Highlights of Physician Self-Referral Law Reform in the IPPS Proposed Rule

On April 14, 2008, the Centers for Medicare and Medicaid Services ("CMS") put the CY 2009 Inpatient Hospital Prospective Payment System rule (the "IPPS" proposed rule) on display1 at the Federal Register. The IPPS proposed rule will be published in the Federal Register on April 30, 2008, with the comment period closing June 13, 2008.

Included in the IPPS proposed rule are changes to the physician self-referral law and a significant number of requests for public comments by CMS. Many of the proposed changes will have far reaching consequences for physician relationships with hospitals and other providers.2 As such, the industry should take full advantage of the opportunity to provide comments to CMS and engage in what could be a collaborative effort to further clarify the physician self-referral law. To that end, interested parties should be mindful of CMS’s upcoming rulemaking schedule and deadlines. By statute, CMS is required to publish the proposed CY 2009 Medicare Physician Fee Schedule ("PFS") on or before August 1, 2008. CMS has indicated that they are aiming to issue that rulemaking prior to the August 1, 2008 deadline. As we have seen in the past, CMS may utilize the physician fee schedule as a mechanism for finalizing self-referral provisions and/or proposing further changes to the physician self-referral law. Therefore, submitting substantive comments to CMS early in the IPPS proposed rule comment period may afford CMS a greater opportunity to respond in its next round of rulemaking.

Detailed Summary of Key Clarifications and Solicitation of Public Comments

"Stand in the Shoes" Doctrine

In the Final Phase III of the physician self-referral regulation ("Phase III")3, CMS included new "stand in the shoes" provisions that address compensation arrangements in which a group practice is directly linked to the physician in a chain of financial relationships between the referring physician and a designated health services ("DHS") entity. Generally speaking, the "stand in the shoes" provisions collapse the distinction

1 The display copy is available at http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=4&sortOrder=descending&itemID=CMS1209719&intNumPerPage=10.
2 Please note that this Advisory focuses on the proposed changes to the physician self-referral law. It is not an exhaustive summary of the 1200 pages of the IPPS proposed rule. For example, CMS proposes modifications to the EMTALA regulations "on-call" and transfer provisions.
between “physician organizations” and physicians for purposes of determining whether a compensation agreement between a physician and an entity to which the physician refers Medicare patients for DHS is a direct or indirect compensation arrangement. That is, a referring physician “stands in the shoes” of, “(1) Another physician who employs the referring physician; (2) his or her wholly-owned professional corporation; (3) a physician practice (that is, a medical practice) that employs or contracts with the referring physician; or (4) a group practice of which the referring physician is a member or independent contractor.”4 Importantly, the referring physician is considered to have the same compensation arrangement as the physician organization in whose shoes the referring physician stands.

Following Phase III, CMS received several comments from industry stakeholders, including academic medical centers (“AMCs”) and integrated tax-exempt health care delivery systems with respect to the application of the “stand in the shoes” provisions and the consequences of applying the provisions in those settings. Subsequently, on November 9, 2007, CMS issued its decision to delay for one year the applicability of “stand in the shoes” provisions set forth in Phase III, as applied to certain arrangements at AMCs and nonprofit health centers.5 The effective date for these provisions was delayed until December 4, 2008.

CMS is now revisiting the “stand in the shoes” provisions in the IPPS proposed rule. CMS proposed two alternative methods to address the issue raised by the “stand in the shoes” provisions, and is seeking comments from the industry on each of its proposals, as well as alternative approaches.

**Physician “Stand in the Shoes” Provisions**

**First Proposal**

Currently, the “stand in the shoes” provisions would apply to any physician and their physician organization regardless of the compensation arrangement. CMS proposes that a physician would be deemed not to stand in the shoes of his or her physician organization if the compensation arrangement between the two satisfied the requirements of one of the following exceptions: bona fide employment relationships (42 C.F.R. § 411.357(c)), personal service arrangements (42 C.F.R. § 411.357(d)), or fair market value compensation (42 C.F.R. § 411.357(l)). That is, under the proposed alternative, if the compensation arrangement between the physician organization and one of its referring physicians satisfies one of the specified exceptions, the referring physician would be deemed not to stand in the shoes of the physician organization for purposes of applying the provisions related to direct and indirect compensation arrangements. CMS is ostensibly taking the view that satisfying these exceptions is sufficient protection that the compensation paid is not exchange for referrals.

