit a report to Congress on: (1) how Medicare pays for opioid and non-opioid pain management treatments in inpatient and outpatient hospital settings, (2) current financial incentives for opioid versus non-opioid prescribing under Medicare inpatient and outpatient prospective payment systems and recommendations to address any identified adverse incentives, and (3) how opioid use data is currently tracked through Medicare claims data and identified areas in which further data and methods are needed to improve understanding of opioid use. [14]

The forthcoming guidance, demonstration programs, and reports arising under the SUPPORT Act may be of significant aid to hospitals in their further development of opioid-related policies in the hospital setting and beneficially support the redesign of relevant care models. Notably, they also have the potential to significantly impact hospital reimbursement for pain management and treatment practices where opioids have played an integral role. [15]

CARA Implementing Regulations

Last spring, CMS issued a final rule that revised the Medicare Advantage program (Part C) and Prescription Drug Benefit program (Part D) regulations to effectuate provisions of CARA aimed at further reducing the number of Medicare beneficiaries who may potentially misuse or overdose on opioids. [16]

CMS's implementing regulations create a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk of prescription drug abuse or misuse. [17] Specifically, under drug management programs, Part D plans will engage in case management of potential at-risk beneficiaries through contact with their prescribers when a beneficiary is found to be taking a specific dosage of opioids and/or when a beneficiary is identified as obtaining opioids from multiple prescribers and multiple pharmacies who may not be aware of the parallel prescriptions or be coordinated. [18]

Further, Part D plan sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are "frequently abused drugs" to selected prescribers or network pharmacies and require case management with the prescribers as a precondition to coverage. [19] Finally, these provisions codify a current Part D Opioid Drug Utilization Review Policy and Overutilization Monitoring System by integrating this current policy with drug management program provisions. [20] To maintain reimbursement, hospitals will have to navigate the resulting case management requirements and coverage limitations.

Proposed Change to HIPAA Regulations

On January 31, 2019, HHS proposed a rule under the administrative simplification provisions of HIPAA that would adopt a modified requirement for use of a "quantity prescribed" field for retail pharmacy transactions involving Schedule II drugs. [21] The modification is intended to enable covered entities, including hospital-based pharmacies, to clearly distinguish whether a prescription is a "partial fill," where less than the full amount prescribed is dispensed, or a complete refill. [22] HHS believes this modification is important to ensure that the information necessary to prevent impermissible refills of Schedule II drugs is available to providers. [23] When coupled with state laws limiting opioid prescribing highlighted below, this type of regulatory development reflects the many opportunities and expectations governmental authorities are placing before providers to prescribe and dispense opioids in a responsible and informed manner.

EXAMPLES OF STATE LAW DEVELOPMENTS

Many states have enacted legislation that limits opioid prescriptions to a certain number of days' supply, often with exceptions for treating chronic pain and cancer, for palliative care, and for medication-assisted treatment. In fact, over 30 states in recent years have adopted some form of legislation, regulation, guidance, or other limits and requirements for prescribing opioids. [24]

For example, in 2018, Tennessee passed multifaceted opioid reform initiative titled "TN Together." The initiative includes provisions that span prevention, treatment, and law enforcement areas. Provisions related to prevention and treatment (i) limit the duration and dosage of opioid prescriptions for new patients, (ii) limit initial morphine prescriptions to a three-day supply, (iii) limit initial fill of higher dosages of opioids and fill durations to half of the total prescribed amount, and (iv) impose additional requirements to demonstrate higher dosages are medically necessary. [25]

Similarly, the North Carolina Strengthen Opioid Misuse Prevention Act (the "STOP Act") [26] requires that physician assistants and nurse practitioners prescribing certain controlled substances personally consult with the supervising physician in the context of pain management services and if the therapeutic use of the prescription exceeds 30 days, to check in every 90 days thereafter to verify that the prescription remains medically appropriate. The STOP Act further limits prescriptions for acute pain and requires, with some exceptions, that practitioners electronically prescribe certain controlled substances to enable better tracking and monitoring.

Utah is another example of a state that is actively increasing oversight of opioid prescribing and monitoring of opioid use. Recent legislation imposes requirements specifying how to document partially filled prescriptions of Schedule II substances, urging health insurers to develop policies to minimize the risk of opioid addition and overdose and establishing guidelines for prescribing an opiate antagonist along with a prescription for an opiate. [27] Each of these state developments illustrate the prevalence of newly introduced prescribing limits as an overlay to health care providers' professional judgement, as well as associated prescribing documentation requirements that hospitals must be mindful of in developing and revising their policies in this space.

