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How the first 20 years of HCCA will influence the next 20 years

an interview with Dan Roach

Chief Compliance Officer / General Counsel, Optum360 and SCCE/HCCA Board Member

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by Scott R. Grubman, Esq. and Samuel M. Shapiro, Esq.

CMS implements important changes to Stark and incident-to regulations

» Under the Stark Law, hospitals may make payments to physicians for the purpose of compensating non-physician practitioners.

» Timeshare arrangements between physicians and unrelated hospitals are now permitted under Stark, if certain requirements are met.

» Under Stark, leases and personal service contracts may continue past expiration as long as the arrangement remains the same.

» For incident-to services, only the physician that directly supervises the auxiliary personnel may bill Medicare.

» Excluded personnel are expressly prohibited from providing incident-to services.

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On November 16, 2015, the Centers for Medicare & Medicaid Services (CMS) published its final rule containing revisions to payment policies under the Medicare Physician Fee Schedule (PFS) and other Medicare Part B payment policies for services provided on or after January 1, 2016.[1] Among other things, the final rule contains two categories of noteworthy updates: one related to the Physician Self-Referral (Stark Law) regulations, and the other related to the requirements for "incident-to" billing.

New Stark exceptions and other Stark clarifications

CMS's final rule includes two new exceptions to the Stark regulations, along with updates and other such clarifications of existing Stark regulations. In promulgating these exceptions, CMS made note of the vastly different healthcare landscape that has emerged since its promulgation of the final Stark regulations (i.e., the Phase III regulations) in 2007.

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For example, with the country's population continuing to grow and age, and with the Affordable Care Act expanding health insurance coverage to the previously uninsured, the demand for primary care services has been ever-increasing, especially in rural and underserved areas. Yet, despite this demand, the supply of primary care physicians has not kept pace. Recognizing these trends, CMS noted that "NPPs [non-physician practitioners], the fastest growing segment of the primary care workforce, may help to mitigate these shortages."[2]

Accordingly, the first new Stark exception permits payments by hospitals, rural health clinics, and federally qualified health centers to physicians for the purpose of compensating NPPs (e.g., physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, clinical social workers, and clinical psychologists) to provide patient care services.[3] In order for this new exception to apply, several conditions must be met, including, among other things, that:

(1) the arrangement is set out in writing and signed by the entity, the physician, and the NPP; (2) the arrangement is not conditioned on referrals by the physician or the NPP to the entity; and (3) the remuneration from the entity does not exceed 50% of the actual compensation, signing bonus, and benefits paid by the physician to the NPP during a period not to exceed the first two consecutive years of the compensation arrangement between the NPP and the physician, and is not determined in a manner that takes into account the volume or value of actual or anticipated referrals by the physician or NPP.

The second new exception to the Stark regulations permits timeshare arrangements for the use of office space, equipment, personnel, items, supplies, and other services.[4] Like the NPP payments exception, CMS had previously (in the Phase III regulations) declined to extend protection to timeshare arrangements, concluding that they fell outside the scope of the Stark exceptions for office and equipment leases. However, in considering the needs of various stakeholders, especially those in rural and underserved areas, CMS determined that such arrangements may serve a legitimate purpose without posing a risk of abuse to patients or the Medicare program.

Unlike lease agreements, timeshare arrangements do not involve a transfer of control over the premises, equipment, personnel, items, supplies, or services of their owner. Instead, similar to a license, timeshare arrangements confer a "privilege to use" during a specific period of time.[5] For example, under such an arrangement, "a hospital or local physician practice may ask a specialist from a neighboring community to provide services in space owned by the hospital or practice on a limited or as-needed basis."[6]

This new exception requires the timeshare arrangement to meet the following nine criteria:

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 physician and a hospital or physician organization of which the physician is not an owner, employee, or contractor.

3. The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used (i) predominantly for the provision of evaluation and management (E&M) to patients; and (ii) on the same schedule.

4. The equipment covered by the arrangement is (i) located in building where the E&M services are furnished; (ii) not used to furnish designated health services other than those incidental to the E&M services furnished at the time of the patient's E&M visit; and (iii) 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 referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.

6. The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined (i) in a manner that takes into account (directly or indirectly) the volume or value of referrals or

other business generated between the parties; or (ii) using a formula based on (A) percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or (B) per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

7. The arrangement would be commercially reasonable, even if no referrals were made between the parties.

8. The arrangement does not violate the Anti-Kickback Statute or any federal or state law or regulation governing billing or claims submission

9. The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

Additionally, the final rule contains an update related to physician-owned hospitals and a number of clarifications regarding existing Stark exceptions and definitions, including a clarification that expired leases and personal services arrangements may continue indefinitely on the same terms if they are otherwise Stark-compliant, including complying with Stark's fair market value requirement.[7] Taken together, these updates, clarifications, and new exceptions serve to alleviate some of the confusion regarding certain Stark provisions, as well as bring the Stark regulations "up to speed" with the current healthcare environment.

Updates to incident-to billing requirements

The final rule also revises CMS's incident-to billing regulations in two important respects. First, the regulations are amended to provide that, although the physician (or other practitioner) supervising the auxiliary personnel providing the incident-to service need not be the same physician (or other practitioner) who is treating the patient more broadly, "only the supervising physician (or other practitioner) may bill Medicare for incident to services."[8] In other words, the physician (or other practitioner) billing for incident-to services must be the same physician (or other practitioner) who provided the requisite level of supervision for the services billed.

Second, the final rule amends the incident-to regulations to explicitly prohibit auxiliary personnel from providing incident-to services if they have been excluded from Medicare, Medicaid, or any other federally funded healthcare program by the Office of Inspector General (OIG), or if they have had their enrollment revoked for any reason.[9] This amendment was presented more as a clarification—rather than a change—to existing incident-to requirements.

Conclusion

CMS's November 16, 2015, final rule contains a number of very important revisions to Medicare payment policies for services provided starting January 1, 2016, including changes to Stark and incident-to regulations. These changes can become traps for the unwary provider and, therefore, all providers should carefully review the changes to ensure that they remain in compliance with these often complicated and confusing regulations.

1. 80 Fed. Reg. 70886 (Nov. 16, 2015).
2. *Id.* at 71301.
3. *Id.* at 71376-77 (to be codified at 42 C.F.R. § 411.357(x)).
4. *Id.* at 71326 (to be codified at 42 C.F.R. § 411.357(y)).
5. *Id.*
6. *Id.* at 71325.
7. *Id.* at 71318-19.
8. *Id.* at 71066-67 (to be codified at 42 C.F.R. § 410.26(b)(5)).
9. *Id.* at 71066 (to be codified at 42 C.F.R. § 410.26(b)(5)).