Stark II Phase II Adds Clarity to Physician Recruitment Arrangements

With the long-awaited arrival of Phase II of the Stark II final regulations, the structure of physician recruitment arrangements between hospitals and recruited physicians has finally taken on a defined shape. Physician recruitment arrangements are commonplace transactions between a hospital and a physician who is relocating to the hospital’s community. Despite the prevalence of such arrangements, there has been an air of confusion regarding the permissible structuring of financial incentives to recruited physicians. This was a result of a lack of final parameters under the Stark law, as well as the uncertain interplay between the requirements of the Stark law, the anti-kickback statute, and tax-exempt standards. Although the varying standards of the different laws still need to be addressed, with the issuance of final Stark II Phase II regulations offering “bright line” specific tests and additional guidance, this confusing area now is more clearly defined – for better and for worse.

Background

The Stark Law prohibits a physician from making a referral for certain “designated health services” payable by Medicare or Medicaid to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies. Although Stark initially applied only to clinical laboratory services, effective 1995, it was expanded to cover 10 additional designated health services, with the expanded law referred to as Stark II. While there are a number of exceptions in the statute, the law basically assumes a financial relationship is impermissible and, if the relationship exists, the physician cannot refer to the entity and the entity cannot bill for the referred service.

Under Stark II, an exception was established for 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 medical staff of the hospital. The conditions to be met for the physician recruitment exception include (i) the physician is not required to refer patients to the hospital; (ii) the amount of the remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician; and (iii) the arrangement meets such other requirements as the Secretary of Health and Human Services may impose by regulations.

Phase II Final Regulations

The final Phase II regulations significantly modify the proposed regulations, which were issued in 1998. The Phase II final regulations clarify and define the parameters set out in the Stark Law by providing specific guidelines and measurements for the structuring of physician recruitment incentives. Essentially, the final regulations allow a hospital to recruit a physician to relocate his medical practice to the geographic area served by the hospital in order to become a member of the hospital’s medical staff by paying the physician financial incentives, so long as (i) the arrangement is set out in writing and signed by both parties; (ii) the arrangement is not conditioned on the physician’s referral of patients to the hospital; (iii) the hospital does not determine (directly or indirectly) the amount of remuneration to the physician based on the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties; and (iv) the physician is allowed to establish staff privileges at any other hospital and to refer business to any other entities.

“Relocation” and “Geographic Area” Defined

Under the final regulations, the determination of whether a physician relocates his practice to the geographic area served by the hospital will be based on relocation of a physician’s medical practice, rather than the physician’s residence. A “bright line” test has been established to determine if a physician relocates his practice. A physician is deemed to have relocated his practice if the physician moves his practice at least 25 miles, or if at least 75% of his patients in the relocated practice are “new patients.” According to the preamble, a “new patient” is a patient that has not been seen by the practice for at least 3 years prior to the relocation. The definition of “geographic area served by the hospital” is defined as the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients.

This test is a substantial departure from the requirements of the proposed rule, which required a recruited physician to reside outside the hospital’s geographic area and actually relocate his residence under

(cont. on page 2)
the final regulations, a physician who lives near the hospital but has a practice outside the hospital’s geographic area may receive recruitment incentives if the physician meets the test of relocating his practice to the geographic area served by the hospital.

Recruitment of Residents and New Physicians

The final regulations also allow recruitment incentives to be made to residents and physicians who have been in medical practice one year or less. This is a welcome and long-overdue provision. When the proposed regulations were issued in 1998, the wording of the physician recruitment exception did not allow incentives to be paid to physicians unless they were relocating to the area. There was no exception for residents, despite the fact that residents had no established practice to relocate. Now, under the final regulations, residents and physicians who have been in practice one year or less will not be subject to the relocation requirement, provided that the recruited physician establishes his medical practice in the geographic area served by the hospital.

