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H.R. 6 and Opioid Crisis Response: Ten Key Opportunities and Challenges for Hospitals and Health Systems

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On October 24, 2018, President Trump signed H.R. 6 into law.[1] More formally known as the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, H.R. 6 is a follow-up to the last bipartisan opioid crisis-focused legislation, the 2016 Comprehensive Addiction and Recovery Act (CARA).[2]

Like CARA, the SUPPORT Act takes sweeping aim at the opioid crisis, focusing on numerous aspects of opioid prevention, treatment, and recovery, including expansion of opioid use disorder (OUD) treatment access and capacity in residential and inpatient care, medication assisted treatment (MAT), and via telehealth and improving medical education and training resources for health care providers to better address addiction, pain, and the opioid crisis.

The takeaways for hospitals and health systems from H.R. 6 include both important specific requirements and strategic trends in addressing opioid-related activities. Hospitals and health systems should pay particular attention to new regulatory and reimbursement requirements, as well as the evolution in best practices reflected in the SUPPORT Act. This article highlights ten significant directives within H.R. 6 that reflect the emerging consensus on best practices to combat the opioid crisis.

10. Jessie's Law: Patient Privacy and Communication Among Physicians and with Families

The opioid crisis has raised questions about whether patient privacy has gone too far. H.R. 6 includes a measure known as Jessie's Law. Jessie Grubb, a 30-year-old woman living in Ann Arbor, MI, died as a result of an OxyContin overdose. Her surgeon had prescribed the opioid for acute, post-surgical pain, without any idea that Ms. Grubb was in recovery from heroin addiction. After being reintroduced to opioids, Jessie ground up the pills to avoid the time-release and overdosed.

Grub's family argued that if her doctor had known of her heroin addiction, he would not have prescribed OxyContin, but that current law prevented Grubb's doctors from accessing records relating to Jessie's substance use disorder (SUD) treatment history and made it difficult to talk to her family about it. The specific criticism was that the Health Insurance Portability and Accountability Act (HIPAA) and the SUD treatment-specific 42 C.F.R. Part 2 discourage doctors from inquiring with family or previous doctors about patients' history of substance abuse or SUD treatment.

In fact, HIPAA makes allowance for disclosures to family members if the patient does not object or—in circumstances where the patient is unable to agree or object to disclosure because of incapacity or an emergency—if the covered entity determines disclosure is warranted in the best interests of the patient.[3] Part 2 is more restrictive, requiring specific patient consent for any information sharing about SUD treatment.

In reality, the new "Jessie's Law" provisions of H.R. 6 do not directly address the foregoing constraints. Instead, Section 7052 of the SUPPORT Act requires the Department of Health and Human Services (HHS) to develop best practices for health care providers and state agencies regarding the display of a patient's history of opioid addiction in the patient's medical records. Presumably, the goal is to find ways to flag the risks of prescribing to a patient in recovery from addiction by making these histories more prominent. In addition, Section 7053 requires the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) to notify health care providers annually about health information that may be disclosed under federal privacy laws to families, caregivers, and health care providers during emergencies, including overdoses.

While the new provisions do not change the details of regulatory compliance around patient privacy, they reflect an evolving view of the balance of harms. The longstanding view has been that we need to keep SUD treatment secret so that stigma does not deter people from seeking treatment. Jessie's Law signals that we may have hit a "high watermark" on privacy considerations, with growing concerning for the countervailing need to prevent more opioid-related tragedies by ensuring that doctors can see records of past treatment of SUDs and talk to families and other doctors who treated the SUD.

At the same time that regulatory compliance must continue to focus on the particulars of health care privacy and data security, Jessie's Law signals that organizations should consider steps that can be taken to encourage permissible communication with families and among providers. For example, nothing in HIPAA or Part 2 should prevent providers from directly seeking patient permission to communicate with families or previous providers related to substance use.

9. Partial Repeal of IMD Exclusion: Residential and Inpatient Care for Medicaid Beneficiaries

The Medicaid Institutes for Mental Diseases (IMD) exclusion dates back to 1965, when Medicaid was first created. It prohibits states from receiving Medicaid funds for people under the age of 65 who are patients in IMDs, which are defined as "hospital[s], nursing facility[ies], or other institution[s] of more than 16 beds" that treat mental health and substance use disorders.