LAWSUITS AND ENFORCEMENT ACTION

Though we have yet to see hospitals or health systems made a central target of opioid-related litigation, multiple actions against opioid manufacturers, distributors, and individual prescribers illustrates that federal, state, tribal, and local authorities, as well as patients and families, are in search of responsible parties to hold accountable for contributing to opioid misuse. For example, *In Re: National Opiate Litigation*, a multidistrict class action in federal court in the Northern District of Ohio, targets the nation's largest drug manufacturers and distributors, alleging the negligent sales of opioids as contributing to the epidemic. [28]

Hospitals are aware, through their controlled substance compliance programs, of requirements enforced by the Drug Enforcement Administration ("DEA") and can reasonably expect additional enforcement action by this agency in response to the opioid crisis. For example, the DEA has entered into multimillion-dollar settlements with major health systems to resolve allegations of drug diversion. [29]

CURRENT TRENDS IN HOSPITAL POLICY AND AVAILABLE TOOLS

Both before and in response to the foregoing legal developments, hospitals and health systems across the country are taking steps to revise existing and devise new policies to assure safe prescribing and to detect and prevent diversion of controlled substances as part of their contribution to the fight against opioid addiction and overdose-related mortality. A survey of available hospital policies and policy development tools made available by hospital associations and other stakeholders demonstrate:

- Enactment of guidelines or recommendations for prescribing opioids to patients presenting in the emergency department ("ED"), particularly those patients presenting with chronic pain, with emphasis on coordinating care through a single clinician who has primary responsibility for overall treatment and long-term medication monitoring.
- The creation of toolkits specifically designed to address misuse of opioids by hospital employees and medical staff through controlled substance diversion prevention programs. [30] These focus on employee wellness, staff education, and diversion monitoring and reporting requirements that are often supported by software solutions that enable provider-level tracking of large orders or routine "wasting" and audits tools that give insight for timely supervisor inquiry and HR-facilitated intervention.
- The establishment of additional pharmacy procedures requiring daily review of controlled substance activities utilizing reports from automated dispensing systems and electronic health record documentation.
- The publication of opioid compliance toolkits specific to outpatient (non-surgical) settings, which includes opioid prescribing requirements with specific guidance based on the type of pain (acute versus chronic), ordering and administration requirements, and overdose reporting requirements. [31]
- The publication of voluntary opioid prescription guidelines that include:
    - Creating a process for identifying patients both at risk for developing a substance use disorder and for those with a substance use disorder;

- Prescriptions for controlled substances that are lost, destroyed, or stolen, or doses of methadone for patients in methadone treatment programs that should be prescribed only by the initial prescriber, primary care provider, or pain specialist;
- Adoption of a multi-modal non-opioid medication model for acute pain management treatment;
- If opioids are used in the ED, recommended use of short-acting opioids only;
- When opioid medications are prescribed, recommendations that:
  - □ Any prescriptions should be written for the shortest duration possible, usually no more than three to five days, unless the treating physician believes additional amounts are medically indicated based on the patient's diagnosis and symptoms;
  - □ A system should be in place to contact the patient's primary opioid prescriber or primary care provider, to notify them of the visit and the medication prescribed;

- ED providers, or their designees, should (and in some states may be required to) consult the states' prescription monitoring program before writing opioid prescriptions. [32]

Hospitals can also be on the lookout for the toolkits and guidance forthcoming from HHS this summer as required under the SUPPORT Act (discussed above).

CONCLUSION

Hospitals must continually evaluate the need to revise or adopt new opioid prescribing and diversion control policies, both in fulfillment of their duty to promote patient well-being and to keep pace with these rapidly evolving legal requirements and litigation risks. As more robust information related to the prescribing, use, and reimbursement of Schedule II controlled substances becomes increasingly available, including through implementation of new reporting requirements and studies outlined in this alert, hospitals will have visibility into data that can enable redesigning care models and dispensing safeguards that involve opioids. In addition to potential reimbursement changes that may result from payors' use of such data, hospitals will also face the increasing expectation, whether memorialized through law and regulation or made a basis of plaintiffs' claims, to use such data to tightly control and calibrate the safe, responsible, and informed use of opioids in their facilities.