Recruitment to Existing Group Practices

In one of the most dramatic developments to Stark, the final regulations clarify that recruitment incentives may be paid, in certain circumstances, to recruit a physician to an existing group practice. This has been an area of great confusion, and the final regulations clarify whether and how a hospital may recruit a physician to join an existing medical group practice. CMS recognized that many new or relocating physicians prefer to join existing practices rather than set up a new practice, for legitimate reasons such as cost, cross-coverage, and professional expertise. However, CMS was concerned that a recruitment arrangement involving direct or indirect payments to an existing physician practice might be used improperly to pay for referrals from that practice. As a result, they created narrowly tailored criteria to allow what they consider appropriate incentives, but curtail abusive arrangements. The changes to this aspect of the physician recruitment exception are some of the most dramatic changes to the Stark law associated with Phase II, since they are a departure from the structure of most current arrangements.

Recruitment incentives provided by a hospital to a physician either indirectly through payments made to another physician or a group practice, or directly to a physician who joins a group practice will meet the physician recruitment exception only to the extent the following conditions are met:

• The arrangement between the hospital and the practice is set out in writing and signed by the parties (including the hospital, the recruited physician, and the practice).

• Except for actual costs incurred by the practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.

• In the case of an income guarantee formula, when allocating costs, it is appropriate to attribute 1/5 of the overhead costs to the recruited physician. Note that this is a major departure from many common income guarantee formulas that the recruited physician is joining a group practice consisting of 4 physicians, when calculating costs, it is no longer appropriate to attribute 1/5 of the overhead costs to the recruited physician. Only those additional costs, such as the hiring of a new nurse or costs associated with the build-out and rental of additional space to accommodate the recruited physician, may be included. It is also important to note the use of the word “actual” when describing the costs. This is an important change, as it is evident that CMS will only consider those specific costs that have actually been incurred, and not projected costs, to be valid costs in calculating an income guarantee.

• Records of the actual costs and passed-through amounts must be maintained for a period of at least 5 years and made available upon request. This presumably includes the actual costs of the direct recruitment payments as well as the actual costs attributable to the physician in calculating an income guarantee.

• The remuneration from the hospital is not to be determined in a manner that takes into account, directly or indirectly, the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice receiving the direct payments from the hospital.

• The practice may not impose additional practice restrictions on the recruited physician, such as a non-compete agreement, other than conditions related to quality of care.

• The arrangement does not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission.

FQHCs

The final regulations expand the physician recruitment exception to allow federally qualified health centers to provide recruitment incentives to physicians in the same manner as a hospital. Prior to this change, the exception applied only to hospitals. This change was added as a result of comments received asking for protection of recruitment payments from entities other than hospitals. CMS extended the exception to cover FQHCs that recruit physicians to join their medical staffs because CMS believes it is consistent with the statutory intent to FQHCs in recruiting adequate staffs to underserved populations.

What Does This Mean to My Existing Recruitment Arrangements?

Existing recruitment arrangements should be immediately reviewed to ensure compliance with the Phase II final regulations. It is likely that most recruitment arrangements between hospitals and physicians who have been recruited to relocate to town to establish their own practice (and not join an existing group) will meet the new requirements. One potential area of concern will be whether the physician’s practice has relocated, and not just his residence. If the physician’s practice has moved at least 25 miles to the hospital’s geographic area, you will be deemed to have met this test. If the practice moved less than 25 miles, you will need to undertake an analysis of whether at least 75% of the physician’s patients in the relocated practice are “new patients,” as defined by Phase II.

The biggest concern from a compliance standpoint will be those recruitment arrangements in which the recruited physician has relocated to an existing group. Any such recruitment agreement involving a payout on or after July 26, 2004 will be subject to the restrictive standards of Phase II, and it will be likely that most agreements involving a group practice will need to be restructured to comply with the specific standards set forth in the final regulations. When reviewing your recruitment agreements, you should pay particular attention to whether all parties signed the agreement and whether only the actual

(cont. on page 3)
What Does This Mean to the Structuring of New Recruitment Arrangements?