The IMD exclusion is a relic of the pre-Medicare, pre-Medicaid era (i.e. pre-1965) when states funded inpatient behavioral health services. The federal government imposed the IMD exclusion to prevent states from shifting mental health and addiction treatment costs for state-run psychiatric hospitals (IMDs) to the federal government. Since the 1960s, however, most of these state-funded institutions have closed, leaving an underfunded shortage of residential or inpatient beds for people with mental health and SUD needs. The effect of the IMD exclusion has been to block Medicaid funding for badly needed residential and inpatient care—without any alternative available. This impediment was particularly a problem for the 12-14% of Medicaid beneficiaries over age 18 with a SUD.[4]

H.R. 6 includes a partial repeal of the IMD exclusion. Until H.R. 6, CMS utilized state-by-state Section 1115 demonstration waivers to circumvent the exclusion and provide Medicaid funding. However, CMS negotiation of waivers to bypass the funding prohibition did not stimulate broad increases in bed capacity.

Section 5052 of H.R. 6 provides a temporary repeal (until a 2023 sunset) of the IMD exclusion, enabling states to reimburse for SUD treatment of patients ages 21-64 in facilities with up to 40 beds, for up to 30 days of care during any 12-month period. Implementation guidance will be forthcoming from HHS.

H.R. 6 includes several other provisions to expand IMD-related access to care. Section 5012 requires the Medicaid and Children's Health Insurance Program Payment and Access Commission to report on IMD service offerings from state to state. Section 1012 amends the Social Security Act to ensure that pregnant and postpartum women receiving SUD care at an IMD can continue to receive other Medicaid-covered services (such as prenatal care) outside the IMD.

With so much demand for access to care within the Medicaid population, hospitals and health systems should consider how to meet that need in a broader continuum of SUD/OUD services.

8. Buprenorphine: Expanded Access to Medication Assisted Treatment

Federal policy continues to seek expanded access to various forms of MAT. In addition to methadone and naltrexone, the principal focus has been on expanding access to buprenorphine, distributed under brands include Suboxone, Subutex, and Sublocade.

Section 3201 of H.R. 6 expands access to MAT, including treatment based on methadone and buprenorphine, by among other things raising the patient limit for physicians prescribing MATs to 275. The Drug Addiction Treatment Act of 2000 (DATA 2000) authorized physicians who undertook the relevant training and obtained a necessary waiver to treat up to 30 patients. After one year, physicians could apply for permission to increase their patient limit to 100. H.R. 6 now sets an even higher limit of 275 for which physician can apply.

Perhaps the even more significant change is that Section 3201 makes permanent the temporary law enacted by CARA permitting physician assistants (PAs) and nurse practitioners (NPs) to provide buprenorphine. In contrast to the eight-hour requirement for physicians to qualify for the Drug Enforcement Administration waiver, Section 303 of CARA requires PAs and NPs to complete 24 hours of training.

Section 2005 of H.R. 6 authorizes Medicare coverage for MAT at outpatient Opioid Treatment Programs (OTPs). Until now, OTPs were not recognized as Medicare providers, essentially requiring beneficiaries to pay out-of-pocket for receiving MAT at OPTs. The SUPPORT Act directs that Medicare will reimburse OTPs via "bundled payments," rather than on a fee-for-service basis, as a pilot program focused on what the Act considers to be a "holistic" approach to treatment.

Section 1006 of H.R. 6 also requires state Medicaid programs to cover MAT, counseling services, and behavioral therapy, from October 2020 through September 2025, unless a state certifies to the Secretary's satisfaction that statewide implementation is infeasible due to provider shortages.

While expanded coverage for MAT in the Medicare population is good news for OTPs, the focus on MAT continues to reflect a tension in addiction treatment. The 2017 President's Commission on Combating Drug Addiction and the Opioid Crisis Report[5] called attention to the small fraction of SUD treatment providers that provide MAT. Federal policy enabling broader coverage of MAT and a broader range of medical professionals who can provide it is based on a public health-focused, harm reduction approach in which buprenorphine reduces opioid overdoses and stabilizes people following opioid addiction.

MAT access continues to be limited, however, based on misgivings of the SUD treatment community that this harm reduction approach leaves many people with a continuing physical dependency on a different substance and fails to address the underlying issues in addiction and the need for a recovery-focused framework to sustain people and prevent relapse. The lack of MAT resources in other SUD settings highlights an opportunity for hospitals in facilitating access to MAT. Among other noteworthy changes, Section 6042 of H.R. 6 establishes a voluntary "demonstration program" for participants providing both MAT and non-MAT services to track outcomes based on established quality measures and to receive rewards for performance based on those measures.

