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HEALTH LAW VITALS

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HEALTH LAW VITALS

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Should States Embrace Telehealth Parity?

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Parity in telehealth is the notion that health services provided via telehealth technology should be treated equally as health services provided face-to-face. This is consistent with coverage parity, which requires payors to provide the same level of insurance coverage for patient encounters and services, while payment parity (a.k.a. reimbursement parity) requires payors to pay or reimburse providers the same rates whether the encounter or service provided occurred in person or via telehealth.

Coverage Parity

There are 35 states, as well as the District of Columbia, that have coverage parity for telehealth services, and four states (Alaska, Massachusetts, Pennsylvania, and South Dakota) that have pending bills on the issue. Many coverage parity laws include provisions to protect patients from cost-shifting. For example, certain coverage parity laws prohibit health plans from imposing different deductibles or copayments or maximum benefit caps for services provided via telehealth.

Of course, while various states' laws share common features, no two state laws are exactly alike, and the precise language of a parity law can affect telehealth adoption and growth. For example, if a coverage parity law only requires payors to cover telehealth services "to the same extent" the service is covered in-person, services like remote patient monitoring will be excluded because most health plans do not have coverage of any in-person equivalent to remote patient monitoring. Conversely, more broadly drafted statutes that explicitly cover virtual care, remote patient monitoring, and novel telehealth services will likely foster growth in those areas, including the development of more companies that offer associated equipment, software, and applications.

Payment Parity

Enactment of payment parity laws is comparatively more limited, as only 10 states have some form of payment rate parity for telehealth providers, and some payors will only pay for telehealth encounters when the provider is in the payor's network of approved providers. These "narrow" networks may adversely affect patient continuity-of-care, possibly severing long-standing patient-provider relationships and denying patients access to some specialty care.

Further, some parity laws limit telehealth coverage or reimbursement to certain types of providers, services, modalities, and/or site locations, and such limiting language may create additional barriers to telehealth utilization. For example, Texas—one of the states with coverage parity but not payment parity—prohibits a health plan from excluding a telehealth service from coverage or from applying cost-shifting measures solely because the service is not provided through a face-to-face consultation.[1] But the state law has modality limitations as it excludes coverage for a telehealth service provided by synchronous or asynchronous audio-only interaction, including a phone consultation, email message, or fax.[2]

In contrast, Missouri provides coverage of and reimbursement for store-and-forward technology and remote patient monitoring but limits them to specific specialties and conditions—orthopedics, dermatology, ophthalmology and optometry in cases of diabetic retinopathy, burn and wound care, dental services that require a diagnosis, and maternal-fetal medicine ultrasounds.[3]

Proponents of telehealth applaud parity laws, as such laws encourage providers to embrace telehealth technology and innovation in their practices. Telehealth, in general, maximizes efficiency, improves access for patients, and reduces overhead for providers.[4] However, as more states push ahead with telehealth parity laws, critics argue that coverage conditions and reimbursement rates should be negotiated between providers and payors rather than mandated by the legislatures. In addition, they argue that the provision of telehealth services does not merit equal reimbursement because the cost of providing such services is already lower. Instead, the argument is that payors could reimburse providers less for telehealth services and pass on the savings to patients in the form of lower premiums. Further, payment parity laws effectively pay providers based on the volume of services—rather than on value or outcomes—and, thus, may encourage overconsumption of telehealth services.[5]

On the other hand, the counterargument would be that most states' payment parity laws do not, and are not intended to, prohibit health plans and providers from entering into at-risk, capitated, or shared savings contracts. For example, Kentucky recently enacted a law to impose both telehealth coverage and payment parity requirements for Kentucky Medicaid, Medicaid managed care organizations, and commercial health plans. However, the new law also allows a telehealth provider and payor "to contractually agree to a lower reimbursement rate for telehealth services."

Payors and providers alike should remain abreast of the telehealth parity landscape to determine whether applicable states' parity laws will help or hinder their business as the country transitions to value-based healthcare. We will continue to monitor telehealth legislation at the state and national levels and provide updates accordingly.

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[1] TEX. INS. CODE § 1455.004(a)–(b).

[2] *Id.* § 1455.004(c).

[3] R.S.MO. § 280.670.

[4] *See, e.g.,* Les Masterson, *Study shows telemedicine potential in EDs,* HEALTHCARE DIVE (Jan. 16, 2018).

[5] See Thomas B. Ferrante and Nathaniel M. Lacktman, *Kentucky's New Telehealth Law Expands Insurance Coverage and Reimbursement,* FOLEY & LARDNER LLP (May 23, 2018).