New recruitment arrangements should, of course, be structured to strictly comply with the final regulations of Stark II. However, compliance with the new Stark II Phase II final regulations should not end the scope of your inquiry. In order to appropriately structure physician recruitment arrangements, it will also be necessary to review the requirements of the anti-kickback statute and, to the extent the hospital involved is exempt from taxes under Section 501(c)(3) of the Internal Revenue Code, the arrangement has to be reviewed from a private inurement perspective as well. A good rule of thumb in structuring physician recruitment agreements is to be sure to evaluate the arrangement in light of all applicable laws and conform each element of the agreement to the most stringent law applicable. The recent indictments of Tenet Health System Hospitals, Alvarado Hospital Medical Center, and its CEO for violations of the anti-kickback statute for the payment of recruitment incentives involving existing group practices underscores the gravity of the consequences of not structuring a recruitment arrangement to comply with all applicable laws.

Recruitment arrangements structured to be consistent with the restrictive standards of Stark likely will meet the requirements of the anti-kickback statute; however, a review should be undertaken to ensure compliance. The anti-kickback statute provides criminal penalties for individuals and entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business for which payment may be made under a federal health care program. If an arrangement meets all of the criteria of a safe harbor, it is fully protected from liabilities under the anti-kickback statute. Arrangements that do not meet a safe harbor are not per se illegal, but will be judged on a case-by-case basis. In 1999, the Office of Inspector General added a safe harbor for physician recruitment activities; however, this safe harbor is very narrow in scope, and protects only those arrangements in which a physician is recruited to relocate to a health professional shortage area (“HPSA”). If the anti-kickback safe harbor cannot be met (which is most likely unless the recruiting hospital is in an HPSA), the arrangement should be structured as closely as possible to the safe harbor, as well as the guidelines set forth in OIG Advisory Opinion No. 01-4 (May 3, 2001). In this Advisory Opinion, the OIG acknowledged that not all appropriate recruitment arrangements are capable of falling within the safe harbor requirements, and offered insight into the factors relevant to a case-by-case evaluation of arrangements that do not meet the physician recruitment safe harbor. In particular, the OIG will consider such factors as whether there is documented evidence of an objective need for the physician’s services, whether the physician has an existing stream of referrals within the recruiting entity’s service area, whether the benefit is narrowly tailored so that it does not exceed that which is reasonably necessary to recruit a physician, and whether the remuneration directly or indirectly benefits other referral sources.

If the recruiting hospital is a tax-exempt entity, it will also be necessary to ensure that any and all recruitment incentives meet the requirements imposed by the Internal Revenue Service (“IRS”). The considerations factoring into an appropriate recruitment structure can be gleaned from IRS Revenue Ruling 97-21 (as well as prior guidance issued by the IRS). For example, a tax-exempt hospital should not enter into a recruitment arrangement unless it documents a need for physicians of that particular specialty in its service area with objective evidence, and the incentives offered are narrowly tailored and reasonably necessary to recruit the physician.

Conclusion

The health care industry has generally welcomed the arrival of the Phase II final regulations, which contain, after a long period of ambiguity, the accepted criteria for structuring physician recruitment arrangements. The “bright-line” changes to the proposed rule have added clarity and guidance to the structuring of these arrangements and constitute some of the most significant changes in the final regulations. The final regulations contain the welcome addition of allowing the recruitment of residents and new physicians to the hospital for designated health services (including inpatient and outpatient hospital services). To the extent you have an arrangement that has not been corrected by the July 26, 2004 effective date, you will likely have an additional 90 days to get into compliance as a result of the new Stark exception for certain arrangements involving temporary noncompliance.