CMS is concerned, however, that considering all physician owners of, or physician investors in, a physician organization to stand in the shoes of the physician organization may be overly inclusive. Consequently, CMS is considering whether physician owners with nominal ownership interests and who have a compensation arrangement that satisfies one of the specified exceptions should have to stand in the shoes of their physician organizations. CMS is seeking comments on this issue. Further, CMS is soliciting comments on whether only owners of a physician organization would stand in the shoes of that physician organization,

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4 Id.

as well as whether and under what circumstances should the “stand in the shoes” provisions apply to a physician organization that has no physician owners.

CMS also proposes that a physician would not stand in the shoes of his or her physician organization (e.g., a faculty practice plan) when his or her referral for DHS is protected under the exception for services provided by an AMC (42 C.F.R. § 411.355(e)). CMS is seeking comments on the best way in which to achieve this policy in its regulatory text. In addition, CMS is proposing that the “stand in the shoes” provisions would not apply to a compensation arrangement between a component of an AMC and a physician organization if the arrangement is for services required for the AMC to meet its graduate medical education (“GME”) obligations.

Based on this first proposal, some referring physicians would no longer stand in the shoes of their physician organization as they currently do under the provisions in Phase III. However, CMS is concerned that there may be potential for abusive arrangements between DHS entities and physician organizations where physicians do not stand in the shoes of their physician organizations because such arrangements may be incorrectly viewed as falling outside the definition of an “indirect compensation arrangement.” As such, CMS may provide additional guidance in the 2009 IPPS final rule with respect to this definition. CMS is seeking comments on the ways in which to ensure that the “full range” of potentially abusive arrangements between DHS entities and physician organizations are appropriately addressed in situations where physicians do not stand in the shoes of their physician organizations.

**Second Proposal**

In the alternative, CMS proposes to make no revisions to the “stand in the shoes” provisions set forth in Phase III and, to the extent necessary, establish a separate exception using its authority under section 1877(b)(4). The new exception would apply to specific types of non-abusive payments or arrangements that are not otherwise covered by existing exceptions. CMS is considering that the exception would apply to compensation arrangements between DHS entities and physician organizations and physicians for “mission support” payments (or similar compensation arrangements). CMS is seeking comments on this proposal, including whether or not the exception should be limited to “mission support” payments, the types of parties that should be permitted to use the exception and the conditions that should apply to such an exception to ensure that a protected compensation arrangement poses no risk of program or patient abuse.

According to CMS, the proposed exception could address compensation arrangements between components of certain well-defined integrated delivery systems. As an example, some industry stakeholders have suggested that CMS establish an exception for compensation arrangements between a DHS entity component of an integrated health care delivery system and a physician organization component of the same integrated health care delivery system. CMS is soliciting comments on defining a fully integrated health care delivery system, the types of compensation arrangements that should be protected and the conditions that should be included in an exception that protects the program and patients from the risk of abuse. Admittedly, the ability to adequately and appropriately define an integrated delivery system may prove challenging.
DHS Entity “Stand in the Shoes” Provisions

In the CY 2008 Physician Fee Schedule proposed rule (“2008 PFS proposed rule”), CMS proposed a corollary provision to the physician “stand in the shoes” provisions that addressed the DHS entity side of the physician-DHS entity financial relationships. CMS proposed that where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity would stand in the shoes of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the entity that it owns or controls. As an example, a hospital would stand in the shoes of a medical foundation that it owns or controls.

CMS received comments from several industry stakeholders, such as physicians, medical associations and their representatives. Many comments expressed concern that the proposal was unclear and overly broad. As a result, CMS is re-proposing the DHS entity “stand in the shoes” provisions with a few modifications. CMS is proposing that an entity that furnishes DHS would be deemed to stand in the shoes of an organization in which it has a 100 percent ownership, and would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the organization that it owns. As such, a DHS entity would stand in the shoes of any wholly-owned organization, not merely a wholly-owned DHS entity.

CMS is seeking comments as to whether the agency should consider a DHS entity to stand in the shoes of another organization in which the DHS entity holds less than a 100 percent ownership interest and, if so, what amount of ownership should trigger application of the entity “stand in the shoes” provisions. CMS is also seeking comments as to whether a DHS entity should be deemed to stand in the shoes of an organization that it controls (e.g., an entity standing in the shoes of a nonprofit organization of which it is the sole member). Finally, CMS is soliciting comments as to the level of control that should trigger application of these provisions.