Differences and Similarities Between the Federal Anti-Kickback Statute and the 2018 Eliminating Kickbacks in Recovery Act

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The Eliminating Kickbacks in Recovery Act of 2018 ("EKRA") marks a significant shift in federal oversight of the healthcare industry, applying the general rule against paying remuneration related to referrals of patients for items or services regardless of payor. For a specific—but broad—subset of providers, paying any remuneration to induce referrals now carries significant potential criminal and civil liability under EKRA and the False Claims Act.

EKRA went into effect October 24, 2018, and contains a broad prohibition on receiving or offering remuneration in exchange for referrals to a recovery home, clinical treatment facility, or laboratory, regardless of payor type. EKRA complicates compliance efforts for these providers by implementing an additional statutory prohibition on referrals that is broader than the federal Anti-Kickback Statute ("AKS") with exceptions that are not entirely consistent with the safe harbors currently found in the AKS.

EKRA was passed as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (the "SUPPORT Act"). Although the SUPPORT Act was primarily intended to address the opioid crisis, EKRA applies to any item or service covered by any healthcare benefit program (i.e., governmental or commercial insurance), not just those items or services relating to substance abuse disorders and not just those covered by federal healthcare programs.

EKRA's far reaching scope means that recovery homes, clinical treatment facilities, and laboratories must evaluate their current arrangements for compliance, and potentially restructure them. For example, while the AKS contains a safe harbor that generally permits compensation as part of a bona fide employment arrangement, EKRA permits payments to an employee only if the payment is not determined by, or does not vary by, (1) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory; (2) the number of tests or procedures performed; or (3) the amount billed to, or received from, in part or in whole, the healthcare benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory. Thus, certain common arrangements between recovery homes, clinical treatment facilities, and laboratories and their employees (such as marketers) that involve variable compensation (such as commission) may need to be evaluated and potentially restructured to comply with EKRA.

A chart comparing some of the key similarities and differences between EKRA and the AKS is included below:

Key Differences and Similarities between the Federal Anti-Kickback Statute (AKS) and the Eliminating Kickbacks in Recovery Act of 2018 (EKRA)		
	AKS	EKRA
Statutory Prohibition		
	(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe,	(1) OFFENSE — Except as provided in subsection (b), whoever, with respect to services

Statutory Prohibition		
	AKS	EKRA
	or rebate) directly or indirectly, overtly or covertly, in cash or in kind — (A) In return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal healthcare program, or (B) In return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal healthcare program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person— (A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal healthcare program, or (B) To purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal healthcare program, — shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both	covered by a healthcare benefit program, in or affecting interstate or foreign commerce, knowingly and willfully — (A) Solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory or (B) Pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind — (i) To induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or (ii) In exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory, — shall be fined not more than $200,000, imprisoned not more than 10 years, or both, for each occurrence.

Scope/Applicability		
	AKS	EKRA
Services Covered by…	Federal healthcare programs – Any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government or a State healthcare program (42 U.S.C. 1320a–7b(f))	Healthcare benefit programs – 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 (18 U.S. Code § 24(b)) *Note that the prohibition applies to all services, not just those relating to substance abuse disorders
Referrals to…	Any healthcare entity (that offers services covered by federal healthcare programs)	Recovery homes, clinical treatment facility, laboratory Recovery home – 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 Clinical treatment facility – 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 Laboratory – A facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings
Exceptions [The following are not "remuneration" under the applicable Statute]		
General Discounts	Discount or other reduction in price obtained by a provider of services or other entity under a Federal healthcare program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal healthcare program	Same[1]

Exceptions [The following are not "remuneration" under the applicable Statute]		
	AKS	EKRA
Bona Fide Employment Relationship	Any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services	A payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by, or does not 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 healthcare benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory
Group Purchasing Organizations	Any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal healthcare program if (i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and (ii) in the case of an entity that is a provider of services (as defined in section 1395x (u) of this title[2]), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity	
Patient Copayments or Coinsurance	A waiver of any coinsurance under part B of subchapter XVIII of this chapter by a Federally qualified healthcare center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act [42 U.S.C. 201 et seq.]	A waiver or discount (as defined in 42 CFR § 1001.952(h)(5)) of any coinsurance or copayment by a healthcare benefit program if (A) the waiver/discount is not routinely provided, and (B) the waiver/discount is provided in good faith