HHSC Considers New Medicaid Fraud Rules

The 78th Texas Legislature adopted sweeping changes to the Medicaid fraud laws last year, providing the State with new authority and resources to ferret out Medicaid fraud. The Texas Health and Human Services Commission (“HHSC”) now has the responsibility of promulgating appropriate rules to implement the revised statutory framework. This has been no easy task given the web of regulatory entities that were created or combined to address Medicaid fraud and abuse in Texas. The Legislature centralized the previously fragmented responsibility of detecting fraud by creating the Office of the Inspector General (“OIG”), an office within HHSC, and the Medicaid Integrity Division (“MI”), the division within the OIG that initiates preliminary investigations into potential fraud and abuse. Furthermore, the Medicaid Fraud Control Unit (“MCFU”) is the division within the Attorney General’s Office that is responsible for investigating suspected Medicaid provider fraud and physical abuse or neglect of patients in institutional settings.

The OIG recently presented draft rules to the Medical Care Advisory Committee (“MCAC”), an internal committee within HHSC charged with considering draft rules before approval for publication. The MCAC received comments from various healthcare associations, and in June 2004, HHSC published the formally Proposed Rules in the Texas Register for official comment. The Medicaid fraud rules propose to rename Chapter 371 of Title 1 “Medicaid and Other Health and Human Services Fraud and Abuse Program Integrity.” Under Chapter 371, the rules create entirely new Texas Administrative Code Subchapters A and B and revise Subchapter G. There are several interesting revisions to the Proposed Rules that appear to address concerns raised about the original draft rules.

Proposed Rules

Proposed rules of particular interest include the following:

• Surety Bonds. The new Medicaid fraud statute authorizes HHSC to require Medicaid providers to post surety bonds in a “reasonable amount” if HHSC identifies a pattern of suspected fraud or abuse should be structured as closely as possible to the safe harbor, as well as the guidelines set forth in OIG Advisory Opinion No. 01-4 (May 3, 2001). In this Advisory Opinion, the OIG acknowledged that not all appropriate recruitment arrangements are capable of falling within the safe harbor requirements, and offered insight into the factors relevant to a case-by-case evaluation of arrangements that do not meet the physician recruitment safe harbor. In particular, the OIG will consider such factors as whether there is documented evidence of an objective need for the physician’s services, whether the physician has an existing stream of referrals within the recruiting entity’s service area, whether the benefit is narrowly tailored so that it does not exceed that which is reasonably necessary to recruit a physician, and whether the remuneration directly or indirectly benefits other referral sources.

If the recruiting hospital is a tax-exempt entity, it will also be necessary to ensure that any and all recruitment incentives meet the requirements imposed by the Internal Revenue Service (“IRS”). The considerations factoring into an appropriate recruitment structure can be gleaned from IRS Revenue Ruling 97-21 (as well as prior guidance issued by the IRS). For example, a tax-exempt hospital should not enter into a recruitment arrangement unless it documents a need for physicians of that particular specialty in its service area with objective evidence, and the incentives offered are narrowly tailored and reasonably necessary to recruit the physician.

Conclusion

The health care industry has generally welcomed the arrival of the Phase II final regulations, which contain, after a long period of ambiguity, the accepted criteria for structuring physician recruitment arrangements. The “bright-line” changes to the proposed rule have added clarity and guidance to the structuring of these arrangements and constitute some of the most significant changes in the final regulations. The final regulations contain the welcome addition of allowing the recruitment of residents and new physicians to the hospital for designated health services (including inpatient and outpatient hospital services). To the extent you have an arrangement that has not been corrected by the July 26, 2004 effective date, you will likely have an additional 90 days to get into compliance as a result of the new Stark exception for certain arrangements involving temporary noncompliance.

HHSC Considers New Medicaid Fraud Rules

The 78th Texas Legislature adopted sweeping changes to the Medicaid fraud laws last year, providing the State with new authority and resources to ferret out Medicaid fraud. The Texas Health and Human Services Commission (“HHSC”) now has the responsibility of promulgating appropriate rules to implement the revised statutory framework. This has been no easy task given the web of regulatory entities that were created or combined to address Medicaid fraud and abuse in Texas. The Legislature centralized the previously fragmented responsibility of detecting fraud by creating the Office of the Inspector General (“OIG”), an office within HHSC, and the Medicaid Integrity Division (“MI”), the division within the OIG that initiates preliminary investigations into potential fraud and abuse. Furthermore, the Medicaid Fraud Control Unit (“MCFU”) is the division within the Attorney General’s Office that is responsible for investigating suspected Medicaid provider fraud and physical abuse or neglect of patients in institutional settings.

