Significant Proposed Changes to Stark Rules Announced

By W. Bradley Tully & David P. Henninger

On July 7, 2015, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule, which would make a number of significant changes to and provide important clarifications of the Stark Law’s regulations (the Proposed Rule). The Stark Law prohibits physician referrals of certain designated health services for Medicare patients to entities with which the physician has a financial relationship unless an exception under the law applies to that relationship.

The Proposed Rule loosens some of CMS’ previous strict interpretations of the requirements under the Stark law’s exceptions, and was prompted at least in part by the agency’s review of the numerous disclosures of Stark law violations it has received in recent years under the Physician Self-Referral Disclosure Protocol (SRDP). The Proposal Rule would also add new exceptions to the Stark law’s prohibitions.

Among the most significant changes being proposed are: (1) clarification of how the writing and term requirements for certain compensation exceptions can be met; (2) a new exception that would allow hospitals to assist physicians in recruiting nonphysician providers; (3) a limited exception for certain so-called “timeshare” arrangements; (4) the extension of permissible holdover arrangements under the rental of office space, rental of equipment and personal service arrangement exceptions; and (5) clarification of the definition of “remuneration” in response to a recent federal court case.

Other important proposed changes include additional guidance for physician-owned hospitals regarding advertising requirements and determining the baseline bona fide investment level, and changes regarding recruitment and retention of physicians by federally qualified health clinics (FQHCs) and rural health clinics (RHCs).

Finally, CMS is soliciting comments on a number of other issues.

Clarifying the Writing and Term Requirements

Prior to the Proposed Rule, the terminology used in exceptions under the Stark law that require a writing created uncertainty as to whether a single integrated agreement was required to meet the writing requirement. For example, the rental of office space and rental of equipment exceptions required that the underlying agreement be set out in writing, whereas the exception for personal services required that the arrangement be set out in writing. The Proposed Rule would clarify that under these exceptions arrangements with physicians do not need to be documented in a single formal contract, but rather a collection of documents can satisfy the writing requirement. Thus, CMS has clarified that multiple writings, which presumably could include such documents as invoices and cancelled checks, may be aggregated together to demonstrate that an arrangement is in writing for purposes of the relevant exceptions.
CMS is also clarifying that for those Stark law exceptions requiring a term of at least one year, it is not necessary to have a written agreement specifying a term of a year or more. As long as the parties have contemporaneous writings demonstrating that an arrangement in fact lasted for at least a year, the one year term requirement is met.

**New Exception for Recruitment of Nonphysician Providers**

To alleviate the shortage of primary care doctors in many areas, CMS is proposing a new nonphysician provider exception that would permit remuneration from a hospital FQHC or RHC to a physician or medical group to assist in recruiting and employing a nonphysician practitioner in the geographic area served by the hospital, FQHC, or RHC. A “nonphysician” is defined as a physician assistant, nurse practitioner, clinical nurse specialist, or certified midwife who furnishes primary care services to the physician practice’s patients. Recruitment of a nonphysician practitioner, who provides specialty care services, such as cardiology or surgical services, would not be protected by the exception. The exception has a number of limitations, including a ceiling on the amount of remuneration that may be provided. The exception is limited to nonphysician practitioners who become bona fide employees of the physician or group receiving remuneration from the hospital.

**New Exception for Timeshare Arrangements**

Another new exception is being proposed for “timeshare” arrangements, under which a provider is given the use of the space, equipment and staff of another provider on a part-time basis. CMS indicates that the exception is being proposed to ensure adequate access to needed specialty care, especially in rural and underserved areas. The exception would protect timeshare arrangements that, among other requirements: (1) are between a hospital or medical group and a physician; (2) where the space and other items provided are used predominantly to provide patient care services; and (3) where any equipment provided is located in the office where patient care services are provided, is used only to provide designated health services that are incidental to, and provided at the time of, patient care services, and is not advanced imaging, radiation therapy, or laboratory equipment.

Importantly, CMS explicitly excluded from the exception timeshare arrangements offered by diagnostic facilities and laboratories, noting that they pose a high risk because they may serve as a vehicle to lock in physician referrals.

