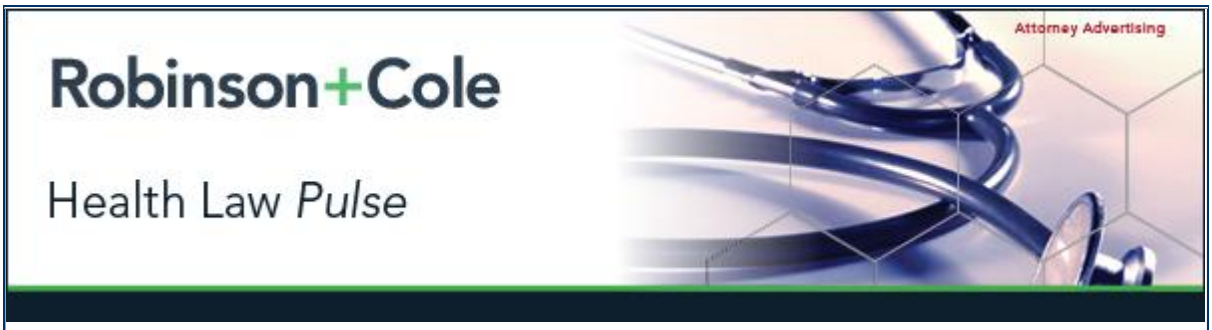

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In This Issue:

OIG ISSUES FAVORABLE ADVISORY OPINION FOR EMPLOYEE LEASING AND SERVICES ARRANGEMENT BETWEEN RELATED ENTITIES

The Office of the Inspector General (OIG) recently issued a favorable advisory opinion (Advisory Opinion) to a nonprofit health system (System) and a nonprofit psychiatric hospital (Center) regarding a proposal whereby the System would lease nonclinician employees and provide operational and management services to the Center in exchange for a fee equal to the System's fully loaded costs (Arrangement). The OIG concluded that, while the Arrangement has the potential to generate prohibited remuneration under the anti-kickback statute (AKS), the OIG would not impose administrative sanctions or civil monetary penalties (CMPs) on the System or Center because the Arrangement presents only a minimal risk of fraud and abuse.

The System is a nonprofit health system that owns multiple hospitals and health care providers. The System and a nonprofit foundation are the sole members of the Center, which itself is part of the System's integrated health network. The Center is reimbursed under the Medicare inpatient psychiatric facility prospective payment system. The Center and some of the System's providers file cost reports with the Centers for Medicare & Medicaid Services (CMS). The Center and the System are possible sources of referral to each other. Currently, the System leases nonclinician employees and provides some operational and management services to the Center in exchange for an amount equal to the System's fully loaded costs plus a 2 percent administrative fee. The System's fully loaded costs include salaries, benefits, and overhead expenses.

Under the Arrangement, the System would continue to lease nonclinician employees and provide operational and management services to the Center, but the Center would pay only the System's fully loaded costs and would no longer pay an administrative fee or any other markup. All leased employees are bona fide employees of the System. According to the System and the Center, the Center cannot obtain the leased employees or the services at a lower aggregate cost than that charged by the System. The System and the Center stated that the goal of the Arrangement (and the current arrangement) is to integrate the Center into the System and to reduce costs by eliminating duplicative administrative functions. The amount the Center would pay to the System would not vary based on volume or value of

referrals or other business generated between the parties; however, the aggregate compensation could not be set in advance, as the System's costs and the Center's personnel and management needs may change during the course of the Arrangement. Additionally, the System's fully loaded costs for the leased employees and services may be below fair market value (FMV).

The System and the Center are "related organizations" and are therefore bound to certain Medicare cost-reporting rules. Under these rules, services furnished to a provider by a related organization can generally be included in the provider's "allowable cost" in an amount equal to the cost of such services to the related organization. These costs, however, cannot exceed the cost of comparable services available from unrelated organizations. As a result, according to CMS, while the Center is not prohibited from paying the 2 percent administrative fee to the System under the existing arrangement, Medicare would not reimburse the Center for any amount that exceeds the System's costs, which would likely include the administrative fee.