The OIG recently presented draft rules to the Medical Care Advisory Committee (“MCAC”), an internal committee within HHSC charged with considering draft rules before approval for publication. The MCAC received comments from various healthcare associations, and in June 2004, HHSC published the formally Proposed Rules in the Texas Register for official comment. The Medicaid fraud rules propose to rename Chapter 371 of Title 1 “Medicaid and Other Health and Human Services Fraud and Abuse Program Integrity.” Under Chapter 371, the rules create entirely new Texas Administrative Code Subchapters A and B and revise Subchapter G. There are several interesting revisions to the Proposed Rules that appear to address concerns raised about the original draft rules.

Proposed Rules

Proposed rules of particular interest include the following:

• Surety Bonds. The new Medicaid fraud statute authorizes HHSC to require Medicaid providers to post surety bonds in a “reasonable amount” if HHSC identifies a pattern of suspected fraud or abuse...
If you are a regular reader of HealthBrief, you know we have periodically reported on the risks associated with physician networks (IPA's and PHO's) that choose to negotiate contracts with managed care plans. Such reports include “Antitrust Safety Zones Offer Guidance to Providers,” Summer 1995; “New FTC Physician Network Guidelines No Collective Bargain,” Winter 1997; “Physician Collective Bargaining: What Impact Will It Have?,” Special Issue 1999; “The FTC Is At It Again: A Note of Caution to Provider Networks,” Fall 2000. (See articles at www.jw.com.) Unfortunately for such networks, those risks have not gone away.

Recent efforts by the Federal Trade Commission (“FTC”) and the Department of Justice (“DOJ”) enforcing the antitrust laws against physician networks dates back to the mid 1990s. While hospital antitrust enforcement often emphasizes hospital mergers, the focus on physician activities is usually contract negotiation by IPA’s. The agencies jointly promulgated antitrust enforcement policies first in 1993, and amended those policy statements to specifically apply to physician network joint ventures in 1996. The 1996 Policy Statements provided hypothetical examples illustrating the practical application of the antitrust principles being applied. One of the primary examples discussed by the FTC involved “messenger-model” IPA arrangements. It is such commonplace messenger models that the FTC Board of Governors considered in their 1993 meeting.

While hospital antitrust cases have been much in the news, the FTC and DOJ have filed 19 cases alleging anti-competitive conduct by physician networks such as IPAs. In 16 of those cases, the agencies jointly promulgated antitrust enforcement policies first in 1993, and amended those policy statements to specifically apply to physician network joint ventures in 1996. The 1996 Policy Statements provided hypothetical examples illustrating the practical application of the antitrust principles being applied. One of the primary examples discussed by the FTC involved “messenger-model” IPA arrangements. It is such commonplace messenger models that the FTC Board of Governors considered in their 1993 meeting.

Top Ten List
IPA’s should carefully monitor their behavior. Managed-care payors are eager to blow the whistle on aggressive IPA’s, and the FTC wants to enforce its jurisdiction. Based on the recent FTC enforcement activities discussed above, the “Top 10” current FTC trouble spots for messenger model IPA’s include:

1. IPA refusal to deal with certain payors;
2. Individual refusal to deal except through the IPA;
3. Failure by messenger to convey all offers to IPA members;
4. Conveying offers with editorial “comment” about the adequacy of the offer;
5. Negotiating “competitively significant” terms;
6. Negotiating price-related terms;
7. Recommending that IPA members terminate their existing individual contracts;
8. Recommending that IPA members only deal through the IPA;
9. Communicating to IPA members price information or contract decisions of other IPA members; and
10. Proposing “suggested” fee schedules.