Application of the “Stand in the Shoes” Provisions

In an attempt to provide further clarification and guidance, CMS sets forth the following conventions for applying the physician “stand in the shoes” provisions and the entity “stand in the shoes” provisions:

• First, parties would apply the physician “stand in the shoes” provisions and deem the physician to stand in the shoes of his or her physician organization (in those instances where the physician “stand in the shoes” provisions apply to the particular physician and physician organization).

• However, if applying the physician “stand in the shoes” provisions would result in only one financial relationship remaining between the DHS entity and the “collapsed” physician/physician organization and that relationship is an ownership interest, the physician “stand in the shoes” provisions would not be applied, and the entity “stand in the shoes” provisions instead would be applied first.

• If more than two organizations remain after first “collapsing” the physician and the physician organization (that is, if at least two links remain in the chain of financial relationships between the physician who is standing in the shoes of his or her physician organization and the DHS entity), the next step would be to apply the entity “stand in the shoes” provisions.

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According to CMS, these conventions ensure that at least one compensation arrangement remains between the DHS entity and the referring physician for purposes of analyzing the chain of relationships under the physician self-referral rules. To illustrate these conventions, CMS provides a few examples, which are summarized below.

- **Hospital – Wholly Owned Home Health Agency – Group Practice – Physician Owner of the Group Practice:** The first step would be to apply the physician “stand in the shoes” provisions such that the physician owner would stand in the shoes of the group practice. The second step would be to apply the entity “stand in the shoes” provisions and deem the hospital to stand in the shoes of its wholly owned home health agency. The remaining financial relationship would be deemed to be a direct compensation relationship between the hospital and the physician.

- **Hospital – Group Practice Wholly Owned by the Hospital – Employed Physician of the Group Practice (whose compensation does not satisfy the requirements of the bona fide employment exception):** If the relationship between the hospital and the group practice is solely an ownership interest, apply the entity “stand in the shoes” provisions first so that the hospital would stand in the shoes of the group practice. The physician would not stand in the shoes of the group practice. The remaining financial relationship would be deemed to be a direct compensation arrangement between the hospital and the physician.

- **Hospital – Group Practice Wholly Owned by the Hospital – Employed Physician of the Group Practice (whose compensation does not satisfy the requirements of the bona fide employment exception and additional compensation relationship):** If the hospital has a compensation arrangement (e.g., an office space rental agreement) with the group practice, in addition to the ownership interest, the physician would stand in the shoes of the group practice, instead of the hospital. The remaining financial relationship created by the rental agreement would be deemed to be a direct compensation arrangement between the hospital and physician.

**Definitions**

In the IPPS proposed rule, CMS revises the definitions of “physician” and “physician organization” to clarify that: (1) A physician and the physician corporation of which he or she is the sole owner are always treated the same for purposes of applying the physician self-referral rules; and (2) a physician who stands in the shoes of his or her wholly owned physician corporation also stands in the shoes of his or her physician organization. As such, CMS intends for the referring physician to stand both in the shoes of his or her wholly owned physician corporation, as well as in the shoes of the physician organization. As an example, hospital – group – physician corporation – physician would be collapsed into hospital – group practice/physician corporation/physician.
Gainsharing

Included in the IPPS proposed rule was a solicitation of comments requesting industry input on whether an exception to the physician self-referral law is warranted for “gainsharing” type arrangements (payments aimed at improving quality, reducing waste and controlling costs). Specifically, CMS is seeking comments on:

- whether CMS should establish an exception to the physician self-referral law for gainsharing arrangements;
- what safeguards should be included in an exception for gainsharing arrangements; and
- whether certain services, clinical protocols, or other arrangements should not qualify for an exception, if one is ultimately proposed by CMS.

The IPPS proposed rule includes a detailed account of the history of gainsharing and the existing statutory impediments to gainsharing arrangements. Gainsharing is a term that has been broadly defined as “an arrangement in which the hospital gives physicians a percentage share of certain reductions in the hospital’s costs for patient care attributable in part to the physicians’ efforts.” In most of these arrangements, including those approved by the Office of Inspector General (“OIG”) through its formal advisory opinion process, the payments are based upon a set percentage of the cost savings achieved.

