
Phase III Stark Rule

On September 5, 2007, the Centers for Medicare and Medicaid Services (“CMS”) published the third phase of its final rule making (the “Phase III Rule”) regarding the federal physician self-referral law (the “Stark Law”), which will become effective on December 4, 2007. The Phase III Rule clarifies, and in some cases substantially revises, various concepts, definitions and exceptions to the Stark Law. The Phase III Rule does not, however, create any new exceptions. This Bulletin highlights some of the more significant changes and clarifications in the Phase III Rule.

Regulatory Framework

The Stark Law prohibits physicians from making referrals for certain “designated health services” (“DHS”) payable by Medicare to an entity with which the physician or a member of the physician’s immediate family has a financial relationship (e.g., an ownership or investment interest or a compensation arrangement), unless an exception applies. The Stark Law also prohibits entities from submitting claims to Medicare for DHS furnished as a result of a prohibited referral. The Stark Law does provide for exceptions, which allow physicians and applicable entities to set up arrangements that do not fall under the Stark Law’s prohibitions. Commonly used exceptions include office space and equipment rentals and the exception for in-office ancillary services.

CMS, on an annual basis, publishes a list of CPT and HCPCS codes that identifies those items and services that are considered DHS, as well as a list of items and services that may qualify for certain exceptions. This list may be found at: http://www.cms.hhs.gov/PhysicianSelfReferral/11listofCodes.asp#TopofPage.

Key Changes

A. Stand in the Shoes

CMS has revised the definition of an “indirect compensation arrangement” in the Phase III Rule. Prior to the enactment of the Phase III Rule, hospitals and other DHS entities could enter into a contractual relationship with a physician practice or a group practice rather than directly with its physicians, and the resulting relationship between the referring physician and the applicable DHS entity was not viewed as a “direct compensation arrangement.” These relationships were instead analyzed as potential “indirect compensation arrangements.” The Phase III Rule now provides that a referring physician has a “direct compensation arrangement” with the DHS entity if the only intervening entity between the physician and the DHS entity is his/her “physician organization.” A “physician organization” is “a physician (including a professional corporation of which the physician is a sole owner), a physician practice or a group practice.” Under the Phase III Rule, the physician will now “stand in the shoes” of the physician organization and the physician is deemed to have the same compensation arrangements (with the same entities providing DHS and on the same terms) as the physician organization does.

This significant revision to the definition of “indirect compensation arrangements” will require hospitals and other DHS entities to review and possibly amend agreements with physician organizations that were previously structured to comply with the indirect compensation exception. Such arrangements must now satisfy one of the Stark exceptions applicable to a “direct compensation arrangement” with a physician (e.g., personal services or fair market value compensation). For purposes of applying the various compensation exceptions, the parties to the arrangement are considered to be the DHS entity and the physician organization, including all members, employees or independent contractor physicians. However, existing arrangements that were structured to satisfy the
requirements of the “indirect compensation arrangement” and were entered into and compliant as of September 5, 2007, need not be amended for the duration of the original term or the current renewal term of the arrangement. Any arrangements involving a physician organization and a DHS entity entered into after September 5, 2007, must be reviewed under the “stand in the shoes” provision and if applicable must satisfy a direct compensation exception by the December 4, 2007 effective date of these regulations. Furthermore, the grandfathering provision will not apply to all arrangements between a physician organization and DHS entity in which the structure did not implicate an “indirect compensation arrangement” (i.e., the arrangement was deemed to be completely outside of the Stark Law). These arrangements must also now qualify for a direct compensation exception.

Please note that the “stand in the shoes” provision applies solely to arrangements between a DHS entity and a physician organization and would not apply to structures involving an intervening entity other than a physician organization. For example, an arrangement with several links not involving a physician organization (e.g., DHS entity–leasing company–physician) should still be analyzed as an “indirect compensation arrangement” subject to the indirect compensation exception.