Conclusion
The pace of FTC investigations against physician networks has accelerated. Providers across the country must be aware of the risks inherent in IPA messenger-model arrangements. In particular, IPA’s should consult closely with counsel about ongoing operations, since well-structured IPA’s can run afoul of the law during the hectic nature of day-to-day operations. Notwithstanding continued FTC actions, however, the agency thus far has declined to aggressively sanction networks, instead relying on prospective relief. Some analysts speculate the FTC, in the future, should or might seek harsher punishment for renegade networks. If that occurs, your IPA does not want to be that first test case.

FTC Chairman Resigns
Shortly before this issue of HealthBrief went to press, FTC Chairman Timothy Muris announced his resignation effective this summer. He will be replaced by Deborah P. Majoras, a former Department of Justice attorney.
HHSC Considers New Medicaid Fraud Rules (cont. from pg. 3)

involving criminal conduct related to Medicaid services. The draft rules before the MCAC, however, made no mention that the surety bond must be in a “reasonable amount.” Instead, with very limited exceptions, the OIG could require a surety bond from a provider “in an amount and manner specified by the Inspector General.” The Proposed Rules have been revised to reflect that surety bonds must be in fact be of a “reasonable amount,” as that term is defined in the related rules on this subject.

1. The key issue in determining whether an exempt organization is engaged in fraud and abuse is whether the organization was clear that there was a charitable purpose. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

2. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

3. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

4. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

5. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

6. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

7. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

8. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

9. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

10. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

11. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

12. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

13. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

14. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

15. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

16. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

17. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

18. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

19. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

20. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

21. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

22. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

23. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

24. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

25. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

26. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

27. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

28. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

29. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

30. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

31. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

32. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

33. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

34. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

35. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

36. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

37. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

38. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

39. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

40. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

41. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

42. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

43. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

44. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

45. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

46. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

47. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

48. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

49. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

50. The OIG could review the organization’s activities and determine whether the organization was engaged in fraud and abuse.

Industry Prayers Answered - St. David’s Prevails

With just two words, a jury ended the six-year struggle of St. David’s Health Care System to retain its tax exempt status. When asked the question “Do you find St. David’s proved by a preponderance of the evidence to have engaged in fraud and abuse?” the jury responded, “We do.” Such a simple end to such a long, expensive process, and such a happy ending for hospital-physician joint ventures.

First, the facts. St. David’s entered into a 54-year partnership agreement with Columbia/HCA Healthcare Corporation in 1996, with each entity donating three hospitals. The IRS revoked St. David’s tax exempt status in 2000, ruling that, as a result of the partnership agreement, St. David’s was no longer operated exclusively for charitable purposes. In 2002, a U.S. District Court granted St. David’s summary judgment, ordering the IRS to return all tax payments received from St. David’s and granting St. David’s over one million dollars in legal fees. In the fall of 2003, the U.S. District Court granted St. David’s summary judgment, ordering the IRS to return all tax payments received from St. David’s and granting St. David’s over one million dollars in legal fees. In the fall of 2003, the U.S. Court of Appeals for the Fifth Circuit overruled the District Court’s decision, and remanded the case to the District Court for trial. With the March 4th jury verdict cited above, St. David’s ordeal is over.

Of course, while the ordeal was excruciating for St. David’s, we all felt its pain. A pall was cast over all hospital-physician joint ventures. To an extent that, pall has been lifted. There are a number of lessons to be learned from the St. David’s case and a number of conclusions that can be drawn.

1. Key Points to Remember
   1. The key issue in determining whether an exempt organization involved in a joint venture with a for-profit partner is operated exclusively for charitable purposes is “control” over the joint venture.

   (cont. on page 6)
2. Whether the tax exempt participant in a joint venture has ceded control over is a facts and circumstances determination. This is not a black-and-white issue. There are only shades of gray. It is strongly recommended that you seek legal advice concerning such matters.

