

Feast on This – Stark, Anti-Kickback and CMP Final Rules Issued



November 24, 2020

By Lori Beam

Just in time for your socially distanced Thanksgiving, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) for the Department of Health and Human Services dropped more than 1,600 pages of final rules on Nov. 20.

The rules have been issued for implementing the Physician Self-Referral Statute (the Stark Law), the Anti-Kickback Statute (AKS), and the civil money penalty rules on beneficiary inducements (CMP).

Over the Thanksgiving weekend you are welcome to dig into the 627 pages of CMS regulations or the 1,049 pages of OIG regulations. Reading them will probably induce a midday nap faster than tryptophan from a heaping helping of turkey.

OR, better yet, let us do it for you and count your blessings on Thanksgiving Day! In the coming days, we will offer a series of more in-depth alerts on these key regulatory changes.

To give you a taste, here's the big picture –

CMS and OIG adopted these final rules as part of their *Health and Human Services' Regulatory Sprint to Coordinated Care* initiative to remove regulatory barriers that inhibit innovative arrangements for coordinating care among hospitals, physicians and other providers and slow the related shift to value-

based reimbursement arrangements among the collaborating providers. The regulatory changes go into effect January 19, 2021 – except for one Stark Law change that goes into effect January 1, 2022.

Main Meal: Value-based Arrangements

In general, the CMS and OIG final rules for value-based arrangements adopt the exceptions/safe harbors initially proposed for public comment. But they make changes that offer greater flexibility for value-based collaborations, such as lower thresholds for qualifying as a protected arrangement assuming downside risk. Specifically –

- **Stark Law.** CMS adopts four new exceptions to the Stark Law for value-based arrangements. The applicable exception depends on the level of risk assumed by the network of providers participating in the value-based arrangement including –
 1. One for full financial risk.
 2. One for meaningful downside risk.
 3. One available regardless of the level of assumed risk that is more stringent than the exceptions for full and meaningful assumed risk.
 4. One for an indirect compensation arrangement with a physician or physician group.

None of these new exceptions contain the typical Stark Law requirement that the compensation be set in advance, consistent with fair market value and not determined in any manner that takes into account the volume or value of referrals or other business generated.

- **AKS.** Similarly, the OIG establishes three new AKS safe harbors for value-based arrangements –
 1. One for collaborators assuming full financial risk.
 2. One for collaborators agreeing to assume substantial downside risk.
 3. One protecting exchanges of *in-kind* remuneration among the collaborating participants.
- **?CMP.** The OIG also made final a new safe harbor for arrangements for patient engagement and support intended to improve quality, health outcomes and efficiency that applies more generally than the initial proposed rule tied to types of patient engagement/support tools used. Further, the final rules clarify that value-based arrangements meeting one of the new AKS safe harbors do *not* trigger CMP.

Side Dishes:

In addition to the main entrée of value-based arrangement protections, the CMS and OIG final rules offer side helpings of industry-friendly guidance and clarifications on other arrangements between physicians and health care providers. For example, the final rules –

- Establish a new Stark Law exception and a new AKS safe harbor allowing health care systems and others to donate cybersecurity technology and related services to physician groups or other providers as long as the technology “is necessary and used predominantly to implement, maintain or reestablish cybersecurity.”
- Expand the existing Stark Law exception and AKS safe harbor for electronic health records to allow donations of hardware in addition to software and services.
- Redefine terms such as designated health services, physician, referral, remuneration and transaction and provide Stark Law guidance on terminology and requirements key to Stark Law compliance such as commercially reasonable, fair market value, and volume or value.

· Modify the AKS safe harbors for personal services and management contracts, warranties and local transportation.

If this first helping doesn't sate your appetite, be on the lookout for our upcoming comprehensive analyses of these important Stark Law and AKS issues.

In the meantime, please know we in the Seigfreid Bingham Health Law Group are thankful for you and wish you a safe and Happy Thanksgiving with all the trimmings.

This article is general in nature and does not constitute legal advice.

Readers with legal questions should consult the author, Lori Beam (lbeam@sb-kc.com) or any other shareholders in Seigfreid Bingham's Health Law Group, including Mark Thompson, Joseph Hiersteiner, Mark Gilgus, John Neyens, Mark Opara, Heath Hoobing and John Fuchs, or your regular contact at Seigfreid Bingham at 816-421-4460.