B. Physician Recruitment

The Stark Law provides for an exception from remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the hospital’s medical staff. The Phase III Rule modifies the physician recruitment exception in a number of ways. The following is a brief overview of some of the more pertinent revisions:

- Most importantly, the Phase III Rule and commentary surrounding the Phase III Rule provide that physicians and physician practices that are parties to a hospital-physician recruitment arrangement may impose restrictions on the recruited physician that would not have a substantial effect on the recruited physician’s ability to remain and practice in the hospital’s geographic services area. Restrictions cited by CMS as not having a substantial effect include reasonable noncompete provisions, restrictions on moonlighting, nonsolicitation provisions (applying to both patients and employees) and requiring the physician to pay reasonable liquidated damages should the physician leave the practice and remain in the community. Restrictions that violate state or local laws such as laws governing noncompetition provisions or agreements would run the risk of being considered unreasonable.

- The Phase III Rule expands the definition of geographic service area served by the hospital. For a hospital that draws fewer than 75% of its inpatients from contiguous zip code zones, the hospital’s geographic service area can be the area represented by all contiguous zip code zones from which the hospital’s inpatients are drawn. This revision is particularly applicable to a hospital with a national reputation, which may draw patients from outside of its geographic service area. This expansion will also allow hospitals to recruit physicians to outlying portions of the hospital’s geographic service area.

- The Phase III Rule permits rural hospitals to determine their geographic services area as the area that encompasses the lowest number of contiguous zip code zones from which the hospital draws at least 90% of its inpatients.

- The Phase III Rule also exempts from the relocation requirement physicians employed on a full-time basis by the federal or state bureau of prisons, the Department of Defense or Veterans Affairs, or facilities of the Indian Health Services for at least two years immediately preceding the recruitment arrangement. To qualify for this exception, the recruited physician could not have maintained a separate private practice while employed by the applicable entity. Residents and fellows in practice for less than a year also continue to qualify for an exception from the practice relocation requirements.

- The Phase III Rule permits a more generous option for allocating costs to a recruited physician joining an existing practice when replacing a physician in a rural area or health professional shortage area who has died, retired or relocated in the past twelve months. A physician practice may, for purposes of an income guarantee, allocate its aggregate overhead and other expenses among physicians, including the
recruited physician on a per capita basis, provided the percentage of costs allocated to the newly recruited physician does not exceed 20% of the practice’s aggregate expenses.

The Phase III Rule permits rural health clinics to utilize the recruitment exception.

C. Shared Space and Equipment

While CMS, in the Phase III Rule, did not make any substantive changes to the regulations governing the in-office ancillary services exception, CMS provided some important clarifications regarding the sharing of such office space or equipment (e.g., sharing a clinical laboratory or imaging center). CMS articulates that a physician sharing a DHS facility in the same building must control the facility and the staffing (for example, the supervision of services) at the time the DHS is furnished to the patient. CMS states that in effect carefully structured block-leasing arrangements may be the only permissible solution in such situations; however, common areas may be shared if the rent is appropriately prorated. As a result, any nonexclusive relationships involving space and equipment in a DHS facility where physicians simultaneously use the facilities and simply share the costs of administration of DHS without separate lease arrangements will need to be restructured. CMS also provided commentary that common per-use fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary service exception and in fact such per-use fee arrangements may violate the Federal Anti-Kickback Statute.

D. Productivity Bonus and Profit Shares Within Group Practices

CMS clarifies in the preamble to the Phase III Rule that productivity bonuses in group practices may be directly related to the volume or value of DHS performed by the physician or to referrals by the physician for services and supplies that are “incident to” the physician’s personally performed services. CMS states that services that have their own separate and independently listed benefit category, except as otherwise expressly permitted by statute, such as “incident to” billing of physical therapy services, cannot be billed as “incident to” services. CMS also clarifies that “incident to” services includes both services and supplies (including drugs). For example, in allocating a productivity bonus a group practice may consider referrals by a physician for outpatient prescription drugs performed “incident to” his/her services. However, a productivity bonus cannot be directly related to any other DHS referrals, such as diagnostic tests. In contrast, the allocation of profits among physicians in a group practice is subject to different rules from those that apply to productivity bonuses. CMS states in the preamble to the Phase III Rule that “profits must be allocated in a manner that does not directly relate to DHS referrals, including any DHS that is billed as an incident to service.”