7. Mandatory E-Prescribing, Improved PDMPs, and Other Recordkeeping

Electronic prescribing (e-prescribing) has received increasing attention as a mechanism to combat opioid and other controlled substance diversion by preventing prescription forgeries or attempts to fill the same prescription at multiple pharmacies. The complaint from many prescribers has been that, without software integration, compliance now requires completion of electronic health record (EHR) documentation, prescription drug monitoring program (PDMP) verification, and e-prescribing—potentially three separate sets of data inputting in the name of reducing controlled substance diversion and opioid abuse.

H.R. 6 formalizes a requirement for e-prescribing and electronic prior authorization approvals for controlled substances covered by Medicare Part D. Section 2003 incorporates the e-prescribing mandate, while Section 6062, part of the Preventing Addiction for Susceptible Seniors Act of 2018 (PASS) Act, requires the secure transmission of prior authorization requests for covered drugs under Medicare. Section 6063 requires the Secretary to establish a secure online portal to allow data sharing among CMS and Medicare Part C and Part D plans to identify and refer substantiated fraud, waste, or abuse for enforcement.

H.R. 6 also contains several provisions related to EHRs and PDMPs. Section 6001 authorizes CMS to test models to provide incentive payments to behavioral health providers for adopting EHR technology and using it to improve quality and coordina-

tion of care. Section 7162 requires state PDMPs and health care providers to verify Medicaid beneficiary's prescription drug history before prescribing controlled substances. Section 7162 also authorizes the Centers for Disease Control and Prevention (CDC) to provide technical assistance and award grants to improve PDMPs and improve overdose data reporting, and authorizes improvements regarding use, data reporting, and intrastate and interstate interoperability.

Hospitals and health systems should prioritize not only compliance with e-prescribing, PDMP, and EHR documentation, but also strategies to reduce the administrative burden on prescribers created by a lack of software integration.

6. Increased Screening for OUDs

Screening patients for OUDs has been a recurrent challenge. Screening, Brief Intervention and Referral to Treatment (SBIRT) refers to the interventional approach to identifying people who are at risk and need treatment, with the goal of referring and getting the person, if willing, into treatment as soon as possible.

Section 2002 formalizes OUD screening in the "Welcome to Medicare" initial preventive physical examinations and annual wellness visits. Doctors are now required to review patients' opioid prescription history and screen for potential risk issues. The goal is early detection and treatment, with heightened sensitivity to the presence of OUDs among Medicare beneficiaries.

While H.R. 6 incorporates the requirement only for Medicare beneficiaries, hospitals would be well-advised to consider promoting screening as a part of the examination process for all patients.

5. Referrals to Treatment to Drug-Seeking Patients

Hospital emergency rooms have been ground zero for several facets of the opioid crisis. Beyond dealing with patients presenting with overdoses, many emergency room physicians have described the challenge of drug-seeking patients requesting opioid prescriptions for pain management and having little interest in referrals to treatment for dependency, addiction, or other forms of pain management.

The Preventing Overdoses While in Emergency Rooms (POWER) Act, Section 7081 of H.R. 6, requires HHS to establish a grant program to develop protocols for discharging patients who are treated for a drug overdose and to enhance the integration and coordination of post-discharge care for individuals with a SUD. Critics have charged that patients are frequently treated for overdoses and discharged, only to remain at risk for a future overdose. This provision is intended to break that cycle by improving the opportunity to get the person to consider treatment.

Section 7091, the Alternatives to Opioids in the Emergency Department (ALTO) Act, requires HHS to establish a demonstration program through which hospitals and emergency departments receive grants to support alternative pain-management protocols and treatments that limit the use and prescription of opioids in emergency departments.

4. Ending Illegal Patient Brokering

Prior to H.R. 6, federal prosecutors predominantly focused on pursuing rampant fraud and abuse in urine drug screening (UDS) laboratory relationships and SUD treatment when it occurred within federal health programs and was covered by the federal Anti-Kickback Statute. In recent years, the Department of Justice has turned to the Interstate Travel Act and the Interstate Wire Act for the legal authority to prosecute fraud against other payers.

Section 8122 removes the need to rely on these laws by adding the Eliminating Kickbacks in Recovery Act (EKRA), which makes it illegal to pay or receive kickbacks in return for referring a patient to recovery residences, laboratories, and clinical treatment facilities. The federal patient brokering law represents a significant expansion of federal oversight of marketing relationships around SUD treatment and UDS. In contrast to the federal Anti-Kickback Statute, EKRA is agnostic as to payer source and applies with equal force to services funded by commercial or employer-sponsored health plans.

