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Fraud laws roadblocks to VBHC?

Reform in the healthcare sector is highlighted by the paradigm change to value-based care. The Affordable Care Act tried to integrate the value-based model into the framework of the American healthcare system through a number of initiatives, such as the Medicare Shared Savings Programme and the implementation of new payment structures.

Despite years of interest and enthusiasm under its belt, "value-based care has yet to save our healthcare system," says Carmel Shachar, JD, MPH, Executive Director, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School.

What's hindering value-based care from meeting its full potential, she points out, is the American regulatory system, which has designed its fraud and abuse laws to penalise overutilisation, a pervasive worry under fee-for-service payment structures.

"The focus on overutilisation, in the age of value-based care, is outdated and only serves to impede the adoption of — and innovation within — value-based care," according to Shachar, also a Lecturer at Law in Harvard Law School.

The Anti-Kickback Statute (AKS) and the Stark law are two such fraud and abuse regulatory regimens well known to healthcare entities seeking to provide value-based care. Specifically, the AKS prohibits the exchange of (or offer to exchange) anything of value in order to induce or reward the referral of federal healthcare programme business. For example, one hospital violated the AKS by providing after-hours phone-answering and waste-removal services to independent physicians at below-market rates in order to induce referrals to the hospital.

Meanwhile, the Stark law prohibits a physician from making referrals to an entity with which the physician (or a member of his or her immediate family) has a financial relationship. Think of a physician who has an ownership interest in an accountable care organisation (ACO). If the physician were to refer a patient to another part of the organization, perhaps for an MRI screening, that referral may violate the Stark law because of his or her ownership interest.

In some instances, government agencies are able to issue waivers or exemptions to mitigate the impact of fraud and abuse laws on value-based care initiatives. For example, regulators began to offer waivers from fraud and abuse laws to ACOs that were formed under the Medicare Shared Savings Programme.

In addition, the Office of the Inspector General of the U.S. Department of Health and Human Services is authorised to issue advisory opinions on how entities can deliver healthcare goods and services without running afoul of fraud or abuse laws in response to specific questions submitted to the Office. In January 2018, for example, the Office reviewed an arrangement in which neurosurgeons agreed to implement cost-reduction measures during certain surgical procedures performed at a particular medical centre in exchange for receiving a percentage of the cost savings resulting from these policies. After evaluating the proposal, the Office concluded that it would not impose fraud and abuse sanctions for the participants in this specific proposal.

"The problem with trying to mitigate the chilling effect that fraud and abuse laws have on value-based care through waivers and advisory opinions is that these limited exemptions will inevitably place problematic boundaries on the types of value-based care arrangements that are possible, thereby limiting innovation," Shachar notes.

Instead of using waivers, advisory opinions, and exceptions to insulate value-based care from misapplied fraud and abuse laws, Shachar advocates for a regulatory system that embodies two central tenets: (1) that all health services, if possible, should be delivered through value-based care, and (2) that value-based care, by its nature, disincentivises the types of fraud and abuse that the traditional statutes were intended to address.

"Value-based care, by its nature, is designed to address the same problem that our current fraud and abuse laws target, making these statues redundant at best and stifling at worst," Shachar says. "Therefore, allowing value-based care to be broadly exempt from those statutes runs a much lower risk of fraud and abuse than allowing more traditional fee-for-service delivery structures to be exempt."

In summary, there's an urgent need to overhaul the current regulatory regime to reflect the idea that value-based care, not fee-for-service, should be the default.

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