E. Utilization of Independent Contractors

CMS, in the Phase III Rule, has modified the definition of a “physician in the group practice” to clarify that the actual contract must be with the individual physician and not with another entity such as another physician practice or a staffing company. This modification will impact many group practices that rely on independent contractor physicians for the provision of various ancillary and physician services billed by the groups. These relationships are often structured in such a manner to ensure that the group practice qualifies for both the physician services and in-office ancillary services exceptions; however, both of these exceptions require that the applicable contracted physician qualify as a “physician in the group practice.” Pursuant to this modification, existing contractual arrangements with independent contractor physicians will need to be amended to ensure that each individual contractor signs the existing contractual arrangement. Additionally, CMS states that leased physicians do not qualify as “physicians in the group practice” since there is not a sufficient nexus between the group practice and the individual. Group practices will want to review any contracts they may currently have involving leased employees, given that an applicable Stark exception may no longer apply.

F. DME

CMS clarifies that, when a DME is personally performed by the referring physician, there is no referral of DHS and no exception would be needed. However, CMS, in the applicable preamble discussion to the Phase III Rule, states that it is highly unlikely that a physician could personally furnish and supply DME to a patient. In order to qualify as personally performing the DME, the physician would need to enroll in Medicare as a DME supplier and personally furnish and supply the DME to the patient. CMS does not provide any further clarification on this issue.
perform the multiple and varied duties of a supplier as set forth in the applicable supplier standards.

G. Miscellaneous Changes
The Phase III Rule contains a few additional noteworthy changes that are briefly outlined below.

- Personal services agreements that satisfy the personal service exception are permitted to continue for a holdover period of six months on the same terms and conditions as the original agreement.

- The Phase III Rule clarifies that a charitable donation by a physician may not be offered or solicited in any manner that is tied to or reflects the volume or value of referrals.

- CMS made two changes to the nonmonetary compensation exception. First, CMS allows entities with a formal medical staff to have one medical staff appreciation function for the entire medical staff each year in addition to the dollar limitation of $300 plus CPI per physician. However, any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the limit set by the nonmonetary compensation exception. Second, CMS created a cure mechanism that may be used if an entity inadvertently exceeds the dollar limitation by no more than 50% during a calendar year. The cure may be effected by having the physician repay the excess amount within the earlier of (i) the end of the calendar year in which the excess compensation was received; or (ii) 180 days from the day the excess compensation was received. A DHS entity may use this provision only once every three years for the same physician. Furthermore, the agency advises that once a DHS entity becomes aware that it has inadvertently provided nonmonetary compensation in excess of the limit, the DHS entity should delay billing and claims submission for the physician’s DHS referrals until the physician has refunded the money in compliance with the above payback provision.

- CMS clarified that the professional courtesy exception applies only to hospitals or entities with formal medical staffs. CMS also eliminated the requirement that a provider provide notice to the insurer that the provider is waiving all or part of the coinsurance.

- The fair market value exception was also amended to apply to compensation provided to a physician from a DHS entity and to compensation provided to a DHS entity from a physician. The expansion of the fair market value exception will limit the use of the “payments by a physician” exception. The “payments by a physician” exception may only be used when no other exception applies to the arrangement.

- The fair market value exception may not be applied, however, to leases for office space. Such office space arrangements must be structured to meet the rental of office space exception.

- The compliance training exception now includes programs that offer CME credit, provided the compliance training is the primary purpose of the program.

- The Phase III Rule also substantially reworked the exception permitting retention payments in underserved areas. The Phase III Rule provides that rural health clinics may now make retention payments. The revised exception also permits retention payments in the absence of a written recruitment offer or offer of employment under certain conditions. Additionally, this offer no longer needs to be from a hospital, but it can now be from a hospital, academic medical center, physician organization, rural health clinic or federally qualified health center.

Conclusion
Although there are not many fundamental changes in the Phase III Rule, the changes to the definition of “indirect compensation arrangements” and the requirement of entering into individual contractor arrangements with independent physicians will require entities and physicians who bill Medicare for DHS services to reevaluate and if necessary amend or enter into new contractual relationships. Another potential concern is the impact of CMS commentary regarding the sharing of space or equipment, which may limit the willingness of some practice groups located in the same building to share ancillary facilities.
Some of the Phase III Rule changes are beneficial, such as eliminating the prohibitions of practice restrictions for hospital recruitment and clarifying policies regarding professional courtesy. Other positive changes include additional guidance regarding productivity bonuses and expansion of the retention payment exception. Additionally, in many ways the Phase III Rule’s modifications to the Stark Law are less worrisome than the proposed changes to the Stark Law under the 2008 Medicare Physician Fee Schedule (“MPFS”). These changes are discussed below.

