Compliance Under The 'Eliminating Kickbacks in Recovery Act of 2018'

By REESA N. BENKOFF, ESQ.
and DUSTIN T. WACHLER, ESQ

Effective Oct. 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) aims to combat the nationwide opioid and other substance abuse crisis by improving treatment and recovery options, increasing education and prevention, safeguarding communities, and fighting deadly synthetic drugs.[1] The SUPPORT Act is a bipartisan, wide-ranging federal law comprised of over 70 individual bills, including the Eliminating Kickbacks in Recovery Act of 2018 (EKRA). EKRA establishes a new all-payor federal anti-kickback law applicable to recovery homes, clinical treatment facilities, and laboratories. While EKRA was intended to prohibit patient brokers who profit from "illicit referrals" of substance abuse patients, EKRA's broad statutory language implicates common healthcare arrangements structured in compliance with existing federal and state fraud and abuse laws. Accordingly, healthcare providers and other entities and individuals in the healthcare industry must review all arrangements with recovery homes, clinical treatment facilities, and laboratories for compliance with EKRA.

EKRA prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for referring a patient to, or in exchange for an individual using the services of, a recovery home, clinical treatment facility, or laboratory with respect to services covered by a health care benefit program.[2] KRA defines the term "health care benefit program" as "any public or private plan or contract affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract."[3] "Recovery home" is defined as "a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders."[4] "Clinical treatment facility" is defined as "a medical setting, other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under state law."[5] Importantly, EKRA defines "laboratory" to include all clinical laboratories and thus the law implicates all referrals to clinical laboratories regardless of whether the referrals involve substance abuse patients. EKRA does not define the term "referral." Based on the Congressional Record, which indicates that Congress intended for EKRA to eliminate all for-profit patient brokering, it is likely that the definition of "referral" under EKRA applies to business generated by lay individuals such as marketers and other sales agents.[6] However, an interpretation of the term "referral" under EKRA is necessary to understand the full scope of the law.[7]

EKRA includes eight exceptions to its broad prohibition on the payment of remuneration.[8] As explained below, while certain exceptions to EKRA appear to correlate with exceptions and safe harbors available under the federal Anti-Kickback Statute (AKS), EKRA's exceptions are inconsistent with existing federal laws, including the federal Stark law.[9] As Michigan state law extends application of the Stark law to referrals of services and items reimbursed by all sources of payment, EKRA's exceptions are also inconsistent with exceptions available to Michigan healthcare providers under Michigan's self-referral law. Violators of EKRA will be subject to a fine of up to $200,000 or imprisonment of 10 years, or both, for each occurrence.[10] Violations of EKRA may also result in collateral consequences such as state licensure sanctions and revocation or exclusion from governmental healthcare programs.[11] For example, Michigan healthcare providers found to violate EKRA may be subject to disciplinary actions under Section 16221 of the Public Health Code.[12]

Existing federal laws, such as the AKS and the Stark law, apply to the same arrangements now subject to EKRA. Further, Michigan state laws applicable to kickbacks, fee-splitting, and self-referral also govern arrangements now subject to EKRA. For example, Michigan maintains a Medicaid anti-kickback law, physician licensure-based anti-kickback law, criminal anti-kickback law, and a laboratory-specific anti-kickback law that all apply to arrangements implicated by EKRA. Due to inconsistencies between EKRA and these existing federal and state laws, healthcare providers and other entities and individuals may experience significant difficulties structuring arrangements to comply with EKRA in addition to the existing applicable laws. For example, the AKS statutory exception and regulatory safe harbor applicable to employees protects all forms of remuneration paid by an employer to a bona fide employee for employment in the furnishing of items or services covered by a Federal health care program.[13] Whereas that AKS exception and safe harbor permits bona fide sales and marketing employees to receive commission-based compensation, EKRA prohibits payments to employees that are determined by or vary by: (a) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory; (b) the number of tests or procedures performed; or (c) the amount billed to or received from, in part or in whole, the health care benefit program from the individual referred to a particular recovery home, clinical treatment facility, or laboratory.[14] Accordingly, as applied in the laboratory context, ERKA requires that traditional commission-based sales arrangements between laboratories and marketers be restructured regardless of whether the laboratory performs testing for substance abuse patients and regardless of whether their marketers are employees or independent contractors.

In sum, healthcare providers and other individuals and entities engaged in the healthcare industry must evaluate whether all arrangements with recovery homes, clinical treatment facilities, and laboratories comply with EKRA. EKRA became effective on Oct. 24, 2018 and is broadly drafted in a manner that appears to exceed its initial legislative intent and, thus, may result in unintended consequences. Until Congress refines EKRA or the Attorney General promulgates regulations or

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Reesa N. Benkoff
Reesa N. Benkoff is a partner at Wachler & Associates, P.C. Reesa practices in all areas of health care law and devotes a substantial portion of her practice to transactional and regulatory matters. She counsels and represents various health providers nationwide on a variety of health care-related issues, including physician in-office ancillary arrangements; physician employment relationships; hospital and physician transactions and contracting; fraud and abuse.

Dustin Wachler
Dustin T. Wachler is an attorney at Wachler & Associates, P.C. Mr. Wachler practices in all areas of health care law. He devotes a substantial portion of his practice to transactional, regulatory, and Fraud & Abuse matters, including counseling health care providers nationwide regarding compliance with the Stark law and Anti-Kickback Statute.
Mr. Wachler also represents all types of health care providers and suppliers in defense of Medicare, Medicaid and third party payor audits.