The K&L Gates' health care and FDA practice group routinely advises hospitals on federal and state legal developments, trends in regulatory enforcement actions, and litigation risks related to behavioral health and requirements emerging from the opioid crisis and is positioned to assist hospitals with the development and refinement of these types of policies and procedures. Our intent is to facilitate hospitals and health systems in achieving their goals and furthering their patient care mission in a compliant fashion.

NOTES:

[1] *See* Jeffrey Rollman, et al., *Assessment of the FDA Risk Evaluation and Mitigation Strategy for Transmucosal Immediate-Release Fentanyl Products*, JAMA, 2019;321(7):676–85 (February 19, 2019) (asserting substantial rates of inappropriate use of Transmucosal Immediate-Release Fentanyl); Lenny Bernstein, *FDA, drug companies, doctors mishandled use of powerful fentanyl painkiller*, WASH. POST, Feb. 19, 2019 ("The Food and Drug Administration, drug companies and doctors mishandled distribution of a powerful fentanyl painkiller.").
[2] Support for Patients and Communities Act, Pub. L. No. 115-271.
[3] Comprehensive Addiction and Recovery Act, Pub. L. No. 114-198.
[4] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.
[5] *See* SUPPORT Act § 6092.
[6] *Id.*
[7] *Id.*
[8] *See id.* § 6094 (Section 6094 requires HHS to convene a technical expert panel on reducing surgical setting opioid use and collecting data on perioperative opioid use. This panel will provide recommendations on best practices for pain management in surgical settings, to be followed by a report with recommendations for broad implementation of pain management protocols that limit the use of opioids in the perioperative setting. The report will also analyze perioperative opioid prescribing data for high-volume surgeries.).
[9] *See id.* § 7091.
[10] *Id.*
[11] *See id.* § 7081.
[12] *Id.*
[13] *See id.* § 6072.
[14] *Id.*
[15] *See id.* § 6104 (Section 6104 revises the measures used under the Hospital Consumer Assessment of Healthcare Providers and Systems ("HCAHPS") survey relating to pain management. This provision requires that starting in 2020, the HCAHPS survey may not include questions about communication by hospital staff with an individual about pain unless such questions take into account whether a patient experiencing pain was informed about the risks of opioids and about non-opioid alternatives for pain management.).
[16] 83 Fed. Reg. 16440 (April 16, 2018).
[17] 83 Fed. Reg. 16440, 16442–43 (April 16, 2018).
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] 84 Fed. Reg. 633 (January 31, 2019).
[22] *Id.*
[23] *Id.*
[24] Survey by the National Conference of State Legislatures, *Prescribing Policies: States Confront Opioid Overdose Epidemic*, http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx.
[25] Tenn. H.B. 1831 & Tenn. S.B. 2257, May 21, 2018.
[26] STOP Act, Session Law 2017-74, H243.
[27] *See* Utah S.B. 258 (2017); Utah H.B. 146 (2017); UC § 31A-22-615.5(2)-(3).
[28] No. 1:17-md-02804 (N.D. Ohio filed Dec. 8, 2017).

[29] *See* Press Release, U.S. Dep't of Just., MGH to Pay $2.3 Million to Resolve Drug Diversion Allegations (Sept. 28, 2015); Press Release, U.S. Drug Enf't Admin., Record Settlement Reached in University of Michigan Hospital Drug Diversion Civil Penalty Case (Aug. 30, 2018).
[30] Phillip Brummond, Phamr.D., M.S., et al., *ASHP Guidelines on Preventing Diversion of Controlled Substances*, 74 Am J Health-Syst Pharm 325–48 (2017); see also Keith Berge, M.D., et al., *Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention*, 87(7) MAY CLIN PROC. 674–82 (2012); MINN. HOSP. ASS'N, Road Map to Controlled Substance Diversion Prevention 2.0 (2015).
[31] Melissa Soliz & Karen Owens, *Arizona Opioid Compliance Toolkit for Outpatient Clinics*, ARIZ. HOSP. & HEALTHCARE ASS'N (July 2018).
[32] TEX. HOSP. ASS'N, Texas Hospital Association Voluntary Guidelines for Hospital Emergency Department Prescribers of Opioids (Feb. 2018).

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