October 30, 2018

The SUPPORT Act of 2018: New All-Payor Anti-Kickback Provisions; Broader Telehealth and Other Coverage

On October 24, 2018, the President signed a far-reaching bill addressing issues related to opioid use and abuse—the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 ("SUPPORT Act"). The SUPPORT Act is a combination of seventy unique bills, and consequently includes a broad array of provisions affecting the healthcare industry. Among other things, they encompass new and revised Medicaid, Medicare, FDA, and Controlled Substance Act ("CSA") laws that seek to address the opioid crisis by expanding Medicaid and Medicare coverage for substance use disorder services; promoting the use of telehealth services; adding program integrity measures in the form of new all-payor anti-kickback provisions; and expanding "sunshine" disclosure requirements on pharmaceutical and device manufacturers' arrangements with ancillary health care providers.

The full Congressional summary of the SUPPORT Act is available here. We summarize below some of the changes most significant for the health care industry at large.

New All-Payor Anti-Kickback Provisions Increase Risk Around Referrals for Recovery Home, Clinical Treatment Facilities, and Clinical Laboratories.

Section 8122 of the SUPPORT Act, known as Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), establishes an all-payor anti-kickback prohibition that extends to arrangements with recovery homes, clinical laboratories, and clinical treatment facilities.

EKRA includes a number of statutory exceptions, and directs agencies to develop further exceptions. Current exceptions in some cases reference and in others differ from the federal Anti-Kickback Statute ("AKS") safe harbors:

General Discounts	EKRA excepts from the prohibition discounts obtained by providers or entities under a health care program, if the discounts are disclosed and reflected in the provider's or entity's costs or charges.
Special Discounts	EKRA mirrors the federal AKS safe harbor for Medicare coverage gap drug discounts.
Individual Compensation	EKRA's compensation exception applies *to both* employees and contractors, unlike the AKS, which has different safe harbors for employees and for contractors. The EKRA exception requires that compensation not be determined by, or vary with, referrals to a facility, the number of tests or procedures performed, or the amount billed or received from the health care benefit program. Until regulatory guidance is developed, organizations will need to consider, for example, the use of percentage-based compensation, particularly for non-employed sales personnel.
Organizational Compensation	EKRA adopts, through cross-reference, the AKS's personal services and management contracts safe harbor.

Patient Copayments or Coinsurance	EKRA excepts copayment waivers that are not routinely provided and are provided in good faith. This thematically reflects the Department of Health and Human Services Office of Inspector General's ("OIG") guidance on waivers for copayments under Medicare.
Transfers to Federally Qualified Health Centers that Service Medically Underserved Populations	EKRA adopts, through cross-reference, the AKS's federally qualified health center remuneration exception for the transfer of goods, items, services, donations, or loans set out in writing that are medical or clinical in nature and contribute meaningfully to the health center's ability (among other requirements) to serve a medically underserved population.
Alternative Payment Models	Payments made as part of an alternative payment model (the shared savings program under Section 1899 of the Social Security Act ("SSA"), a model created by the Center for Medicare and Medicaid Innovation other than a health care innovation award, a demonstration under the Health Care Quality Demonstration Program (Section 1866C of the SSA), or a demonstration required by federal law), or any alternative payment model used by a state, health insurance insurer or group health plan if approved by the U.S. Department of Health and Human Services ("HHS") as necessary for care coordination and value-based care. This exception does not currently have a direct federal statutory AKS counterpart.
Any Other AG-determined Exceptions	EKRA allows the Attorney General, in consultation with the Secretary of HHS, to add any other payments, remuneration, discounts, or reduction by regulation.