Children's Hospital Of Michigan Launches First Neuro-Neonatal Intensive Care Unit In The State

DETROIT — To address the significant need to manage and minimize neurological complications associated with preterm and term newborn babies, Children's Hospital of Michigan announced its newly developed Neuro-Neonatal Intensive Care Unit (NeuroNICU).

Children's Hospital of Michigan's NeuroNICU is the first-of-its-kind in the state of Michigan and one of a select few across the nation, according to DMC sources. This program offers a specially trained team of clinicians dedicated to providing an appropriate environment that will help optimize neurologic and developmental outcomes for this highly vulnerable population.

"We are excited to join other select premier children's hospitals throughout the country in establishing the NeuroNICU program," said Girija Natarajan, MD, Co-Chief Division of Neonatology, Clinical Operations and Education at Children's Hospital of Michigan and Hutzel Women's Hospital. "This program is aimed at ensuring preterm and term newborns at risk for brain injury and future developmental problems are meticulously cared for by a team of specialists."

The NeuroNICU offers a six-bed unit housed within part of the newly expanded and renovated single room Neonatal Intensive Care Unit (NICU) on the third floor of the Children's Hospital of Michigan Tower. The program will offer key pillars of care including neurological assessments, diagnostics, neuro-protection therapies and advancements in neurodevelopmental care. Transport cooling by the Tecotherm device with the dedicated pediatric and neonatal transport team (PANDA) will allow infants with birth asphyxia to be started early with cooling and be transported to the NeuroNICU at Children's Hospital of Michigan. The program will also provide prevention and treatment of neonatal brain hemorrhage and its complications among extremely low gestational age neonates. The program is a collaborative effort between neonatologists, pediatric neurologists and neurosurgeons, pediatric neuroradiologists, neonatal nurses with special interest in brain injury, EEG technologists, psychologists, occupational therapists, physical therapists, dietitians and social workers.

After the patient is released from the NeuroNICU, continuum of care includes a multidisciplinary developmental assessment clinic where all neonatal neurocritical care patients will be followed for five years. Collective care includes specialists from physical medicine and rehabilitation, neonatology and neuropsychology.

"As the state's first and oldest pediatric hospital, Children's Hospital of Michigan has always been dedicated to treating the most vulnerable – this NeuroNICU program was created specifically for them," said Luanne Thomas Ewald, CEO of Children's Hospital of Michigan. "Our hospital is at the forefront of research on neurological protection, preservation and treatment and with the increasing survival rate of NICU patients, there is a greater need to focus on improving neurodevelopment among high-risk survivors."

The NICU at Children's Hospital of Michigan is a Level IV NICU, offering the highest degree of care for premature or critically ill newborns. It is a regional referral center for advanced neonatal therapies, such as extracorporeal membrane oxygenation, high-frequency ventilation, advanced neonatal neuroimaging, and therapeutic hypothermia, or for coordination of complex care requiring multiple types of pediatric specialists only available at a children's hospital.

"The opening of this state-of-art neonatal care program will greatly enhance the research capabilities of Children's Hospital of Michigan and elevate its position as a premier center for research trials in neonates in the state and the country," said Seetha Shankaran, M.D., neonatologist at Children's Hospital of Michigan and Hutzel Women's Hospital and principal investigator for the first randomized controlled trial conducted by NICHD Neonatal Research Network on whole body cooling for hypoxic-ischemic encephalopathy. The significant benefits of cooling in reducing death or disability shown by the trial she led established cooling as standard of care throughout the world. "We are able to offer innovative care for newborns with neurological needs; stem cells are a recent example. This addition of the NeuroNICU program to Children's Hospital of Michigan will surely advance the standard of prenatal care for our city."

Compliance

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other guidance interpreting EKRA, many existing relationships in the healthcare industry will need to be revised in order to comply with EKRA to avoid risk of criminal liability.

NOTES

1 See 164 Cong. Rec. H5512, H5521 (June 22, 2018) (statements of Reps. Walberg, Walden, Bishop).
2 18 U.S.C. § 220(a); H.R. 6 – 215.
3 18 U.S.C. § 220(e)(3); 18 U.S.C. § 24(b).
4 18 U.S.C. § 220(e)(5).
5 18 U.S.C. § 220(e)(2).
6 See 164 Cong. Rec. H9244, H9249 (September 28, 2018).
7 See 56 Fed. Reg. at 35974 (as applicable to the federal Anti-Kickback Statute, 42 U.S.C. 1320a-7(a)(1)); see also OIG Advisory Opinion 98-1 (March 19, 1998).
8 18 U.S.C. §§ 220(b), (c).
9 See 42 U.S.C. § 1320a-7b(b); 42 U.S.C. § 1395nn; C.F.R. § 1001.952; see also 42 C.F.R §§ 411.355 through 411.357.
10 18 U.S.C. § 220(a).
11 See e.g., 42 U.S.C. 1320a-7(a)(1).
12 See e.g., MCL § 333.16221(b)(x).
13 42 U.S.C. § 1320a-7b(b)(3)(B); 42 C.F.R. § 1001.952(i).
14 18 U.S.C. § 220(b)(2). Notably, the statutory language is confusingly written and seems to blur the lines between a contractual and employment relationship.