**Extending Holdovers**

The current exceptions for the rental of office space, rental of equipment and personal service arrangements allow “holdover” arrangements after the expiration of the term of the written agreement where the parties continue to perform on the same terms and conditions, but only for up to six months. CMS notes that, in administering the SRDP, a large number of arrangements have been reviewed which failed to meet applicable exceptions under Stark solely because a holdover exceeded the six month cutoff. CMS has now determined that longer holdovers beyond six months do not pose a risk of abuse so long as the underlying arrangements continue on the same terms and conditions as the original, are set out in writing, and can be supported by documentary evidence. CMS is proposing to either eliminate any time limits on holdovers, or to extend permissible holdovers for a longer period, such as 1, 2 or 3 years, and has asked for comments on these alternatives.

CMS is also proposing to amend another exception for fair market value compensation arrangements. That exception currently does not specifically permit holdovers, but does allow for arrangements of less than one year to be renewed on the same terms and compensation any number of times. The proposed change would permit arrangements of any duration to be renewed any number of times, which effectively would permit the unlimited continuance of an arrangement as long as there is no change in the arrangement.

**Clarification of Remuneration for Hospital-Based Physicians**

In a relatively recent case, U.S., ex. rel. Kossenske v. Carlisle HMA, the Third Circuit Court of Appeals held that a hospital-based physician’s use of a hospital’s resources (e.g., examination rooms, nursing personnel, and supplies) when treating hospital patients constituted remuneration from the hospital to the physician, even though the hospital billed and collected from third party payers for the resources and services used by the physician and the physician billed and collected from payers the physician’s professional fees only. Contrary to the court’s holding in Kossenske, CMS took the unusual step of stating for the record that it does not believe that this type of “split billing” arrangement results in remuneration between the parties, and therefore such arrangements do not implicate the Stark law.

However, it remains unclear whether there may be circumstances where a split billing arrangement could result in remuneration where, for example, as was the case in Kossenske, the hospital builds out space at significant expense solely for the use of the contracting physicians.
In such cases the hospital may not recover its expenses through third party billing.

Non-Compliance With Signature Requirements

Current regulations include an exception for temporary non-compliance with the requirement in several compensation exceptions that the arrangement must be signed by the parties. The parties have 90 days to obtain signatures where the non-compliance was inadvertent, and 30 days to obtain signatures where the non-compliance was not inadvertent. The Proposal Rule would allow 90 days to obtain signatures regardless of whether or not the non-compliance was inadvertent.

Additional Guidance for Physician-Owned Hospitals

The Proposed Rule would amend current disclosure requirements for physician-owned hospitals, clarify the definition of “public advertising,” and change existing regulations for determining the baseline bona fide investment level.

Current regulations require physician-owned hospitals to disclose on any public website for the hospital and in any public advertising, that the hospital is owned or invested in by physicians. CMS is proposing to revise those regulations to specify that a “public website for the hospital” does not include certain types of websites that may display limited information about the hospital but are generally unavailable to the public, such as social media websites, electronic patient payment portals, electronic patient care portals, or electronic health information exchanges.

Additionally, the Proposed Rule 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, but does not include communications made for the primary purpose of recruiting hospital staff, public service announcements, and community outreach.

CMS also clarified the types of statements that constitute a sufficient statement of physician ownership. Such advertising may include any language that would put a reasonable person on notice that the hospital may be physician owned. CMS further notes that a hospital’s name alone may be sufficient, such as, for example, “Doctors Hospital at Main Street, USA,” as the name would put a reasonable person on notice that the hospital may be physician-owned.

Recruitment and Retention for FQHCs, RHCs

Current regulations allow FQHCs and RHCs to utilize the physician recruitment exception. Those regulations define the “geographic area served by the hospital”, which is the area into which the recruited physician must relocate, as the area from which a hospital draws inpatients, but do not provide guidance as to the geographic area into which FQHCs and RHCs may recruit a physician. The Proposed Rule seeks to correct this oversight by offering two alternative approaches to determine the geographic area served by a FQHC or RHC, each of which is based not on the level of inpatients but rather on patient encounters in general.

