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Proposed Rule Has New Stark Exceptions, Eases Some Technical Requirements

Some Stark walls may come tumbling down if CMS finalizes proposals in the 2016 Medicare physician fee schedule regulation, which was published in the July 15 *Federal Register*. Hospitals would have new exceptions for time-sharing arrangements with physicians and recruitment incentives for nonphysician practitioners, and their compliance wouldn't be in jeopardy because of certain technical violations, such as expired agreements. There's also something in the regulatory black bag for CMS, which wouldn't be swamped by submissions to the self-referral disclosure protocol based solely on technical violations.

"It's clear they are trying to simplify and reduce the amount of self-disclosures they have on their docket and focus on issues where there really is fraud and abuse," says Albany, N.Y., attorney John D'Andrea, with Drinker Biddle. The proposed regulation also has an eye on the future, with CMS asking for insight on how the Stark regulations get in the way of the transformation of payment models from fee for service to fee for value.

CMS proposed a new Stark exception for time-share arrangements that satisfy certain criteria. With time-share arrangements, hospitals rent space to physicians for a small amount of time, perhaps a half day or full day once a week or once a month. Physicians sign up for time shares so they can see certain patients in a clinic setting at a location other than their primary office, for the convenience of the patients, the physician or both. Physicians pay their hospital-landlord on a prorated basis for the time they occupy the space, and for the staff and equipment they use. Many hospitals have time-share arrangements. They allow specialists to essentially expand their service area by providing services in a hospital-owned location in addition to their private practice. Renting full-time for a part-time gig would be cost-prohibitive, but that wouldn't be the case if the cardiologist alternates the rental with other specialists with the same needs. But time shares must comply with a Stark exception (e.g., leases, equipment rentals), with the agreement set forth in writing and payment at fair-market value. At least one hospital has settled a case over time-share noncompliance *(RMC 6/3/13, p. 4)*.

The proposed rule set forth eight criteria in the time-share exception:

(1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies and services covered by the arrangement;

(2) The arrangement is between a hospital or physician organization (licensor) and a physician (licensee) for the use of the licensor's premises, equipment, personnel, items, supplies or services;

(3) The licensed premises, equipment, personnel, items, supplies and services are used predominantly to furnish evaluation and management services to patients of the licensee;

(4) The equipment covered by the arrangement, if any: (i) is located in the office suite where the physician performs evaluation and management services, (ii) is used only to furnish designated health services (DHS) that are incidental to the physician's evaluation and management services and furnished at the time of such evaluation and management services, and (iii) is not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests);

(5) The arrangement is not conditioned on the licensee's referral of patients to the licensor;

(6) The compensation over the term of the arrangement is set in advance, consistent with fair-market value and not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties;

(7) The arrangement would be commercially reasonable even if no referrals were made between the parties; and

(8) The arrangement does not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission.

The other exception in the proposed rule would protect recruitment incentives for nonphysician practitioners (NPPs), such as physician assistants and nurse practitioners. Hospitals could give their employed physicians money to use to recruit NPPs to provide primary care services. The exception includes many of the standard Stark safeguards, such as a written agreement signed by

the hospital, the physician and the NPP, and remuneration that does not take into account the volume and value of referrals.

"That's a big change," D'Andrea says. "CMS went through a fair amount of discussion about how there will be a shortage of primary care physicians, and that will limit patient access to care. One solution is having more nonphysician practitioners to treat primary care patients."

CMS also proposed several changes that would reduce hospitals' and physicians' vulnerability to violations for procedural errors, D'Andrea says. For one thing, CMS said in the regulation that numerous submissions to the self-referral disclosure protocol are for actual or potential violations of the "writing" requirement that are in many compensation exceptions (e.g., lease of office space and equipment), with providers saying they're unclear whether an arrangement has to be memorialized in a single document that covers all aspects of the arrangement. CMS said that while a single document provides "the surest and most straightforward means" of compliance, "a collection of documents evidencing the course of conduct between the parties may satisfy the writing requirement." This policy change would apply to all compensation exceptions that must be in writing, regardless of the terminology. Similarly, for the rental of office space and equipment exceptions, and the exception for personal service arrangements, the requirement of a one-year term may be demonstrated by a collection of documents, including contemporaneous documents, rather than by a formal document in which the term is set out.

CMS Wants Feedback on Reform

CMS also would allow parties to an unsigned agreement 90 days to obtain all necessary signatures, regardless of whether the lack of signature is inadvertent. Another change being floated would mellow out the holdover provisions for expired arrangements. CMS now allows a six-month extension, but it envisions allowing it to go on indefinitely or for a definite period that is greater than six months as long as there are safeguards to avoid renegotiations of short-term leases or contracts. Holdovers must continue to be at fair-market value; if they fall below, they sacrifice the exception. CMS also would revise the fair-market-value exception to permit renewals of arrangements of any length of time subject to safeguards.

Finally, CMS turned to the question of how the Stark law may interfere with health reform. "Entities furnishing DHS face the predicament of trying to achieve clinical and financial integration with other health care providers, including physicians, while simultaneously having to satisfy the requirements of an exception to the physician self-referral law's prohibitions if they wish to compensate physicians to help them meet the triple aim and avoid financial penalties that may be imposed on low-value health care providers," CMS says. It asked for comment on 10 questions that will help it fulfill the statutory mandates to provide Congress with reports on payment models, gainsharing and fraud in alternative payment models. For example, which exceptions to the physician self-referral law apply to financial relationships created or necessitated by alternative payment models? Are they adequate to protect such financial relationships? Is there a need for new exceptions to the physician self-referral law to support alternative payment models?

Hospitals and physicians already have fraud and abuse waivers for Medicare Shared Savings Plans and the gainsharing exemption from the Medicare Access and CHIP Reauthorization Act of 2015, but "Stark still poses barriers to health reform," D'Andrea says. CMS is looking for guidance from the health care community on whether "additional guidance or rulemaking is needed to relax or remove barriers to health reform initiatives without compromising fraud and abuse prevention."

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