Proposed Revisions to Payment Policies Under the Physician Fee Schedule

On July 2, 2007, CMS announced its proposed MPFS for the calendar year 2008. As expected, the proposed MPFS includes a 9.9% decrease in physician payments; however, this is a wide-ranging proposal that will impact far more than the amounts paid to physicians. If finalized, the proposal would make significant changes to the diagnostic test payment rules, independent diagnostic testing facility standards and the Stark Law. These changes could significantly impact existing or planned physician provider relationships.

In fashioning the Phase III Rule, CMS accepted comments on the proposal through August 31, 2007. It is unclear when CMS will finalize the MPFS; however, the rate portion of the MPFS must be finalized before the end of this year.

A. Anti-Markup Provision

In response to comments that physicians purchasing diagnostic tests may inappropriately realize profits from their own referrals for diagnostic tests to an outside supplier, CMS is proposing significant revisions to the “purchased diagnostic test rule,” also known as the “Anti-Markup Provision,” for both the professional component (“PC”) and the technical component (“TC”) of diagnostic tests performed by “outside suppliers.” CMS defines “outside suppliers” as anyone other than a full-time employee of the physician or medical group billing for diagnostic services. These changes would impact tests that were purchased by the billing entity and tests that were reassigned to the billing entity.

With respect to the PC (e.g., an independent contractor radiologist reassigned the PC fee to the medical group), the billing entity would be prohibited from charging Medicare more than its actual “net charge.” CMS proposes the following criteria for calculating the “net charge.” Under the proposed rule, the amount billed to Medicare must be the least of (i) the physician or other supplier’s “net charge” to the billing entity; (ii) the billing entity’s actual charge; or (iii) the physician fee schedule amount. To prevent “gaming,” CMS defines “net charge” to mean an amount exclusive of any lease of equipment or space to the physician or supplier furnishing the test. For example, if the physician charges the billing entity $60 for the test, the billing entity charges the physician or other supplier performing the test $10 for the lease of the equipment to perform the test, the billing entity’s usual charge for the test is $100 and the physician fee schedule amount is $80, the “net charge” for the test would be $50. The billing entity could charge Medicare only $50 for the test.

Similar provisions would apply to the TC of diagnostic tests. This means that if a technician is not a full-time employee of the billing physician or medical group, then the billing entity will be limited to billing Medicare its actual cost in acquiring the technician’s services. This is true regardless of whether the medical group or a physician supervises the technician.

If the proposed changes to the Anti-Markup Provision are adopted, they may impact the ability of a billing entity (e.g., an IDTF or radiology group) to utilize the services of part-time employees or independent contractors. These revisions would also impact management companies that manage laboratories for physicians who have entered into POD lab arrangements. However, CMS states that the proposed PC revisions to the Anti-Markup Provision will not apply to independent laboratories.

B. IDTF

In the proposed MPFS, CMS has revised several of the previously published independent diagnostic testing facilities (“IDTF”) performance standards and has added several new IDTF performance standards. These standards include prohibitions on the sharing of space, revising the supervision standard, requiring that the IDTF list its Medicare administrative contractor (“MAC”) on any liability insurance policy and changes to the effective date of an IDTF’s enrollment. These changes are discussed below.

CMS is proposing a new performance standard that states that, in order for a fixed IDTF to satisfy the Medicare conditions of participation, the IDTF must certify that it does not share space, equipment or staff with, or sublease
operations to, another individual or organization. CMS clarifies that the prohibition on sharing office space applies to shared waiting rooms and the prohibition on sharing staff applies to supervising physicians. The aim of this proposal is to ensure that an IDTF’s operations are distinct from the operations of other businesses. Currently, CMS is limiting the proposed standard to apply only to fixed-based IDTF locations, but is soliciting comments on whether it should also apply to mobile IDTFs. This proposal would eliminate the ability of an IDTF to enter into a sublease arrangement with a physician practice or other applicable entities such as a hospital.

