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Baker Donelson Comments on CMS's Proposed Changes to the Stark Regulations

By Alan Rumph, Danielle Trostorff, Jennifer Summa and Hannah Metzger

The law firm of Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C., sincerely appreciates the opportunity to comment upon the proposed clarifications and changes to the Stark regulations issued by the Centers and Medicare and Medicaid Services (CMS) at 80 Fed. Reg. 41686, 41909 (July 15, 2015). The numbering of the sections and subsections below corresponds to those in the proposed rulemaking and the Federal Register pages on which each item begins are indicated.

III.N.2. Recruitment and Retention

a. Assistance to Employ a Nonphysician Practitioner [80 FR 41910]

We applaud CMS for recognizing the need for more physician extenders and to incentivize practitioners to use these individuals in their practices in the interest of quality care, increasing access to care and cost containment.

The current recruitment exception does not permit a hospital to subsidize a physician practice's costs of recruiting and employing nonphysician practitioners. This new exception would permit hospitals, FQHCs, and RHCs to provide remuneration to a physician to assist with the employment of a nonphysician practitioner in the geographic area served by the hospital, FQHC or RHC. We think that the categories of providers eligible for the exception should not be further limited, based upon rural location or other factors.

We urge CMS to expand the recruitment exception to define "providing primary care services" to include any specialist who, by the ACO definition as set forth in 42 CFR 425.20 and 425.404 (or similar attestation for parties at commencement of Recruitment Agreement), would qualify as a primary care provider. We also request that CMS make eligible for the exception recruitment of nonphysician practitioners who perform exclusively primary care services for specialist physicians and to include independent contractor as well as employee nonphysician practitioners.

We also ask CMS to include registered nurse anesthetists as nonphysician practitioners providing "primary care services" since this group of nonphysician practitioners routinely fulfill certain primary care needs of patients and enable physicians as well as hospitals, FQHCs and RHCs to better meet the needs of patients.

We urge the overhead cap to be increased to 60%, as that percentage is more closely aligned with added overhead associated with adding a nonphysician practitioner. We believe that no additional safeguards are needed to protect patients and the Medicare program.

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b. Geographic Area Served by Federally Qualified Health Centers and Rural Health Clinics [80 FR 41914]

We recognize the need for clarification of the definition of "geographic area served" and urge CMS to adopt the alternative that permits the broadest definition of "geographic area served," in the interest of expanding needed services by increasing the availability of nonphysician practitioners.

c. Conforming Terminology: "Takes into Account" [80 FR 41914]

We also commend CMS's proposal to define the "volume or value" standard consistently throughout the compensation exceptions to prohibit referring physician compensation that "takes into account" referrals. We also believe, however, that CMS should distinguish between compensation that "takes into account" referrals and compensation that "varies with" referrals.

The distinction between "takes into account" and "varies with" has generated much confusion among stakeholders and their counsel – and now in the courts. Many apparently believe that "varies with," which appears only in the definition of "indirect compensation arrangement" (ICA), and "takes into account," which appears both in the ICA definition and in the ICA exception (and many other exceptions), mean essentially the same thing. The plain language of the terms, however, suggests otherwise. Compensation that "varies with" referrals would appear to be present where there is merely a close correlation between referrals and compensation. On the other hand, compensation that "takes into account" referrals suggests that there must be some causative effect of referrals upon compensation.

The rulemaking history also supports the above distinction. As CMS noted in the instant proposed 2016 changes to the Stark regulations, Phase I defined an ICA to include physician compensation that "varies with or otherwise reflects" referrals. In the Phase III rulemaking, CMS replaced "otherwise reflects" with "takes into account." The fact that the Agency did not simply delete "otherwise reflects," but also added "takes into account," strongly suggests that "varies with" and "takes into account" have different meanings. Moreover, in the present proposal, CMS proposed replacing "based on" and "without regard to" with "takes into account" in each instance where the two former phrases appear in the compensation exceptions. It stated that there is no substantive difference between the three phrases and that they have previously been used interchangeably in the compensation exceptions. Like "takes into account" (and unlike "varies with"), "based on" and "without regard to" suggest a causal connection between referrals and compensation. Indeed, CMS has never proposed a change to "varies with" in the ICA definition or indicated that it has the same meaning as "takes into account."