Finally, the Proposed Rule addresses the physician investment level requirement for physician-owned hospitals. Current regulations require that the percentage of total ownership held by physicians cannot exceed in aggregate the percentage as of March 23, 2010. CMS had previously taken the position that ownership interests of non-referring physicians need not be considered in this calculation. In the Proposed Rule CMS is changing this position, and now is requiring that ownership interests of all physicians be included, whether or not they make referrals.

Solicitation of Comments

CMS has solicited comments on a broad range of topics related to the Proposed Rule, which must be submitted by September 8, 2015. Of particular interest to CMS are comments in the following categories: (1) the perceived impact of the physician self-referral law on health care delivery and payment reform, (2) barriers to achieving clinical and financial integration posed by the physician self-referral law generally, and (3) whether stakeholders need additional guidance on the application of CMS regulations regarding physician compensation that is unrelated to participation in alternative payment models. Clearly, CMS is now intending to look closely at whether compliance with the Stark Law could impede desirable health reform and integration efforts.

For additional information, please contact Brad Tully, David Henninger or Charles Oppenheim in Los Angeles at 310.551.8111; Bill Eck in Washington, D.C. at 202.580.7700; or Ben Durie in San Francisco at 415.775.8500.

Hospital Hit With $237 Million Stark Law Judgment

By Charles B. Oppenheim

The U.S. Court of Appeals for the Fourth Circuit affirmed a $237,454,195 judgment against Tuomey Healthcare System (Tuomey), a small, nonprofit hospital held by physicians.
in Sumter, South Carolina, on July 2, 2015. This may be the final chapter in a long-running legal drama that offers a number of important cautionary lessons for hospitals and other healthcare organizations struggling to stay compliant with the complex and evolving standards of the Stark law.

Originally, a jury in federal district court found that Tuomey had violated the Stark law, based on allegations that physicians were paid in excess of fair market value, and in a manner that took their referrals into account. That jury, however, found no False Claims Act (FCA) violations, concluding that Tuomey did not “knowingly” violate the Stark law and hence did not knowingly submit false claims. The district court vacated the jury’s verdict and ordered a new trial after concluding that certain testimony by a Tuomey executive had been erroneously excluded from the first trial. The jury in the second trial found that Tuomey had knowingly violated the Stark law and knowingly submitted false claims, thus leading to a verdict in favor of the government (and the qui tam whistleblower) of $237,454,195, which Tuomey challenged on appeal to the Fourth Circuit, but which the Fourth Circuit has just affirmed.

The heart of the case involves 19 part-time physician employment agreements that Tuomey entered into with surgeons on its medical staff. The impetus for these arrangements apparently arose from a concern that these physicians were increasingly performing outpatient surgeries at their offices or at ambulatory surgery center (ASC) facilities, rather than as outpatient hospital surgeries, and thus Tuomey was losing revenue it would otherwise receive from the facility fees generated by outpatient hospital services. According to the whistleblower and the government, Tuomey entered into these part-time employment agreements in order to stem the loss of this business. The part-time arrangements were unusual in a number of respects, but primarily because, while they were “part-time,” they were not based on working during specific hours of the day or days of the week, but rather were based solely on activity. Specifically, the surgeons were employees of Tuomey only when they performed outpatient surgeries, and at all other times, they remained in independent practice. Also, these part-time employment agreements were for 10-year terms, required that the surgeons perform all of their outpatient surgeries exclusively at Tuomey, and included a two-year period after the agreements expired or terminated, during which the surgeons were prohibited from performing outpatient surgeries anywhere else within 30 miles of the hospital.

The physicians were largely paid based on their productivity, including productivity bonuses, and their compensation typically exceeded the collections generated by their professional services, which the government asserted meant that their compensation exceeded fair market value and, in effect, included a portion of the facility fees collected by Tuomey, which were generated each time they performed their surgeries. The government alleged that the physicians’ compensation consequently took their referrals into account, which is prohibited by the Stark law and its exceptions. (Tuomey attempted to counter this position with the opinion of a valuation consultant it had engaged when entering the compensation arrangements who opined that they were consistent with fair market, value, and by pointing to the employment exception in the Stark law that permits paying physicians a bonus based on their personal productivity.)