Significantly, the prohibitions apply with respect to the soliciting or receipt of remuneration for *any* referrals to recovery homes, clinical treatment facilities, or clinical laboratories, whether or not related to treating substance use disorders. Further, the prohibitions cover the payment or offer of remuneration to induce a referral to, or in exchange for, an individual using the services of, such providers. That is, of course, particularly relevant for any health care provider that has arrangements with these providers premised on existing fraud and abuse laws—those must now be reassessed in light of the new kickback prohibitions. Organizations will, for example, need to assess how these laws apply to inducements provided to patients and interact with the beneficiary inducement provisions of the Civil Monetary Penalties Law. Moreover, compensation arrangements that these homes, facilities, and clinical laboratories have with their sales force will need to be reviewed for compliance with the applicable employee and independent contractor exceptions.

Telehealth Provisions Provide Greater Medicaid and Medicare Reimbursement Opportunities

Medicare currently provides coverage for telehealth services only in geographic regions that are experiencing provider shortages and, even in those areas, requires that beneficiaries receive telehealth services in a designated originating site, such as a physician's office, hospital, rural health clinic, or critical access hospital. The SUPPORT Act eliminates these restrictions for certain services as of July 1, 2019, authorizing Medicare coverage for telehealth services furnished to beneficiaries with substance use disorders wherever they receive services.

Apart from Medicare, Congress has signaled expanded Medicaid coverage for telehealth services involving substance-use disorder treatment, directing the Centers for Medicare and Medicaid Services ("CMS") to issue guidance to states by October 2019 on reimbursement for various substance use disorder services delivered via telehealth. The SUPPORT Act

requires CMS to address federal financial participation for Medicaid expenditures related to telehealth services associated with substance use assessment, medication-assisted treatment, counseling, medication management, and adherence to prescribed medication regimes.

The SUPPORT Act also requires the Attorney General to promulgate, prior to October 2019, final regulations under the CSA specifying the limited circumstances in which a special registration may be issued to physicians, nurse practitioners, and other providers to prescribe controlled substances via telemedicine. The regulations would side-step in-person exam and other narrow telemedicine setting requirements contained in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Haight Act"). To date, the Drug Enforcement Administration had not issued final rules under the Haight Act on the application process for such special telemedicine registration.

New Provider Opportunities: Medicare Coverage Expansion for Opioid Treatment Programs and Medicaid Demonstration Project

In addition to the broader coverage for telehealth services described above, the SUPPORT Act expands Medicare coverage to include opioid treatment programs ("OTPs") that deliver medication-assisted treatment to Medicare beneficiaries. Under the expanded coverage, Medicare will pay outpatient OTPs a bundled payment for the furnishing of FDA-approved opioid agonist and antagonist treatment medications, substance use counseling, individual and group therapy sessions, toxicology testing and other items and services authorized by the Secretary of HHS (but not including things like meals or transportation). In the past, beneficiaries of OTPs had to pay out-of-pocket for many of these services, adversely affecting access for Medicare beneficiaries to substance use treatment at OTPs.

The law also directs CMS to carry out a demonstration project aimed at establishing long-term sustainable provider networks to treat substance use disorders treatment and recovery services. Under the demonstration project, CMS must choose ten states and provide a significant federal match of state dollars spent on substance use disorder treatment or recovery services. Overall, this should increase beneficiary access to substance use treatment and recovery services and Medicaid spending for those services.

Expansion of Sunshine Act Reporting Requirements Increases Risks for Manufacturers

The SUPPORT Act expands reporting requirements for pharmaceutical and medical device manufacturers under the Physician Payments Sunshine Act ("Sunshine Act"). The SUPPORT Act requires that, as part of submissions required on or after January 1, 2022, manufacturers report on the Open Payments system any transfer of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. This means that, beginning in the 2021 reporting year, pharmaceutical and device manufacturers will need to broaden their recording and reporting systems, while physicians and teaching hospitals will need to expand their Open Payments tracking.

* * *

The SUPPORT Act presents both new opportunities and risks for health care entities. Hospitals and health systems, clinical laboratories, clinical treatment facilities, recovery homes, and physicians. Precise ramifications will become clearer when various agencies promulgate implementing guidance. In the meantime, please feel free to contact any member of Ropes & Gray's health care practice group with any questions concerning the SUPPORT Act's broad impact.