

CMS proposes new Stark Law exceptions

On July 15, 2015, Centers for Medicaid and Medicare Services (CMS) proposed updates for the Stark Law regulations. The proposals included two absolutely new exceptions (recruitment assistance for non-physician practitioners and time share office sharing arrangements), a very practical clarification of the “written agreement” requirements for a number of the exceptions, and a solicitation for comments on guidance necessary to advance alternative payment models and value-based purchasing. This article will address only what I consider to be the most significant developments with respect to physician private practices.

New recruitment of non-physician practitioners exception

CMS has proposed to establish a new exception as 42 C.F.R. § 411.357(x) to permit remuneration from a hospital, a federally qualified health center (FQHC), or a rural health center (RHC) to a physician to assist the physician in employing a non-physician practitioner in the geographic area served by the hospital, FQHC, or RHC providing the remuneration.

1. The proposed exception would apply only where the non-physician practitioner is a *bona fide* employee of the physician receiving the remuneration from the hospital (or of the physician’s practice), and the purpose of the employment is primarily to provide primary care services to patients of the physician practice. CMS believes employment is greater proof of a sincere commitment than just an independent contractor relationship.

2. Primary care services include



general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology patient care services.

3. “Non-physician practitioner” is defined for purposes of this exception, to include only physician assistants, nurse practitioners, clinical nurse specialists and certified nurse midwives.

4. There is a two-year limit on the assistance which is intended to prevent ongoing payment to the physician that could serve as a reward for past referrals or an inducement to continue making referrals to the hospital, FQHC, or RHC, and the amount is proposed to not exceed 50 percent of actual salary, signing bonus and benefits or the amount equal to the excess of these costs over actual NPP receipts.

New timeshare exception

CMS acknowledges that arrangements for the use of another provider’s premises, equipment, personnel, items, supplies or services by physicians who, for various legitimate reasons, do not require or are not interested in a traditional office space lease arrangement could be appropriate. Under timeshare arrangements, a hospital or local physician practice may ask a specialist from a neighboring community to provide the services in space owned by the hospital or practice on a limited or as-needed basis. CMS

believes timeshare arrangements that include the use of office space can be structured in a way that do not pose a risk of program or patient abuse.

Therefore, CMS has proposed a new exception at 42 C.F.R. § 411.357(y) that would protect timeshare arrangements that meet certain criteria, including:

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, is:

i. located in the office suite where the physician performs evaluation and management services,

ii. used only to furnish DHS that is incidental to the physician’s evaluation and management services and furnished at the time of such evaluation and management services, 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 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 (section 1128B(b) of the Act) or any federal or state law or regulation governing billing or claims submission.

The proposed exception would apply only to timeshare arrangements where the licensor is a hospital or physician organization; it would not protect arrangements where the licensor is another type of DHS entity.

Clarification of written agreements

CMS has acknowledged that arrangements among providers to satisfy the Stark exceptions need not be cre-

ated in a single document. Although a single written document memorializing the key facts of an arrangement could provide the surest and most straightforward means of establishing compliance with the applicable exception, there is no requirement under the physician self-referral law that an arrangement be documented in a single formal contract. Depending on the facts and circumstances of the arrangement and the available documentation, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing in any or all of the following exceptions:

- Office and equipment leases
- Bona fide employment agreements
- Personal service agreements
- Electronic health records

Miscellaneous

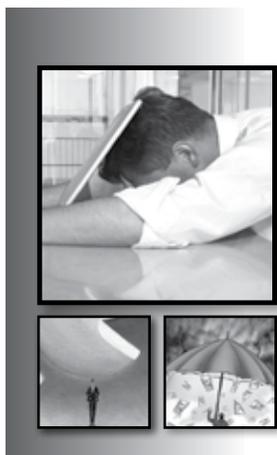
Perhaps the most noteworthy of the lesser proposals were clarifications that “hold over arrangements” are permitted to satisfy the appropriate exception

indefinitely as long as the agreement was in place for the term of at least a year and otherwise complied with the exception requirements and a proposal to modify the current regulations to allow parties 90 days to obtain required signatures, regardless of whether the failure to obtain the signature in the first place was inadvertent.

Conclusion

While nobody has described CMS lately as a kinder, gentler version, these proposals at least make it appear that CMS is attempting to be reasonable with respect to certain compliance items, such as the holdover amendment and the “collective written agreement” clarification. The new proposed timeshare exception and the exception for the recruitment of non-physician practitioners also could be a significant benefit in appropriate circumstances.

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