We do not believe that whether a causal relationship between referrals and compensation exists must be determined solely by the terms of the compensation agreement. Instead, all facts, including those both within and outside the compensation agreement, should be evaluated to determine whether referrals have a causative effect upon compensation.

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The *Tuomey* case illustrates the practical implications of our proposal, particularly if one compares the District Court's and Fourth Circuit's opinions after the second trial. The District Court effectively applied the familiar two-part Stark analysis of first determining whether financial relationships existed between the hospital and the referring physicians and then determining whether an exception applied to the relationships. As to the first issue, the court implicitly concluded that an ICA existed because the physicians' compensation "varied with" referrals: Each time a physician performed a procedure at the hospital, the physician's compensation increased. The court then implicitly determined, based upon witness testimony, that the hospital "took into account" the physicians' anticipated referrals in establishing the compensation. The effect of this conclusion was that the ICA exception was not available.

The Fourth Circuit, by contrast, only analyzed whether the physicians' compensation "varied with" their referrals. Like the District Court, the Fourth Circuit correctly concluded that the close correlation between referrals and compensation resulted in the compensation "varying with" referrals. The Fourth Circuit, however, did not separately analyze whether the compensation "took into account" referrals. It thus effectively ignored the ICA exception, perhaps because it assumed that "varies with" and "takes into account" have identical meanings.

We do not assert that the ultimate result in *Tuomey* was contrary to the law or regulations. We simply believe that the reasoning of the Fourth Circuit will lead to disastrous results for legal and appropriate hospital-physician compensation arrangements. For example, it is very common for hospitals to compensate physicians based upon their personal productivity, e.g., w/RVUs or collections from personally performed services. Compensation under such methodologies may "vary with" referrals and therefore constitute ICAs. Yet if referrals do not have any causative effect whatsoever upon the compensation (whether under or outside the terms of the compensation agreement), the compensation should not be deemed to "take into account" referrals and the ICA exception (or another compensation exception) should potentially be available.

In conclusion, we believe that our proposed distinction between "varies with" referrals and "takes into account" referrals will prohibit egregious arrangements in which referrals have a causative effect upon compensation (such as the arrangement in *Tuomey*), but will not punish hospitals that do not take referrals into account when establishing or implementing compensation arrangements. We respectfully request that CMS expressly recognize this distinction in the final 2016 rulemaking.

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N.3. Reducing Burden and Improving Clarity Regarding the Writing, Term, and Holdover Provisions in Certain Exceptions and Other Regulations

We believe that all proposals in this section reflect a carefully considered and appropriate balance among statutory fidelity, practicality, and protection against abuse. Our specific comments on the individual subsections are as follows:

a. Writing Requirements in Certain Compensation Exceptions and Other Regulatory Provisions [80 FR 41915]
We strongly agree with and appreciate CMS's clarification that the "writing" requirements in the various exceptions do not mandate that the writing be reflected in a single, formal agreement. Instead, as CMS states, the writing requirement can be satisfied through multiple, contemporaneous documents that collectively establish compliance with the applicable exception. As the Agency noted, before this clarification many stakeholders were confused about this issue. Virtually the only judicial authorities on the issue are *Bradford* and *Kosenske*, both of which ruled adversely.