Exceptions [The following are not "remuneration" under the applicable Statute]		
	AKS	EKRA
Risk-Sharing Arrangements	Any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1395mm of this title or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide	See Alternative Payment Model exception
Pharmacy Waivers/ Part D Cost-Sharing	The waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of subchapter XVIII of this chapter, if the conditions described in clauses (i) through (iii) of section 1320a–7a (i)(6)(A) of this title are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1395w–114 (a)(3) of this title), section 1320a–7a (i)(6)(A) of this title shall be applied without regard to clauses (ii) and (iii) of that section)	
FQHCs & MA Organizations	Any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1395w–23 (a)(4) of this title	
FQHCs & Donors	Any remuneration between a health center entity described under clause (i) or (ii) of section 1396d (l)(2)(B) of this title and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity	Same [Direct cross-reference to the AKS exception]

Exceptions [The following are not "remuneration" under the applicable Statute]		
	AKS	EKRA
Medicare Coverage Gap Discounts	A discount in the price of an applicable drug (as defined in paragraph (2) of section 1395w–114a (g) of this title) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w–114a of this title	Same
Organizational Compensation	No exception that mirrors the EKRA exception here, but Personal Services & Management Contracts Safe Harbor	A payment made by a principal to an agent as compensation for the services of the agent under a personal services and management contract that meets the requirements of 42 CFR § 100.952(d), as in effect on the date of enactment of this Section *If within the AKS Personal Services & Management Contract Safe Harbor, it is excepted under EKRA
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 healthcare 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
Subsequently Enacted Regulations		Any other payment, remuneration, discount, or reduction as determined by the Attorney General, in consultation with HHS, by regulation

For more information about EKRA, the AKS, or other healthcare regulatory and compliance questions, please contact the Haynes and Boone Healthcare Practice Group members below.

[1] This means the EKRA exception is the same as the AKS exception, notwithstanding the distinctions already discussed, e.g., that the AKS exception refers to "discount[s] [] obtained … under a federal healthcare program," whereas EKRA's exception refers to "discount[s] [] obtains … under a healthcare benefit program."

[2] *As used here, "this title" refers to 42 USC § 1320a-7b.*

District Court Overturns 60 Day Rule for Medicare Advantage Plans

Stacy Brainin, Nicole Somerville, Taryn McDonald

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UnitedHealthcare Insurance Co. recently secured a significant victory with potentially far-reaching consequences when the United States District Court for the District of Columbia vacated the 60-Day Overpayment Rule applicable to Medicare Advantage plans (the "Overpayment Rule"). The court's decision could potentially impact traditional Medicare providers as well since the language at issue in the case tracks the separate but similar 60-day overpayment rule applicable to traditional Medicare.

Overpayment Rule

The Centers for Medicare & Medicaid Services ("CMS") promulgated the Overpayment Rule in 2014 to implement and clarify the Affordable Care Act's ("ACA") 60-day repayment obligation. The ACA states that "[a]n overpayment must be reported and returned" within "60 days after the date on which the overpayment was identified."[1] Failure to timely return an overpayment constitutes a violation of the federal False Claims Act ("FCA").[2] The Overpayment Rule states that a Medicare Advantage organization has "identified" an overpayment "when it has determined, or should have determined through the exercise of reasonable diligence," that it received an overpayment.[3] CMS explained in the preamble that such diligence would require "at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments.[4] Thus, under the Overpayment Rule, as written by CMS, failure to conduct reasonable diligence arguably could result in False Claims Act liability.

District Court Opinion

UnitedHealthcare Insurance Co. ("United") filed suit against the government in D.C. district court challenging the Overpayment Rule on several bases, including that it impermissibly expands the scope of liability under the FCA.[5] The FCA only imposes liability for false claims that are submitted "knowingly." The FCA defines "knowingly" as (i) actual knowledge of the information, or (ii) deliberate ignorance of the truth or falsity of the information, or (iii) acting in reckless disregard of the truth or falsity of the information.[6] In other words, the FCA does not premise liability on negligence alone. In contrast, the Overpayment Rule's definition of "identified" could subject Medicare Advantage plans to potential FCA liability based on merely negligent inaction (i.e., failing to proactively search for and find overpayments). United argued this was inconsistent with the FCA's knowledge standard.