OIG Findings

The AKS makes it a crime to knowingly and willfully offer or receive remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. The OIG found that the Arrangement could implicate the AKS because the System would charge the Center a potentially below-FMV for personnel and services, which could constitute remuneration in exchange for the Center's referrals to the System. The OIG also found that the Arrangement would not satisfy the AKS safe harbor for personal services and management contracts (or any other safe harbor) because the compensation could not be set in advance and may be less than the FMV.

Although the Arrangement could implicate the AKS and does not satisfy a safe harbor, the OIG determined that the Arrangement presents a low risk of fraud and abuse. Specifically, the OIG stated that the following features of the Arrangement minimize the risk of prohibited remuneration: (1) the Arrangement is structured to adhere to the Medicare cost-reporting rules for related organizations, and therefore, the Center would not make payments in excess of the System's allowable costs; (2) the Arrangement reduces the costs of the System's integrated health system of which the Center is a member, and the savings will ultimately influence Medicare's inpatient psychiatric facility prospective payment system and benefit the health care system as a whole; and (3) no evidence suggests that the Arrangement will increase current incentives for referrals between the System and the Center or that the purpose of the Arrangement is to induce referrals.

Conclusion

Although the Advisory Opinion is limited to the specific facts of the Arrangement, organizations contemplating an arrangement that involves leasing nonclinician employees or providing services to a related entity for a fee that may be below the FMV may wish to carefully consider the OIG's interpretation of the AKS in the Advisory Opinion.

ADVANCE CARE PLANNING PAYMENTS, STARK LAW UPDATES, AND CHANGES TO "INCIDENT TO" BILLING RULES ALL INCLUDED IN CMS'S PROPOSED CHANGES TO THE PHYSICIAN FEE SCHEDULE

On July 15, 2015, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule (Proposed Rule) that revises physician payment policies and rates for the Medicare Physician Fee Schedule. Among the many proposals in the rule, CMS proposes new payment codes for advance care planning, updates to the physician self-referral law (Stark Law), and changes to Medicare's "incident to" billing rules. Below are highlights from the Proposed Rule.

Public comments to the Proposed Rule are due by September 8, 2015.

Advance Care Planning Payments

Medicare currently reimburses physicians and qualified nonphysician practitioners for certain end-of-life planning discussions with beneficiaries during the "Welcome to Medicare" visit, available to new Medicare beneficiaries. End-of-life planning includes discussion of a patient's advance directive and whether the provider is willing to follow the individual's wishes as set forth in it. End-of-life planning is currently bundled with other services provided in the Welcome to Medicare visit and paid to the provider as a single payment.

The Proposed Rule establishes two new payment codes for "advance care planning" (a term that encompasses end-of-life planning) provided to Medicare beneficiaries by physicians or qualified nonphysician practitioners, such as physician assistants and nurse practitioners. One code reimburses providers for the first 30 minutes spent discussing and planning for advance care with the patient, and the second code reimburses providers for each additional 30 minutes of advance care planning. These codes are used when it becomes necessary to provide advance care planning for the diagnosis or treatment of an illness or injury. If this discussion takes place in connection with a physician's evaluation and management of a patient's condition, the physician reports both the evaluation and management code and one or both of the advance care planning codes as appropriate.

Although the Proposed Rule designates the status of the advance care planning codes as "active," CMS is explicit that the Proposed Rule does not constitute a Medicare national coverage determination for advance care planning services; rather, Medicare contractors remain responsible for local coverage decisions.

If the Proposed Rule is finalized in its current form, CMS could begin to separately reimburse advance care planning services on January 1, 2016. CMS has not set a payment value for the advance care codes but intends to adopt the values recommended by the Relative Value Update Committee.

Stark Law Updates

The Stark Law prohibits a physician from making referrals for "designated health services" (DHS) to an entity with which the physician (or an immediate family member) has a financial relationship unless the relationship satisfies an exception. The Proposed Rule makes several regulatory updates and clarifications to the exceptions as part of an effort by CMS to "accommodate delivery and payment system reform, to reduce burden, and to facilitate compliance" with the Stark Law. Notable proposed Stark Law changes are highlighted below.

