

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

CMS Proposes Dramatic Changes to Stark Rules and Medicare Payment Rules

July 23, 2007

On July 2, 2007, the Centers for Medicare & Medicaid Services (CMS) released the proposed Medicare physician fee schedule for calendar year 2008 (the Proposed PFS). This proposed rule, published in the Federal Register on July 12, 2007,¹ includes several noteworthy revisions to the rules implementing the federal physician self-referral prohibition (the Stark Law), as well as revisions to other payment policies, which could have a significant impact on the healthcare industry. Selected provisions of the Proposed PFS are briefly described below.

Anti-Markup Provision Relating to Purchased Diagnostic Tests

Medicare rules currently prohibit the markup of the *technical* component (TC) of diagnostic tests that are performed by outside suppliers and billed to Medicare by a different individual or entity – i.e., a physician or medical group may not bill Medicare an amount for the technical component of a diagnostic test performed by an outside supplier that is greater than the “net charge” the billing physician or medical group paid to the outside supplier that performed the test (commonly referred to as the “purchased diagnostic test rule”). In the 2008 PFS, CMS proposes to:

- Expand the scope of the anti-markup provision of the purchased diagnostic test rule to also prohibit the markup of the *professional* component (PC) of these diagnostic tests.
- Expand the scope of the anti-markup provision so that it would apply regardless of whether the TC or the PC of the test was purchased by the billing physician or medical group or whether the right to bill for the test or interpretation was reassigned to the billing physician or medical group by the supplier.

¹ See 72 Fed. Reg. 38122 *et seq.* (July 12, 2007).

- Define “outside supplier” as including anyone other than a full-time employee of the physician or medical group. Thus, even with part-time employees or independent contractors who might be considered part of the staff of a physician practice or medical group, the parties must somehow determine a “net charge” for each TC or PC performed by this staff.
- Define “net charge” as exclusive of any amount the supplier pays to the billing physician or medical group for the use of space or equipment. According to CMS, this definition is necessary to prevent “gaming” of the net charge to enable the physician or medical group to bill a higher amount.

CMS is also considering, and soliciting comments on, whether to apply the anti-markup provision to a scenario that the current and proposed rules would not otherwise cover, i.e., the performance of the TC of tests performed by a part-time or leased employee technician of a group practice in a centralized building. In these situations, CMS appears to recognize that the group would not be purchasing the TC from the technician and also recognizes that there may be no separately billable charge that the technician can reassign to the group.

Per-Click Lease Arrangements

The Stark Law regulations currently allow healthcare providers to enter into space and equipment lease arrangements that include per-unit-of-service (or per-click) lease payments, provided the payments are fair market value and do not change during the term of the arrangement in a manner that takes into account the volume or value of any referrals or other business generated between the parties. In an apparent reversal of its former thinking, CMS now states that per-click space and equipment lease arrangements, particularly those arrangements where a physician (or presumably an entity owned in whole or in part by physicians) leases space or equipment to a designated health services (DHS) entity, are “inherently susceptible to abuse.”²

Accordingly, CMS is proposing to prohibit per-click lease payments to a space or equipment *lessor* to the extent that such charges reflect services provided by a lessee to patients who are referred by the lessor. CMS is also soliciting comments on whether the agency should prohibit time-based or per-click payments to an entity-lessor by a physician-lessee, to the extent that such payments reflect services rendered to patients sent to the physician-lessee by the entity-lessor. CMS gives the example of a physician renting an MRI machine from a hospital only when the physician refers a patient for an MRI and then provides the facility portion of the MRI service under arrangements with the hospital.

“Set in Advance” and Percentage-Based Compensation Arrangements

Several of the compensation exceptions under the Stark Law require that the compensation be “set in advance.” Under the current regulations, percentage-based compensation is deemed to be “set in advance” as long as the percentage is determined by a specific formula that is set forth in detail before the furnishing of items or services, and the formula is not modified during the arrangement in any manner that reflects the volume or value of referrals or any other business generated between the parties.

² 72 Fed. Reg. at 38183.