CMS has narrowed the scope and responsibilities of physicians who provide general supervision of the IDTF. The language requiring the supervising physician to be responsible for the “overall administration and operations of the IDTFs … and assuring compliance with applicable regulations” has been deleted. In addition, CMS proposes to clarify that a supervising physician providing general supervision can oversee a maximum of three sites. This prohibition applies to both fixed and mobile IDTFs. However, CMS stated this limitation is not meant to apply to physicians providing direct or personal supervision services to IDTFs.

An IDTF must now also add its MAC as a certificate holder on its liability insurance policy and notify its MAC of any policy changes or cancellations. Failure to maintain the required insurance results in revocation of billing privileges retroactive to the date of the lapse. One potential problem with this revision will be that insurance companies may no longer be willing to underwrite these policies, since this addition could potentially give the MAC certain rights to payment or indemnification that it would not normally have. This proposal will likely meet with some resistance and be subject to extensive comment from the insurance industry.

CMS has also revised the guidelines for ascertaining an IDTF’s enrollment date in the Medicare program. Currently, Medicare permits IDTFs to bill for services furnished to Medicare beneficiaries up to twenty-seven months prior to the IDTF’s actual enrollment in the Medicare program. CMS is proposing that retroactive billing would now be permitted only from the later to occur of: (i) the filing of the Medicare application (which is subsequently approved); or (ii) the date that the IDTF began rendering services at its location. This proposal would adversely impact IDTFs that apply for Medicare supplier status after a prolonged period of business.

C. Proposed Changes to the Stark Law

In the proposed MPFS, CMS has suggested several changes to the Stark Law. Some of the more significant proposals are discussed below. The proposed changes would close some potential loopholes currently found under the Stark Law and may result in the elimination of certain types of arrangements.

Services Furnished “Under Arrangements.” The most significant change under the proposed MPFS is CMS’s proposal to prohibit certain arrangements where physicians supply items and services to hospitals, skilled nursing facilities (“SNFs”), home health agencies (“HHAs”) and hospices. Citing concerns that referring physicians are improperly profiting as a result of financial relationships with “under arrangement” service providers that do not submit claims, CMS is proposing to expand the definition of what constitutes an “entity” under the Stark Law. Stark currently defines “entity” to include only the entity or person that submits the claim for DHS to Medicare. CMS is now proposing to expand the definition of “entity” to include not only the entity or person that submits the claim to Medicare, but also the entity or person that provides the service and the entity that caused the claim to be presented. This modification would impact many “under arrangements” transactions in which a physician has an ownership interest in the entity furnishing the DHS. Under this proposal, the referring physician would now need to satisfy the ownership/investment exception under the Stark Law, instead of the indirect compensation exception. If this proposal were to be finalized, many currently permissible physician-ownership interests in “under arrangements” providers would be forced to restructure.

In-Office Ancillary Services Exception. CMS is currently reviewing services that it believes were not contemplated as in-office ancillary services when the Stark Law was enacted. As a result, CMS is interested in reining in the “migration of sophisticated and expensive imaging or other equipment to physician offices” when this equipment is not closely related to the physician’s practice. CMS is also concerned with services furnished in a remote “centralized building” or “turnkey arrangements” in which third parties other than the group practice are responsible for much if not all of the patient care. Some of the services that will likely receive close scrutiny by CMS will be certain radiology services, physical therapy services and anatomic pathology
services that are furnished in the “same building” where the physician practice is located or in a separate “centralized building.”

CMS has not issued a specific proposal to revise the in-office ancillary services exception and no revisions were made in the Phase III Rule, but instead CMS is requesting comments in reference to the exception. In particular, CMS is soliciting comments on the following: (i) whether certain services should qualify for the exception; (ii) whether CMS should change the definitions of “same building” and “centralized building”; (iii) whether nonspecialist physicians should be able to refer patients for specialized services involving the use of equipment owned by nonspecialist physicians; and (iv) any other restrictions on ownership or investment in services that would curtail program or patient abuse.

