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HHS Proposes Changes to Protect Value-Based Payments and Coordinated Care

The U.S. Department of Health and Human Services ("HHS") issued proposed changes to the Physician Self-Referral Law (the "Stark Law") and the Federal Anti-Kickback Statute ("AKS") on October 9, 2019, in an attempt to promote value-based arrangements and coordinated care.

The proposed new exceptions to the Stark Law would allow healthcare providers to transition away from fee-for-service arrangements toward more value-based arrangements where compensation is based on how efficiently and effectively certain patient populations are managed. In recognizing that incentives are different in a healthcare system that pays for value, rather than the volume of services provided, the proposed changes would ease the compliance and administrative burdens for healthcare providers that drive up costs by giving them flexibility to improve the quality of patient care, while still maintaining safeguards to protect patients and healthcare programs from overutilization, fraud and abuse. The proposed rule also addresses the price transparency directives set forth in the June 24, 2019, Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First.

Under the AKS, three new safe harbors to specifically protect value-based arrangements are proposed:

- care coordination arrangements would include in-kind remuneration for services or infrastructures;
- employee-sharing protections for various tasks related to care coordination; and
- provider participation in value-based arrangements to offer in-kind patient engagement tools and supports to patients; however, monetary inducements for patients are prohibited.

In a recent press release by HHS, Deputy Secretary Eric Hagan stated that "[the proposed rules] are part of a much broader effort to update, reform, and cut back our regulations to allow innovation toward a more affordable, higher quality, value-based healthcare system, while maintaining the important protections patients need."

Below are several examples involving the kind of coordinated care, value-based care, data sharing, and patient engagement activities that could potentially be protected under the proposed changes to the Stark Law and AKS if all applicable conditions are met:

- specialty physician practices could share data analytics services with primary care physicians;
- hospitals and physicians could use remote monitoring technology to alert physicians or caregivers when a
 patient needs healthcare intervention to prevent unnecessary ER visits and re-admissions;
- local hospitals could donate cybersecurity software to local physician providers that refer patients to their hospitals; and
- physician practices could provide their patients with smart pillboxes, free of charge, to help them remember to take their medications and refill their prescriptions on time.

The proposed rules were submitted to the Federal Register and published on October 17, 2019. The HHS will accept mail and electronic comments about the proposals until 5:00 p.m. on December 31, 2019.

Please consult with Rebecca J. Maziarz, Jeffrey R. Hantz, or Gabrielle M. Carbonara with Dickie, McCamey & Chilcote, P.C. They can answer any questions about how these proposed revisions may apply to your business.



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Ms. Maziarz was the Director of Medical Information Management for two Western Pennsylvania hospitals and one in West Virginia. Additionally, she served as a Long Term Care Consultant to area nursing homes. Her background in the healthcare industry provides clients with an invaluable resource and unique perspective into the ever-evolving healthcare landscape.

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