However, CMS has developed a concern that percentage-based compensation is being used in a potentially abusive manner in the context of equipment and office space leases, such as arrangements in which equipment or office space is leased on the basis of a percentage of the revenues generated by the equipment or in the medical office space. According to CMS, the use of percentage-based compensation extends beyond the agency's original intent that such compensation should only be used for compensating physicians for personally performed services. In response, CMS proposes that percentage-based compensation be considered "set in advance" only when used for paying for personally performed physician services and that such compensation must be based on the revenues directly resulting from the physician services. In all other instances, percentage-based compensation would not be deemed to be "set in advance."

Services Furnished "Under Arrangements"

Under the current Stark Law regulations, an "entity" is not deemed to be furnishing DHS unless it is the entity that receives payment from Medicare for the services provided. Therefore, a physician's interest in an entity that does not receive payment from Medicare for DHS is not an "ownership or investment interest" in a DHS entity for purposes of the Stark Law, and such an arrangement does not have to fit within one of the limited exceptions under the law for ownership or investment interests. This result currently applies even if the entity in which the physician has an interest performs DHS "under arrangements" for a hospital (or other DHS entity), since it is the hospital (or other DHS entity) that receives payment from Medicare for those services.

CMS states in the Proposed PFS that a risk of overutilization currently exists for services provided "under arrangements" by physician-owned entities, particularly in the case of hospital outpatient services for which Medicare pays on a per-service basis. Accordingly, CMS proposes to revise the definition of "entity" under the Stark Law regulations so that a DHS entity includes both the person or entity that performs the DHS and the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS. In addition, CMS is seeking comments on whether the agency should implement the recommendation from the Medicare Payment Advisory Commission (MedPAC) March 2005 Report to Congress to expand the definition of physician ownership under the Stark Law to include interests in an entity that derives a substantial proportion of its revenue from a provider of DHS, and, if so, what should constitute "substantial" in those circumstances.

If either the CMS proposal or the MedPAC recommendation is adopted, many hospital-physician "under arrangements" joint ventures will have to be unwound or restructured. Since such arrangements have proliferated in recent years, the potential impact on the industry could be significant.

Ownership or Investment Interest in Retirement Plans

Concerned that some physicians are using retirement plans to purchase DHS entities to which they refer patients, CMS is proposing expressly to limit the retirement plan exception to the Stark Law's definition of "ownership or investment interest" to an interest in a retirement plan offered by an entity to a physician (or immediate family member) as a result of the physician's (or immediate family member's) employment with *that entity*. If the retirement plan purchases an interest in another entity, *e.g.*, DHS entity, the physician (or immediate family member) would be deemed to have an ownership or investment interest in the DHS entity through his or her interest in the retirement plan.

Burden of Proof

CMS is proposing to add a new regulation to codify its current policy that in an appeal of a denial of payment for DHS made on the basis that the service was furnished pursuant to a prohibited referral, the burden is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral.

Other Areas In Which CMS Is Seeking Comment – No Actual Rule Changes Proposed At This Time

In-Office Ancillary Services Exception. The in-office ancillary services exception, which CMS and most healthcare attorneys would characterize as one of the most important exceptions to the physician self-referral prohibition, allows a physician or physician group to provide certain DHS that are ancillary to the physician's or physician group's medical practice, provided certain conditions are satisfied. In the Proposed PFS, CMS expresses concern that some services purportedly furnished under the in-office ancillary services exception are often not as closely connected to the physician practice as originally intended. CMS asserts that many of these arrangements appear to be "nothing more than enterprises established for the self-referral of DHS." Although the Proposed PFS does not include any specific proposals for amending the in-office ancillary services exception, CMS is soliciting comments as to whether changes are necessary and, if so, what changes should be made.

Obstetrical Malpractice Insurance Subsidies. CMS is concerned that the current exception for obstetrical malpractice insurance subsidies is unnecessarily restrictive and is proposing to revise the exception to specifically list the conditions that CMS believes are appropriate to safeguard against program or patient abuse when hospitals provide these subsidies to physicians. The agency is seeking recommendations for how the exception could be changed without creating a risk of program or patient abuse.