The in-office ancillary service exception is one of the most widely used exceptions under the Stark Law, and any changes to this exception will have a significant and far-reaching impact. However, based on CMS’s solicitation of comments on the topics listed above, it is likely that these changes would be beneficial to radiologists, independent laboratories and physical therapy companies that have lost business to these physician practices. The impacted physician practices would now be required to refer patients to an unrelated source.

Per-Click Lease Payments. It is currently permissible under the Stark Law exceptions for space and equipment leases to provide for payment on a per-use or per-click basis as long as certain other conditions are satisfied. The current provisions permit such arrangements even when a physician makes a referral to a DHS entity that leases space or equipment from the physician for use in furnishing the service.

In light of the potential for overutilization by the lessor physician, CMS is proposing to prohibit per-use or per-click charges for services provided to patients referred by the lessor physician to the lessee. As a result, per-use or per-click charges would be allowed only to the extent that the rental payments not include payments for services furnished to patients referred by the lessor physician to the lessee. For example, the exception would prohibit a cardiologist from leasing an MRI to an IDTF and receiving per-click payments for scans performed on patients referred by the physician. The payment provision of any such leasing arrangement would need to be restructured to that of a fixed-rate rent. Additionally, under the Phase III Rule, this prohibition would extend to relationships between a physician organization and a DMS entity. CMS is also seeking comments as to whether the prohibition should apply when the physician is the lessee (e.g., a physician leases a piece of equipment on a per-click basis from a hospital).

Percentage-based Compensation. CMS has proposed to prohibit most percentage-based compensation structures by changing the definition of what it means for compensation to be “set in advance.” CMS, in particular, wants to prohibit percentage arrangements for equipment and office space. As a result, CMS is proposing that the only percentage compensation arrangements that would meet the “set in advance” requirement would be compensation directly resulting from personally performed physician services and such compensation must be based on revenues generated by the professional services rather than some other factor, such as a percentage of savings by a hospital department. CMS also clarified that a physician may not receive a portion of the TC receipts that result from the physician’s diagnostic testing referrals.

Ownership or Investment in Retirement Plans. The Stark Law currently states than an investment in a retirement plan is not an ownership interest, and as a result, physicians who hold such interests have not been subject to the Stark Law’s prohibition on this basis. The proposed regulation would limit the exclusion to state that an interest in a retirement plan does not constitute ownership under the Stark Law only if the interest in the retirement plan is offered to a physician (or his/her immediate family member) through the physician’s (or family member’s) employment. CMS intends to eliminate arrangements where physicians have created a retirement plan to purchase entities that bill DHS and to which the physician then refers patients for DHS.

D. Miscellaneous Provisions
The MPFS contains many additional provisions. The more significant ones are set out below:

- CMS is proposing to increase the number of imaging services that are subject to a payment cap to the lower of the physician fee schedule amount or the hospital outpatient prospective payment amount.
- CMS is proposing several Medicare Part B reimbursement changes. These changes would include defining “bundled arrangements” and providing the methodology of how drug companies include “bundled drugs” in the calculation of average sales price (“ASP”). The proposal would also require
a drug manufacturer to allocate the total value of all bundled price concessions proportionately to the dollar value of each drug sold under the “bundled arrangements.”

Conclusion

While the changes proposed in the MPFS seem significant, these changes are only proposals and as a result it is not necessary to comply with them now. CMS is currently reviewing the responses it receives pursuant to this proposed MPFS, and as a result the final MPFS may look entirely different. For those physicians or entities whose arrangements may be impacted by the proposed MPFS, it may be best to take a wait-and-see approach before making significant changes to any existing structural arrangements. Additionally, there will be a period between final publication of the MPFS and the effective date of the MPFS. For those structuring new arrangements, it may be prudent to wait until publication of the final MPFS. Alternatively, the arrangements could be drafted to comply with the applicable proposals under the proposed MPFS and then modified if necessary.

We will keep readers advised on important regulatory developments concerning both the Phase III Rule and the final MPFS and will issue an update upon publication of the final MPFS. Should you have any questions regarding this bulletin or other health law issues, please contact Richard H. Sanders, Esq., Health Law Practice Area Leader (312/609-7644), Aileen T. Murphy (312/609-7967) or any other Vedder Price attorney with whom you regularly work.

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