NEWS *in brief*

Exceptions and clarifications

Finally, CMS resolves stark inconsistencies in Stark Law.

By Dustyn Jones

JONES

On November 16, 2015, the Centers for Medicare and Medicaid Services (CMS) published final rules that add two new exceptions to the Stark Law and clarify several existing definitions and standards. With the new rules, CMS hopes to "accommodate delivery and payment system reform, to reduce burden, and to facilitate compliance," and to "expand access to needed healthcare services."

Stark Law

Stark law, actually three separate provisions, governs physician self-referral for Medicare and Medicaid patients. The law is named for United States Congressman Pete Stark, who sponsored the initial bill.

New Exceptions

The new rule added two new exceptions to the Stark Law: (1) Assistance to Compensate a Nonphysician Practitioner; and (2) Timeshare Arrangements.

Assistance to Compensate Nonphysician Practitioners: The new Assistance to Compensate Nonphysician Practitioners exception (the NPP Exception) permits payments from hospitals, federally qualified health centers (FQHCs), and rural health clinics (RHCs) to physicians and group practices to assist with "employing a nonphysician practitioner in the geographic area" served by the healthcare facility. The healthcare facility can pay the physician or group practice up to fifty percent of the actual aggregate compensation, signing bonus, and benefits paid to the NPP. The regulation sets several detailed limits on the use of the exception, but the highlights are as follow:

- The arrangement is set out in writing and signed by the hospital, the physician, and the NPP.
- Substantially all the services provided by the NPP must be primary care services or mental healthcare services.
- For purposes of the exception, a NPP is a physician assistant, nurse practitioner, clinical nurse specialist, certified nurse-midwife, clinical social worker, or a clinical psychologist, as these NPPs typically provide the required services.
- The exception is not available unless the NPP, within one year of being compensated by the physician: (1) has not practiced in the geographic area served by the health care facility providing the assistance; and (2) has not been employed or otherwise engaged to provide patient care services by a physician that has a medical practice in the geographic area served by the healthcare facility providing assistance.
- The regulations set out a specific definition of "referral" for the purposes of the exception: "A request by a nonphysician practitioner that includes the provision of any [designated health services (DHS)] for which payment may be made under Medicare, the establishment of any plan of care by a NPP that includes the provision of such DHS, or the certifying or recertifying of the need for such DHS, but not including any DHS personally performed or provided by the NPP."

Timeshare Arrangements: The new Timeshare Arrangements Exception protects license-type arrangements, which often cannot meet the "exclusive use" or "one-year" term requirements of the "rental of office space" or "rental of equipment" exceptions. CMS intended the exception to allow healthcare facilities to arrange to use certain space and equipment on a part-time or "as needed" basis for periods less than one year. "The exception protects only those arrangements that grant a right or permission to use the premises, equipment, personnel, items, supplies, or services of another person or entity without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises. The regulation sets several detailed limits on the use of the exception, but the highlights are as follow:

- The arrangement must be set out in writing, signed by the parties, and specify the premises, equipment, personnel, items, supplies, and services covered by the arrangement.
- The agreement must be between a physician, and either a hospital or a physician organization of which the physician is not an owner, employee, or contractor.
- The premises, equipment, personnel, items, supplies, and services covered by the arrangement must be used predominantly for provision of evaluation and management ("E/M") services and on the same schedule.
- The equipment must be located in the same building where the E/M services are furnished.

Practitioners should also be aware that CMS warns against potentially abusive arrangements that may be fraudulently structured to fit within the four corners of the exception, including "arrangements that essentially function as full-time leases for medical practice sites; arrangements in which physicians are selected or given preferred time slots based on their referrals to the party granting permission to use the premises, equipment, personnel, items, supplies, or services; or consecutive short-term arrangements that are modified frequently in ways that take into account a physician's referrals."

With the new rules, CMS hopes to "accommodate delivery and payment system reform, to reduce burden, and to facilitate compliance," and to "expand access to needed healthcare services."

Clarifications Made

CMS clarifies and revises the "in writing" requirements: Many Stark exceptions require that an arrangement be set out in writing and signed by the parties. The medical community was confused, however, regarding whether

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the arrangement must be set out in a single, formal contract. CMS clarified that although the arrangement must be memorialized in writing, "a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing exception." Further, "[to] determine compliance with the writing requirement, the relevant inquiry is whether the available contemporaneous documents (that is, documents that are contemporaneous with the arrangement) would permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made." CMS went even further to state that the "multiple writing" standard was CMS' existing policy, and that "[p]arties considering submitting self-disclosures to the SRDP for conduct that predates the proposed rule may rely on guidance provided in the proposed rule" on the writing issue.

CMS clarifies the "one-year term" requirement: CMS clarified that exceptions requiring a one-year contract term can be satisfied "as long as the arrangement clearly establishes a business relationship that will last for at least one year." Thus, CMS revised the text of several exceptions to replace the word "term" with "duration." CMS also stated that this clarification memorialized CMS' existing policy and can be relied upon for arrangements predating the effective date of the proposed changes.

CMS revises the holdover limitations in several exceptions: Previously, the Stark Law permitted holdover arrangements for only six months. CMS will now permit holdover arrangements indefinitely (or for another definite period of time outlined in a contract) if the following three safeguards are satisfied: (1) the arrangement complies with an applicable exception when it expires; (2) the holdover continues on the same terms and conditions; and (3) the relationship continues to meet all of the applicable Stark exception requirements. However, CMS emphasizes the importance of contemporaneous documents that prove compliance with the holdover safeguards.