We only request that CMS explicitly confirm the above clarification is a statement of the existing law and regulations. Thus, the effectiveness of the clarification does not require the finalization of a rulemaking, but can be relied upon at any time prior to the effective date of a final rule.

b. Term Requirements in Certain Compensation Arrangements Exceptions [80 FR 41916]
We similarly agree with CMS's clarification that the one-year term requirement in certain of the exceptions need not be explicitly stated in the compensation agreement. In the Agency's words, "An arrangement that lasts as a matter of fact for at least 1 year satisfies this requirement," if the parties have contemporaneous documentation that establishes this fact. Again, we request that CMS confirm that this clarification represents a statement of the existing law and regulations.

c. Holdover Arrangements [80 FR 41917]
At the risk of sounding like a broken record, we also agree with and much appreciate CMS's proposal to extend indefinitely the permitted "holdover" period following expiration of the explicit term in an agreement. Although we think that the proposed amendments to the regulations may not technically be effective until they are finalized, we believe that the above clarifications of the writing and term requirements make this essentially a moot issue.

4. Definitions

a. Remuneration (§411.351) [80 FR 41918]
CMS's clarification that no remuneration passes between a hospital and a physician where the physician provides services in the hospital and each party bills for the items and services it provides is a welcome development, given the contrary (and, in our view, erroneous) conclusion in *Kosenske*. Again, we would appreciate CMS expressly confirming that this clarification represents its statement of existing law.

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6. New Exception for Timeshare Arrangements [80 FR 41920]

We much appreciate CMS proposing a new exception for time-sharing arrangements and believe the proposal reflects an appropriate balance between facilitating the provision of medically necessary services and providing safeguards against abuse. We ask CMS not to limit this exception to rural or underserved areas, as there are needs for such innovative, flexible arrangements in urban areas as well.

We have heard that certain CMS officials have informally stated that hospitals should not lease space within the hospital building to physicians and other providers. We believe that neither leases nor timeshare arrangements that comply with the Stark exceptions should be prohibited, provided that each hospital, physician, or other provider satisfies all applicable conditions of participation, including clearly indicating to patients and the public the identity of the other provider and the specific space and times utilized, as well as the space being used exclusively by the lessee or licensee during such times.

7. Temporary Noncompliance With Signature Requirements (§411.353(g)) [80 FR 41922]

We strongly support the proposal to allow 90 days to sign an agreement, regardless of whether the absence of the signature was inadvertent or not inadvertent. We have seen situations in which it is very difficult to determine whether a failure was inadvertent and do not believe that 90 days is excessive, if all other requirements of the applicable exception are satisfied.

Also, sometimes services and other items provided under an exception must commence immediately, before a written agreement can be drafted (or other writings obtained). We therefore request that CMS also allow up to 30 days after commencement of services or other items for preparation of the agreement.

9. Solicitation of Comments: Perceived Need for Regulatory Revisions or Policy Clarification Regarding Permissible Physician Compensation [80 FR 41926]

As to the "deeming rules," under which certain compensation formulas are deemed not to take into account referrals or other business generated, we appreciate CMS confirming that these rules are only "safe harbors." Nevertheless, some stakeholders have expressed confusion over the discussion of the deeming rules in Phase III regarding percentage compensation methodologies. We would therefore appreciate CMS confirming that the deeming rules may apply to percentage-based compensation, as long as it does not relate to leases and all other requirements of the deeming rules are satisfied.

We also reiterate our request in Item 2 above that CMS distinguish between "varies with" and "takes into account."

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Conclusion

Again, we sincerely appreciate the opportunity to submit these comments and believe that CMS has already done a masterful job in making Stark more intelligible and facilitating provider compliance, without increasing the potential for abuse. Please do not hesitate to contact one of us listed below, if you have any questions or would like to discuss our comments further.

Alan Rumph
Baker Donelson
arumph@bakerdonelson.com
404.443.6757

Danielle Trostorff
Baker Donelson
dtrostorff@bakerdonelson.com
504.566.5224

Jennifer Summa
Baker Donelson
jsumma@bakerdonelson.com
202.508.3408

Hannah Metzger
Baker Donelson
hmetzger@bakerdonelson.com
615.726.5680