Stand in the Shoes. CMS is considering some changes (although it has not formally proposed any rule revisions at this time) that may have the effect of converting certain indirect compensation arrangements into direct compensation arrangements, meaning that the parties could no longer rely on the indirect compensation arrangement exception, but would have to find an exception applicable to direct compensation arrangements in order to shelter their transaction. Specifically, CMS is considering whether to amend the Stark Law regulations to provide that, where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity will be deemed to "stand in the shoes" of the controlled entity for purposes of analyzing compliance with the Stark Law.

CMS believes that it is necessary to "collapse" these types of relationships in order to safeguard against program abuse by parties who endeavor to avoid the application of the Stark Law "by simply inserting an entity or contract into a chain of financial relationships linking a DHS entity and a referring physician."³ CMS has apparently addressed this issue in the eagerly anticipated Stark Phase III rules. CMS reminds those who would comment on the proposed rule that "we finalize [sic] (or may

³ 72 Fed. Reg. at 38184.

already have finalized) a provision that treats physicians as standing on [sic] the shoes of their group practices or other physician practices.”⁴

Period of Disallowance for Noncompliant Financial Relationships. CMS is soliciting comments on how the agency might, to the extent practicable, set forth a period of disallowance (i.e., a period during which a physician could not refer DHS to an entity and an entity could not bill for DHS provided to patients referred by the physician) for arrangements that implicate, but fail to satisfy the requirements of, one or more of the various Stark Law exceptions. As a general rule, CMS believes that the statute contemplates that such a period of disallowance should begin with the date that a financial arrangement failed to comply with the Stark Law and end with the date the arrangement came into compliance or ended. In those instances where it is not clear when a particular financial arrangement ended, CMS is considering whether the period of disallowance should be determined on a case-by-case basis or whether certain types of arrangements should be deemed to continue for a prescribed period of time.

CMS is also soliciting comments as to whether such a period of disallowance should terminate if the parties repay the value of the consideration, where neither party knew or reasonably should have known, that the arrangement did not satisfy the requirements of an exception. In addition to whatever period of disallowance might apply, CMS is also considering whether parties should be prospectively disqualified from relying on an exception for a period of time where a past arrangement has failed to satisfy the requirements of that exception. The commentary does not clearly delineate the intended scope of such a disqualification. For example, it is not clear whether such a disqualification would only apply to the particular arrangement that failed to satisfy the requirements of an exception or to all future arrangements between the parties during the proscribed period.

Alternative Criteria for Satisfying Certain Exceptions. In an effort to provide some relief from the significant consequences that can result from inadvertent minor or technical violations of the Stark Law, CMS is considering whether to provide for an alternative method of satisfying certain Stark Law exceptions. The proposal is intended to address only inadvertent violations in which an agreement fails to satisfy the procedural form requirements of an exception (e.g., agreement is missing a signature) and would be not applicable to arrangements that fail to comply with more substantive requirements (e.g., compensation that is not fair market value, compensation that is related to the volume or value of referrals, or compensation that is not set in advance). If adopted, the alternative method for compliance would provide that, if an arrangement does not meet all of the existing prescribed criteria of an exception, the arrangement nevertheless would be protected under the exception if:

- the facts and circumstances of the arrangement are self-disclosed by the parties to CMS;
- CMS determines that the arrangement satisfies all but the prescribed procedural form requirements of the exception at the time of the referral for DHS at issue and at the time of the claim for such DHS;
- the failure to meet all the prescribed criteria of the exception was inadvertent (i.e., there was an innocent or unintentional mistake);

⁴ Id.

- the referral for DHS and the claim for DHS were not made with knowledge that one or more of the prescribed criteria of the exception were not met (CMS would apply the same knowledge standard as that applicable under the False Claims Act);
- the parties have brought (or will bring as soon as possible) the arrangement into complete compliance with the prescribed criteria of the exception or have terminated (or will terminate as soon as possible) the financial relationship at issue;
- the arrangement did not pose a risk of program or patient abuse;
- no more than a set amount of time had passed since the time of the original noncompliance with prescribed criteria; and
- the arrangement at issue is not the subject of an ongoing federal investigation or other proceeding (including, but not limited to, an enforcement matter).