The district court agreed, adding that Congress had no intention to turn the FCA, which was enacted to combat fraud, into a vehicle for punishing honest mistakes or incorrect claims submitted through mere negligence. Because the court concluded that the definition of "identified" in the Overpayment Rule was inconsistent with the definition of "identified" in the FCA, the court vacated the Overpayment Rule.[7]

Impact on Medicare Advantage Plans

Plans watched closely last year when the DOJ for the first time intervened in FCA whistleblower suits alleging Medicare Advantage fraud. The first intervened suit was voluntarily dismissed late last year after the judge found the complaint too vague. The second intervened suit, United States ex rel. Poehling v. UnitedHealth Group, Inc., survived a motion to dismiss and remains pending in California.[8] Just last week, the DOJ intervened in yet another suit, United States ex rel. Ormsby v. Sutter Health et al.,9 in which the relator alleged that Sutter Health knowingly submitted inaccurate risk adjustment data and knowingly retained overpayments it received based on that inaccurate or false data.[10] The DOJ has not yet filed its own complaint, so it remains to be seen whether the DOJ will directly address

the UnitedHealthcare Ins. Co. case's impact on the Overpayment Rule. In any event, this intervention demonstrates that the DOJ continues to be focused on FCA litigation involving Medicare Advantage plans.

Impact on Traditional Medicare Providers

Also interesting is the impact the UnitedHealthcare Ins. Co. decision will have outside of the Medicare Advantage context. In 2016, CMS promulgated a separate but similar overpayment rule applicable to traditional Medicare providers. The "identified" definition in that rule also includes a "reasonable diligence" standard. Traditional Medicare providers facing allegations that they failed to exercise "reasonable diligence" to identify an overpayment may now argue that the 2016 60-day overpayment rule, like the Overpayment Rule applicable to Medicare Advantage providers vacated in UnitedHealth Ins. Co., also impermissibly broadens the knowledge standard articulated by the FCA. Given the similarity of the two rules, it is likely that a court will have to address this issue as to traditional Medicare providers in the near future. The ultimate impact of UnitedHealthcare Ins. Co. could be far-reaching and remains to be seen.

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[1] 42 U.S.C. § 132a-7k(d)(2).

[2] 42 U.S.C. § 132a-7k(d)(3).

[3] 42 C.F.R. § 422.326(c).

[4] 79 Fed. Reg. at 29,923.

[5] *UnitedHealthcare Ins. Co. v. Azar*, No. 1:16-cv-00157 (RMC), 2018 WL 4275991 (D.D.C. Sept. 7, 2018).

[6] 31 U.S.C. § 3729(b)(1). Note that CMS filed a Motion for Reconsideration on November 5, 2018 and a Notice of Appeal on November 6, 2018.

[7] While this article focuses on the FCA issue, the court's decision was also based on two other findings: (1) the Overpayment Rule violated the statutory mandate of actuarial equivalence between CMS payments for coverage under traditional Medicare and Medicare Advantage, and (2) the Overpayment Rule's definition of "identified" was finalized without adequate notice as required by the Administrative Procedure Act.

[8] No. 2:16-cv-08697, 2018 WL 1363487 (C.D. Cal. Feb. 12, 2018).

[9] No. 15-cv-01062 (N.D. Cal.).

[10] See Compl. at 12.

QUICK SHOTS

The OIG addressed whether a health plan's proposal to incentivize Early and Periodic Screening, Diagnostic and Treatment (EPSDT) services qualified under the Eligible Managed Care Organization (EMCO) safe harbor.

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The DOJ asked multiple courts to dismiss 11 declined FCA cases against 38 defendants brought by special purpose entities against a variety of pharmaceutical providers for wasting government resources.

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The DOJ filed an amicus brief in a long-running FCA case stating its intention to dismiss a declined case in the event of an unfavorable ruling on materiality.

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UPCOMING SPEAKING ENGAGEMENTS

ICYMI

Franchising Wellness Concepts
Dallas Bar Association
Suzie Trigg and Phil Kim
December 18, 2018

COMING SOON

Webcast on False Claims Act: 2018 Year in Review
PLI
Stacy Brainin and Nicole Somerville
January 14, 2019

False Claims Act: 2018 Year in Review
Dallas Bar Association Health Law Section Meeting
Chris Rogers, Stacy Brainin, and Nicole Somerville
March 20, 2019

Enforcement Trends
UT Law 2019 Annual Health Law Conference
Stacy Brainin
March 28, 2019

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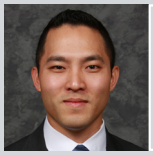

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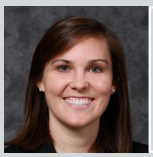

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