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Health Care Newsletter

Compliance Corner

By Anne M. Brendel

Will the Movement toward Value-Based Reimbursement Cause a Roll-Back of the Stark Law?

Industry trends present a clear move from fee-for-service to value-based reimbursement models, particularly as patient engagement increases with the use of efficient technologies. As a response, new care delivery and payment models seek to improve quality of care and encourage reimbursement linked to outcomes. In fact, by the end of this year, the Department of Health and Human Services ("HHS") expects the vast majority of Medicare fee-for-service payments to include quality measures and roughly one half of payments to made be under an alternative payment model ("APM").

Earlier this year, the Centers for Medicare and Medicaid Services ("CMS") requested comments on how CMS could reduce regulatory burdens associated with care coordination under the Stark Law. With more than 2,600 responses from stakeholders, CMS identified the burden of complying with the Stark Law as a target for reform. With the trajectory of payment and care models evolving at a furious pace, the outdated elements of the Stark Law continue to constrain providers.

The Stark Law dates from the 1980s, and it was enacted in response to a perceived growing pattern of physician self-referrals, which were deemed to present an inherent conflict of interest and result in the overutilization of services. The Stark Law prohibits providers from referring patients to an entity in which the referring physician has a financial interest for designated health care services that are payable by a federal health care program. The Stark Law originally applied to clinical laboratory services only; over time, additional designated health services were added, including, among others, inpatient and outpatient hospital services, imaging services, and physical therapy services.

CMS specifically requested feedback on the Stark Law's impact on coordinated care, the use of APMs and novel financial arrangements, the sufficiency of existing exceptions, and the ability of providers to successfully use them.

For example, under the current Stark Law regulatory framework, providers cannot test an APM without a financial waiver from CMS, yet such waivers cannot be granted unless the provider has an approved APM. This requires providers to speculate as to how their proposed care delivery and financial models might impact their patients. Further, the waivers are granted on an individual basis, creating even more uncertainty among providers who seek to transition to value-based care.

The narrow scope of protections in Stark Law's exceptions and the Anti-Kickback Statute's safe harbors also provide little protection with respect to modern reimbursement trends. Rewarding physicians for cost savings generated from coordinated care programs involving non-clinical and clinical partners and financial arrangements that include the allocation of risk based on patient outcomes could result in federal scrutiny under the current regulatory scheme.

The result is an illogical and restrictive system that prevents providers from developing services that incorporate existing types of value-based reimbursement. Regulatory reform could be a significant benefit

to patients in a pay-for-performance environment, where financial incentives and disincentives are tied to performance measures and provider sponsored health plans, as well as the shared savings, shared risk, and capitation models

Considering the industry shift toward coordinated care, the Stark Law's strictures are impediments that have outlived their usefulness. Reform could permit providers to develop delivery models that can appropriately respond to modern healthcare challenges and patient needs.

HIPAA Alert: HHS Released New Guidance Clarifying Remote Access of Protected Health Information by Researchers

The 21st Century Cures Act was enacted in 2016 to help accelerate medical product development and bring new innovations and advances to patients in a timely and efficient manner. The primary focus is to bolster research and modernize clinical trial designs. The promise of the 21st Century Cures Act is almost immediately inhibited by HIPAA regulations which appear to prohibit Protected Health Information ("PHI") from being removed from a covered entity by a researcher.

HHS issued guidance clarifying that researchers are not prohibited from remotely accessing PHI in preparation for research, as long as the PHI is not copied or retained. The guidance interprets remote access connectivity (i.e. out-of-office computer access achieved through secure connections with access controls and authentication) as being distinct from removing PHI, which refers to downloading, printing, copying, or physically removing PHI from a facility. While covered entities are free to permit their workforce or other researchers to access PHI through a remote access connection, it is important to note that covered entities are still subject to the HIPAA Security Rule requirement for implementing and maintaining appropriate safeguards to protect their electronic PHI.

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