Under the proposal, CMS would have sole discretion in determining whether an arrangement satisfies the requirements of the alternative method of compliance. Parties would have no right to receive any such CMS determination. In addition, there would be no time period by which CMS would be required to make a determination, and any determination made by CMS would not be subject to administrative or judicial review. The extent to which physicians and DHS entities would self-report under these provisions, if adopted, is uncertain since the waiver of any Stark violation would rest solely with CMS' subjective determination.

Conclusion

At this time, the changes described in this article are only proposed. It is unclear whether any of these proposed changes will become final, and if so, when they might become effective or how they might be implemented. Healthcare providers should consider the potential impact of these proposals on their existing arrangements and evaluate whether those arrangements will need to be restructured. Please contact one of our attorneys in our Healthcare Practice Area listed below if you have any questions or need additional information regarding the Proposed PFS or this Update.

Bass, Berry & Sims Healthcare Attorneys

H. Stanford Adams, Jr.
(615) 742-7775
sadams@bassberry.com

Mary Beth Fortugno
(615) 742-7739
mfortugno@bassberry.com

Pooneh Ghiassi
(615) 742-7782
pghiassi@bassberry.com

Clevonne M. Jacobs
(615) 742-7769
vjacobs@bassberry.com

David King
(615) 742-7890
dking@bassberry.com

T. Scott Noonan, Co-Chair
(615) 742-6273
snoonan@bassberry.com

Cynthia Y. Reisz
(615) 742-6283
creisz@bassberry.com

Danielle M. Sloane
(615) 742-7763
dsloane@bassberry.com

Elizabeth S. Warren
(615) 742-7719
ewarren@bassberry.com

H. Lee Barfield, II
(615) 742-6202
lbarfield@bassberry.com

Renard François
(615) 742-7792
rfrancois@bassberry.com

Anna Grizzle
(615) 742-7732
agrizzle@bassberry.com

J. James Jenkins, Jr.
(615) 742-6236
jjenkins@bassberry.com

Leslie Maclellan
(615) 742-7818
lmaclellan@bassberry.com

Brenda N. Phillips
(615) 742-6237
bnphillips@bassberry.com

Scott B. Shanker
(901) 543-5932
sshanker@bassberry.com

Krista L. Thornton
(615) 742-7734
kthornton@bassberry.com

Philip F. Berg
(615) 742-7908
pberg@bassberry.com

Valere B. Fulwider
(615) 742-7742
vfulwider@bassberry.com

Angela Humphreys
(615) 742-7852
ahumphreys@bassberry.com

Seth A. Killingbeck
(615) 742-7707
skillingbeck@bassberry.com

Claire F. Miley
(615) 742-7847
cmiley@bassberry.com

Shannon Pinkston
(615) 742-7727
spinkston@bassberry.com

Catherine J.B. Sloan
(615) 742-7789
csloan@bassberry.com

Leigh Walton, Chair
(615) 742-6201
lwalton@bassberry.com

The materials contained herein have been abridged from the statutory sources and should not be construed or relied upon for legal advice. Readers are urged to consult legal counsel concerning particular situations and specific legal questions.

To ensure compliance with requirements imposed by the IRS, we inform you that this message is not intended to be used, and cannot be used, by the addressee or any other person for the purpose of avoiding penalties that may be imposed under the Internal Revenue Code.

NASHVILLE Downtown
AmSouth Center
315 Deaderick St. · Ste. 2700
Nashville, TN 37238-3001
(615) 742-6200

KNOXVILLE
1700 Riverview Tower
900 S. Gay St.
Knoxville, TN 37902
(865) 521-6200

MEMPHIS
The Tower at Peabody Place
100 Peabody Place · Ste. 900
Memphis, TN 38103-3672
(901) 543-5900

NASHVILLE Music Row
29 Music Square East
Nashville, TN 37203-4322
(615) 255-6161