Recruitment of Nonphysician Practitioners

The Proposed Rule establishes an exception allowing hospitals, federally qualified health centers (FQHCs), and rural health clinics (RHCs) to pay physicians to help them employ nonphysician practitioners. The nonphysician practitioner must be located within the geographic area served by the hospital, FQHC, or RHC providing the payment. Nonphysician practitioners include only physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives. This exception applies only when the nonphysician practitioner is a formal employee of the physician or the physician's practice and when the employment purpose is to provide primary care services to patients of the physician practice. Eligible practitioners are subject to geographic and temporal restrictions to prevent the "cycling" of practitioners through multiple practices in the area. The exception is subject to a two-year limit on assistance per nonphysician practitioner and a cap on the payment amount.

Physician-Owned Hospitals

The Patient Protection and Affordable Care Act imposes additional restrictions on hospitals seeking to maintain physician ownership under the rural provider and whole hospital ownership exceptions. For a hospital to qualify for these exceptions, it must, among other things, disclose on public websites and advertisements that it is fully or partially owned or invested in by physicians and maintain the percentage of the total value of physician ownership or investment in the hospital (the bona fide investment level) as of March 23, 2010.

The Proposed Rule provides examples of several websites that are not considered public websites for the hospital, such as social media websites and electronic patient portals. The Proposed Rule also defines "public advertising for the hospital" as "any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital." Physician ownership disclosure statements are sufficient if they contain "language that would put a reasonable person on notice that the hospital may be physician-owned."

Additionally, the Proposed Rule changes the method for determining the bona fide investment level. Currently, CMS does not include ownership by nonreferring physicians when calculating the bona fide investment level. The Proposed Rule reverses this position and requires that the bona fide investment level take into account the ownership or investment interests of both referring and nonreferring physician-owners.

Timeshare Arrangements

CMS has also proposed a new Stark Law exception allowing timeshare arrangements for the use of office space, equipment, personnel, supplies, and other services that meet the following criteria: (1) the arrangement must be set out in writing, signed by the parties, and specify the premises, items, and services covered by the arrangement; (2) the arrangement must be between a hospital or physician organization and a physician; (3) the licensed premises, items, and services must be used predominantly for evaluation and management services; (4) the equipment covered must be located in the office suite of the physician, must be used only to furnish DHS that are incidental to evaluation and management, and cannot be advanced imaging, radiation therapy, or clinical or pathology laboratory equipment; (5) the arrangement must not be conditioned on patient referrals; (6) compensation must be set in advance at fair market value without consideration of referrals; (7) the arrangement must be commercially reasonable even if no referrals take place; and (8) the arrangement cannot violate the federal anti-kickback statute or any laws governing billing or claims submission.

Additional Clarifications and Changes

The Proposed Rule includes a few additional changes and clarifications that affect several exceptions to the Stark Law, including the following:

- For Stark exceptions that require arrangements to be set out in "writing" or in a "written agreement," the Proposed Rule clarifies that there is no requirement for a particular kind of writing or even a singular document, such as a formal contract; rather, depending on the facts, a collection of documents, including contemporaneous documents proving the course of conduct between the parties may suffice.

- The Proposed Rule amends the holdover provisions in office space rental, equipment rental, and personal services exceptions to allow arrangements that have expired to continue indefinitely if certain safeguards are met. The holdover must continue on the same terms and conditions as the original arrangement, and the holdover must continue to satisfy the applicable exception throughout its duration. The Proposed Rule also specifies that arrangements satisfying the fair market value compensation exception (regardless of the duration of the initial term) may be renewed any number of times as long as the terms and compensation do not change.

Changes to "Incident to" Billing Rules

Physicians and other practitioners may bill Medicare for “incident to” services provided by auxiliary personnel supervised by a physician or other practitioner as long as certain criteria are satisfied. Regulations currently specify that the physician or other practitioner supervising the auxiliary personnel does not need to be the same individual upon whose service the incident to service was based. To bill for incident to services, the Proposed Rule clarifies that a physician or other practitioner must have supervised the auxiliary personnel who performed the incident to services. A question still remains as to whether another physician in the ordering physician’s practice can serve as the supervising physician for this purpose. Stakeholders will likely seek clarification on this point.

If you have any questions, please contact a member of Robinson+Cole’s Health Law Group:

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