The Stark law has an exception for *bona fide* physician employees, who may be paid productivity bonuses, and there is commentary which accompanied the Stark regulations saying that, just because a physician’s productivity may correspond with the physician’s referrals to the hospital, it does “not invalidate” paying the physician for productivity, subject to fair market value. The Fourth Circuit, however, concluded it was reasonable for the district court jury to find that the compensation Tuomey paid these physicians impermissibly took account of their referrals. While not entirely clear, the court seems to suggest, among other things, that these physicians might not have been *bona fide* employees, given the unconventional nature of these relationships.

Accordingly, one of the takeaways of this case is that physician compensation may present risk under the Stark law, even if it arguably is consistent with fair market value in the eyes of an independent valuation consultant, if some or all of the following factors are present: (1) the party paying the physician compensation is motivated by a desire to retain or secure referrals, (2) the terms and conditions contained in the compensation arrangement are highly unusual, (3) the compensation correlates with or is affected by the physician’s referrals, or (4) the compensation paid to the physician exceeds the professional fees generated by the physician.

Another key takeaway concerns the testimony that was erroneously excluded from the first trial (where the jury found no FCA violations) and allowed in the second trial (where the jury did find FCA violations). In fact, the Fourth Circuit seems to think the inclusion of this testimony in the second trial was a key reason the second jury found what the first jury did not – that the FCA was violated. The testimony that came before the second jury showed that after Tuomey’s regular outside counsel approved the ar-
rangements, and in response to a lawyer for one of the physicians questioning their compliance, Tuomey engaged a lawyer with expertise in the Stark law to advise it on the proposed part-time employment arrangements and that lawyer raised significant compliance concerns and said the arrangements would make an “an easy case to prosecute” for the government.” Tuomey disregarded this advice, told this lawyer not to put the advice in writing, and terminated the lawyer’s engagement. Tuomey then hired another lawyer (who was not told about the other lawyer’s opinion) who appears to have advised that the arrangements were permissible.

The Fourth Circuit focused on Tuomey “shopping” for a favorable opinion and seemed to think this was critical to the second jury’s conclusion that Tuomey had engaged in “knowing” FCA violations (“knowingly” violating the FCA means acting with actual knowledge, reckless disregard or deliberate ignorance). The takeaway is that obtaining a second legal opinion or valuation opinion, if you do not like the first one, must be done cautiously (if at all) because it might later be used as evidence of improper intent. For example, if a second expert is hired, at some point in the process it might be prudent to consider sharing the first expert’s opinion with the second expert and asking the second expert to explain the basis for reaching a different conclusion, e.g., changes in facts since the first expert’s review, information overlooked by the first expert, or other reasons why the second opinion should be given more weight (besides that it is the answer the organization hiring the expert was hoping to hear).

One final note of interest comes from the concurring opinion, which acknowledges that the outcome of the case follows from the application of the law to the facts, but laments “the picture this case paints: An impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area.” In making this point about the complexity of this area of law, the concurring opinion cites a book on the Stark law authored by HLB Attorney Charles B. Oppenheim, The Stark Law: Comprehensive Analysis + Practical Guide (AHRA 5th ed. 2014): “[t]he Stark law is infamous among health care lawyers and their clients for being complicated, confusing and counter-intuitive; for producing results that defy common sense, and sometimes elevating form over substance. Ironically, the Stark law was actually intended to simplify life by creating “bright lines” between what would be permitted and what would be disallowed, and create certainty by removing intent from the equation.”

The practical takeaway from the point made in the concurring opinion is the importance of engaging qualified legal counsel when addressing Stark law issues, given both the complexity of this area of law, and the potential magnitude of the problems arising from Stark law violations. This is even more critical when contemplating unusual or innovative arrangements.

For additional information, please contact Charles Oppenheim, Patric Hooper, Brad Tully, or David Henninger in Los Angeles at 310.551.8111; Ben Durie in San Francisco at 415.875.8500; Mark Johnson in San Diego at 619.744.7300; or James Segroves in Washington, D.C. at 202.580.7700.
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