CMS also indicates that the new holdover provisions can be relied on retroactively, so long as: (1) as of January 1, 2016, the holdover was in compliance with the current holdover regulations

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Clarifications

- CMS clarifies and revises the "in writing" requirements.
- CMS clarifies the "one-year term" requirement.
- CMS revises the holdover limitations in several exceptions.
- CMS revises the temporary noncompliance with signature requirements.
- CMS clarifies the definition of "geographic service area" served by FQHCs and RHCs.
- CMS clarifies the use of "takes into account" terminology to describe the "volume or value of referrals" standard.
- CMS clarifies the policy regarding retention payments in underserved areas.

COMMENTARY

A long road ahead

The Institute of Medicine Future of Nursing recommends 80 percent BSN workforce by 2020, Ky. at 33 percent.

By Marcia Hern

Nursing will long remain a high demand career choice. Not only does being a nurse provide an opportunity to make a significant impact on human lives, but it provides job security for those entering the profession. The Bureau of Labor Statistics continues to rank nursing as one of the top two job growth areas. The registered nurse workforce is expected to grow from 2.71 million in 2012 to 3.24 million in 2022, cited by the American Association of Colleges of Nursing. The public seems well versed in this high demand workforce need as evidenced by our large pool of undergraduate nursing students.

> In the state of Kentucky, our numbers of registered nurses sound sufficient with 65,856 RNs, yet only 33 percent (22,006) hold a bachelor of science in nursing.

But numbers and/or quantity alone are not the sole variable driving this workforce demand. More importantly, it is the quality of registered nurses that help make some of the most strident contributions. One cannot dismiss the seminal research conducted by Dr. Linda Aiken from University of Pennsylvania about the improved patient outcomes with less mortalities and complications under the care of a baccalaureate nursing workforce. Nor can we dismiss the accolades from our physician colleagues who know working at a hospital with nursing magnet designation and a large BSN workforce ensures the highest level of nursing care with significant patient satisfaction.

Our current and future nursing workforce must be highly educated with the majority of nurses having a minimum of a bachelor's degree.

> Our nursing workforce landscape looks bumpy, but as educators and hospital administrators we must expect every person who wants to be a nurse to earn the BSN.

They can think critically, analyze a vast amount of patient data, manage very complex acute and chronic health conditions and leave the patient feeling satisfied through safe, high quality compassionate care.

Kentucky Lagging

In the state of Kentucky, our number of registered nurses sound sufficient with 65,856 RNs, yet only 33 percent (22,006) hold a bachelor of science in nursing. That puts Kentucky near the bottom of the 50 states, with a ranking of 46th. Further, this number lags far behind the Institute of Medicine Future of Nursing recommendation to have an 80 percent BSN workforce by 2020. For schools and colleges of nursing, and for hospitals that continue to be the largest employer of nurses that means we have only four years to jump another 47 percent to help reach the 80 percent national goal!

Our nursing workforce landscape looks bumpy, but as educators and hospital administrators we must expect every person who wants to be a nurse to earn the BSN. This degree will then afford a nurse an even stronger career outlook to further his or her professional journey to earn a master's degree as an advanced practice nurse practitioner, nurse midwife, nurse anesthetist or clinical nurse specialist, and eventually earn the clinical Doctor of Nursing Practice or research PhD.

— Marcia Hern is dean and professor at the University of Louisville School of Nursing.

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prior to the Final Rule's changes; and (2) the safeguard requirements of the indefinite holdover provisions of the final rule are met.

CMS revises the temporary noncompliance with signature requirements: Currently, if parties to an arrangement otherwise meet all requirements of an applicable exception, but fail to obtain a signature, then there is a grace period only for the purpose of obtaining the signature – within 90 days if the missing signature is inadvertent, and within 30 days if it is not inadvertent. CMS changed this rule to allow 90 days to comply with the signature requirement "regardless of whether or not the failure to obtain the signature(s) was inadvertent."

CMS clarifies the definition of "geographic service area" served by FQHCs and RHCs: The Stark Law permits FQHCs and RHCs to provide financial assistance to physicians and group practices to induce new providers to relocate to the healthcare facility's geographic service area. The definition of "geographic service area," however, was unclear. The new rule defines the geographic area served by the healthcare facility as the area composed of the "lowest number of contiguous or noncontiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients as determined on an encounter basis."

> The Stark Law permits FQHCs and RHCs to provide financial assistance to physicians and group practices to induce new providers to relocate to the healthcare facility's geographic service area.

CMS clarifies the use of "takes into account" terminology to describe the "volume or value of referrals" standard: Several Stark Law exceptions contain different language when describing the same "volume or value" standard of physicians' referrals. For example, the physician recruitment exception and the obstetrical malpractice insurance subsidies exception indicate that remuneration cannot be "based on" the volume or value of referrals. The medical staff incidental benefits exception and the professional courtesy exception indicate that remuneration must be "without regard to" the volume or value of referrals. The rental of office space and rental of equipment exceptions indicate that rental charges cannot be determined in a manner that "takes into account" the volume or value of referrals. CMS sought to standardize this language. Thus, now, all exceptions indicate that entities may not "take into account" the volume or value of referrals.

CMS clarifies the policy regarding retention payments in underserved areas: MS noted that there was inadvertent confusion regarding the physician retention payment exception. In the Phase III Stark Regulations, CMS amended the exception to permit hospitals, RHCs and FQHCs to pay a retention payment to a physician if the physician provided written certification that he/she had a bona fide opportunity for future employment. The retention payment, however, may not exceed the lower of: (1) an amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months); or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area. The text of the regulation, however, allowed that the income be "measured over no more than a 24-month period," which could allow manipulation of the intended calculation. CMS amended the regulatory text to reflect that the entire previous 24 months must be included in the calculation.

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