In the 2008 PFS proposed rule, CMS noted its concern about compensation arrangements between entities and physicians where the amount of compensation is determined on a percentage basis and proposed revising the special rules for compensation under the physician self-referral law. In the 2008 PFS proposed rule, CMS indicated that it may revise the special rules on compensation to permit the use of percentage-based compensation only when paying for personally performed physician services and not “on some other factors such as a percentage of the savings by the hospital department.” If those changes are finalized, the ability of hospitals and physicians to participate in “gainsharing” type arrangements will be significantly impaired. In the IPPS proposed rule, CMS acknowledges this result and more importantly, acknowledges the value to the Medicare program and its beneficiaries where properly structured gainsharing arrangements result in improvements in quality of care.

An exception to the physician self-referral law for gainsharing/quality based payments would be significant to hospitals and physicians and would provide much needed flexibility in efforts to improve quality of care, efficiency in the delivery of care and the ability to control costs. It would also provide long-awaited CMS guidance on the appropriateness of these arrangements.

Physician-Owned Implant and Other Medical Device Companies (“POCs”)

Coming on the heels of increased OIG scrutiny of physician-owned device companies (“POCs”) and a clear message from the OIG that fraud in the medical device industry is an enforcement priority, the IPPS proposed rule includes a solicitation of comments on this topic. In the solicitation, CMS acknowledges the increase in physician investment in implant and other medical device manufacturing, distribution and purchasing companies.
In the IPPS proposed rule, CMS notes the increase in physician investment in implant and other medical device manufacturing, distribution and purchasing companies. While CMS acknowledges the value physician involvement can add to device manufacturing, it questions the benefit of physician involvement in distribution and purchasing companies. CMS expresses its concerns regarding potential program and patient abuse when physicians profit from the referrals they make to hospitals through POCs, and the potential anti-competitive effects of such ownership interests. CMS also notes that the OIG believes these ventures merit close scrutiny under the fraud and abuse laws, particularly when a large portion of a venture’s revenue comes from patient-driven referrals.

Noting that even under the present rules, many POC financial relationships will fail to meet the requirements for an exception to the physician self-referral statute, CMS solicits comments on the following:

- what specific actions CMS should take to address POCs under the physician self-referral rules;
- whether concerns regarding POCs are better addressed through enforcement of the False Claims Act, the anti-kickback statute and similar fraud and abuse laws, and through other applicable Federal, State and local regulations;
- whether and to what degree physician investment in POCs and similar organizations presents risks of overutilization, substandard care and increased costs to the Medicare program and its beneficiaries; and
- whether the risk from physician investment in POCs and similar organizations is confined to anti-competitive behavior.


In the IPPS proposed rule, CMS revisits its planned collection of information regarding ownership and investment interests and compensation arrangements between hospitals and physicians on the Disclosure of Financial Relationships Report (“DFRR”). The IPPS proposed rule includes the proposed DFRR instrument at Appendix C. Section 1877(f) of the Social Security Act requires completion of the DFRR, and CMS believes the information will allow it to analyze various types of hospital-physician financial relationships, understand trends and assess compliance with the physician self-referral law.

CMS proposes that the DFRR be completed and certified by the appropriate hospital officer and returned within 60 days. Untimely responses will trigger civil monetary penalties ($10,000 per day) unless good cause can be shown. CMS has calculated that the DFRR should take 31 hours for hospitals to complete but solicits comments on this figure, on whether 60 days is an appropriate amount of time to allow for completing the DFRR, and on the cost of completing the Report. In addition, CMS solicits information on:

- whether the collection effort should be recurring (annual or on some other periodic basis);
- whether the DFRR solicits too much or not enough information, and whether it collects the correct (or incorrect) type of information;
- whether CMS should direct the DFRR to all hospitals, and, if so, whether CMS should stagger the collection so that only a certain number of hospitals are subject to it in any given year; and
whether hospitals, once having completed the DFRR, should have to send in yearly updates and report only changed information.

CMS is proposing to send the DFRR to 500 hospitals to determine compliance and to assist the agency with future rulemaking related to reporting requirements. Specifically, CMS had indicated that it may use information from the DFRR to finalize the changes to the physician self-referral rules proposed in the 2008 PFS proposed rule.

The proposed DFRR instrument includes a certification page and eight worksheets addressing Hospital Characteristics; Direct Ownership in Hospital; Indirect Ownership in Hospital; Payments Made to Hospital by Direct Owners; Payments Made to Hospital by Indirect Owners; Investment Reconciliation; Compensation Arrangements – Rentals, Personal Service Arrangements and Recruitment (42 C.F.R. § 411.357); and Other Types of Compensation Arrangements (42 C.F.R. § 411.357).