The new law raises the stakes for problematic marketing practices, and should be integrated into hospital compliance programs, particularly for contractual relationships with outside entities, including SUD treatment providers.

3. Expanding Peer Recovery Support

Anecdotally, one successful hospital strategy in addressing the opioid crisis has been the provision of access to peer recovery coaches in emergency room settings to support patients in making the decision to discontinue illegal drug use and begin the process of treatment and recovery.

H.R. 6 calls attention to peer recovery as a critical piece of the puzzle in numerous provisions. Sections 7151 and 7152 establish grants to recovery community organizations to provide regional training and technical assistance to expand peer recovery support services nationwide. These provisions reflect a growing awareness of how much health care organizations need to learn from recovery community organizations. Section 8082 provides $15 million to HHS to replicate a "recovery coach" program for parents with children in foster care due to parental substance use.

The Peer Support Communities of Recovery Act, including Section 7151, authorizes the Substance Abuse and Mental Health Services Administration (SAMHSA) to award grants to nonprofits that focus on SUDs to establish regional technical-assistance centers that implement peer-delivered addiction-recovery support services and establish recovery community organizations and centers.

Hospitals and health systems should identify recovery community organizations and other resources to develop peer recovery coach resources as a support mechanism.

2. Expanding Focus on Social Determinants Relevant to OUDs

Beyond peer coaching services, H.R. 6 also highlights an investment into and focus on other critical social determinants relevant to OUDs. Section 7183, the CAREER Act, is intended to improve resources and wraparound support services for individuals in recovery from a SUD in the transition from treatment programs to independent living and reintegration into the workforce.

Section 7031, the Ensuring Access to Quality Sober Living Act, requires HHS to develop best practices for operating recovery housing (shared living environments free from alcohol and illegal drug use and centered on peer support and connection to services that promote recovery from substance-use disorders).

The ability to focus on social determinants appears to be an essential piece of supporting the initial decision to seek treatment and preventing relapse. At the same time, traditional reimbursement mechanisms do not provide funds to meet these needs. Hospitals and health systems should consider opportunities to identify resources offering housing and transitional support for patients in treatment and recovery from OUDs and to provide information and as seamless a transition as possible.

1. Improving Training

Perhaps the biggest opportunity for all health care organizations is to improve training to prevent opioid dependency. Section 7101 of H.R. 6 expands medical education and training resources for health care providers to better address addiction, pain, and the opioid crisis. Section 6092, the Combating Opioid Abuse for Care in Hospitals (COACH) Act, requires CMS to publish guidance for hospitals on pain management and OUD prevention strategies for Medicare beneficiaries.

Additional lessons for hospitals are likely to be forthcoming. Section 6104 prohibits hospital patient pain surveys (unless the questions address the risks of opioid use and the availability of non-opioid alternatives). In their place, the Treatment, Education, and Community Help (TEACH) to Combat Addiction Act, Section 7101, requires SAMHSA to designate Regional Centers of Excellence in SUD Education to improve pain management and SUD education by developing evidence-based curricula for health care professional schools. Section 7121 also requires SAMHSA to award grants to establish or operate at least ten comprehensive opioid recovery centers across the country to conduct outreach and provide a full continuum of treatment and recovery services, including job-placement assistance.

Training also extends to Medicare beneficiaries: Section 6021 requires CMS to provide Medicare beneficiaries with educational resources regarding opioid use and pain management, as well as descriptions of covered alternative (non-opioid) pain-management treatments. Some hospitals have focused specific training efforts on naloxone administration, enabling greater numbers of patient family members and loved ones, as well as first responders, to act quickly in response to overdoses.

Conclusion

H.R. 6's extensive provisions addressing the opioid crisis go beyond the ten challenges and opportunities discussed above, including provisions for expanding use of telehealth in treating SUDs and addressing opioids in other settings. These ten items, however, stand out as reflecting legal changes not only related to evolving compliance requirements but also to best practices in reducing opioid risks and improving outcomes in treatment of opioid and other substance use disorders.

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1 Pub. L. No. 115-271 (2018).

2 Pub. L. No. 114-198.

3 Dep't of Health and Human Servs., Office for Civil Rights, *How HIPAA Allows Doctors to Respond to the Opioid Crisis*, https://www.hhs.gov/sites/default/files/hipaa-opioid-crisis.pdf.

4 The 12% statistic was reported in a 2011 SAMHSA National Survey of Medicaid beneficiaries over 18 with a Substance Use Disorder. More recent surveys have shown the number on the rise.

5 *Available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.