Period of Disallowance

There has been ongoing confusion surrounding the period of disallowance resulting from a financial relationship between a DHS provider and a physician that does not fit within an exception. Many have questioned how long the referrals for such an arrangement remain “tainted” for purposes of the physician self-referral prohibition. In the 2008 PFS proposed rule, CMS opened the discussion on how to establish the period of disallowance by formally soliciting public comments on the issue. In the 2008 PFS proposed rule, CMS indicated that the physician self-referral statute contemplates that “the period of disallowance begins with the date that a financial relationship failed to comply with the statute and the regulations, and ends with the date that the arrangement came into compliance or ended.” CMS acknowledged, however, that determining when the financial relationship ended may not always be clear. CMS did not receive many public comments in response to its original solicitation. Nevertheless, CMS is proposing in the IPPS rule the following periods of disallowance for situations where all other requirements of an applicable exception are satisfied:

- where noncompliance is due to reasons unrelated to compensation (for example, a missing signature), the period of disallowance would begin on the date the arrangement was first out of compliance and end no later than the date the arrangement was brought into compliance.

- where noncompliance is due to the payment (or receipt) of excess compensation (for example, the provision of excess nonmonetary compensation beyond the limits in 42 C.F.R. § 411.357(k)), the period of disallowance would begin on the date the arrangement was first out of compliance and end no later than the date the excess compensation (including interest, as appropriate) was returned by the party receiving it to the party that provided it.

- where the noncompliance is due to the payment of compensation in an amount insufficient to satisfy the requirements of an applicable exception (for example, below fair market value rent), the period of disallowance would begin on the date the arrangement was first out of compliance and end no later than the date the shortfall was paid to the party to which it is owed.

In its discussion, CMS specifically noted that noncompliance may be for reasons that are related to compensation (for example, payment that takes into account volume or value of referrals), but which do not involve the payment or receipt of excess compensation or a shortfall in compensation paid or received.
In such instances, CMS stated that a case-by-case analysis would be necessary and therefore CMS did not propose a period of disallowance. CMS is soliciting comments generally on the three situations set forth above. Of note, CMS did not propose a period of disallowance where noncompliance is due to reasons other than those set forth above.

**Disclosure Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership**

Physician ownership in hospitals continues to garner increased attention and scrutiny. Advocates and proponents of physician-owned hospitals continue to debate the appropriateness of these ventures and the impact on patient care. In the FY 2008 IPPS final rule, CMS addressed the requirements governing Medicare provider agreements with particular emphasis on physician ownership. Once again in the FY 2009 IPPS final rule, CMS proposes additional clarifications to the disclosure requirements of certain hospitals and critical access hospitals regarding physician ownership. CMS is proposing the following clarifications:

- revise the definition of “physician-owned hospital” to include a hospital that a physician, or an immediate family member of a physician, has an ownership or investment interest in a hospital;

- except from this disclosure requirement physician-owned hospitals that do not have any physician owners who refer to the hospital, providing that the hospital submits an appropriate attestation and maintains appropriate documentation;

- require that the disclosure listing the physician or physician-related owners or investors be furnished at the time the patient or someone on the patient’s behalf requests it;

- require a hospital to include, as a condition of continued medical staff privileges, that physicians disclose (in writing) to all patients who they refer to the hospital any ownership or investment interest in the hospital held by the physician or immediate family member of the physician. Disclosure would be required at the time the physician refers the patient to the hospital;

- revise the regulations to permit termination of the Medicare provider agreement if a hospital fails to comply with the disclosure requirement. CMS did not include a similar proposal with respect to medical staff bylaws; and

- set forth penalties (termination of provider agreement) for failure to comply with the patient safety measures currently set forth at 42 C.F.R. § 489.20(v).

CMS is also soliciting public comments on whether and by what means hospitals should educate patients about the availability of information regarding physician ownership.

**Conclusion**

Many of the proposed changes to the physician self-referral law will continue to have far-reaching consequences for physician relationships with hospitals and other providers. The regulatory landscape is still unsettled and, as such, industry stakeholders should take advantage of this opportunity to provide CMS with substantive comments as CMS continues to grapple with the complexities of the physician self-referral law.
If you have any questions or would like additional information, please contact your Alston & Bird attorney or a member of our Health Care Group.

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