3. There is an inverse relationship between the amount of control a tax-exempt entity must retain in a joint venture with a for-profit participant and the nature and extent of the other charitable activities carried on by the exempt organization. The more substantial the other charitable activities the exempt organization participates in, the less control it needs to retain over the joint venture in order to retain its tax-exempt status. For example, in the St. David’s case, the joint venture constituted 100% of the hospital’s exempt activities. In such a case, the requirement for “control” is extensive. In this respect, St. David’s represents the most extreme example of the control an exempt entity will have to retain in a joint venture with a for-profit organization in order to remain tax-exempt.

4. Absolute control of the governing body of the joint venture is not required even in the most extreme of cases. Fifty-fifty representation is sufficient so long as there are other indicia of control. In the St. David’s case, the jury decided that such indicia existed, particularly including a blanket statement in the documents creating the joint venture that all hospitals owned by the partnership operate in accord with the community benefit standard required of all charitable organizations. If the hospitals fail to do so, St. David’s can unilaterally dissolve the partnership. Additionally, St. David’s appoints the chairman of the partnership’s governing body. Finally, St. David’s retained significant authority over the for-profit manager of the joint venture to assure the achievement of its charitable purpose. In other words, even in the most extreme cases involving the necessity to retain control of a joint venture

UPDATE: Principle Behind St. David’s Confirmed

Daniel J. Hayes

In a recent revenue ruling, released May 6, 2004, the Internal Revenue Service confirmed the principle behind the jury’s decision in the St. David’s case. In Revenue Ruling 2004-51, the IRS held that a tax-exempt university’s equal participation in a joint venture with a for-profit entity (which expanded the university’s teacher training activities) did not result in the loss of the university’s tax-exempt status or result in unrelated business income. A “facts and circumstances” analysis was used to find that the activity did not constitute a substantial part of the university’s activities and was in furtherance of its exempt purposes. Although the ruling did not involve a healthcare provider, the IRS has indicated publicly it will apply the same analysis to healthcare industry ancillary joint ventures.

CMS Overhauls “Incident To” Billing By Physicians

Jed Morrison

In a little-noticed Medicare program transmittal, effective May 24, 2004, the Centers for Medicare and Medicaid Services (“CMS”) has dramatically changed the requirements for physicians who wish to bill for services provided by their staff “incident to” the physician’s professional services. The service must now be billed under the name of the physician who actually supervised the service, rather than the treating physician.

Medicare historically has paid for services provided directly by physicians, as well as services furnished “incident to” the physician’s professional service. Such services are of a type that is commonly included in the physician’s bill, and for which payment is not made under any separate Medicare payment category. To be covered as “incident to” services, the services must be:

- An integral, although incidental, part of the physician’s professional service;
- Commonly rendered without charge or included in the physician’s bill;
- Of a type that is commonly furnished in physician’s offices or clinics; and
- Furnished by the physician or by auxiliary personnel under the physician’s direct supervision.

Thus, chemotherapy drugs furnished to cancer patients in the oncologist’s office are paid by Medicare “incident to” the physician’s professional service. Similarly, diagnostic imaging tests, although they do have their own Medicare benefit category, are also eligible to be paid “incident to” the physician’s professional service. Historically, the physician treating the patient who ordered the “incident to” service is the physician under whose name the service is billed. Only that physician is truly able to sign the certification that appears on the back of the CMS 1500 Claim Form which says that the services were medically reasonable and necessary for the treatment of the patient, and were furnished at his order.

The final requirement for “incident to” billing states that the services must be furnished under the direct supervision of the physician who ordered the service or another physician in the group practice. Direct supervision means the physician must be in the office suite and immediately available to render assistance should it be needed. This supervision requirement creates new headaches for physicians.

New CMS Manual Provision

Apparently believing that the direct supervision requirement was being evaded by physician practices, CMS issued Transmittal 148, which amends the requirements for completing the CMS 1500 Claim Form. Under the revised manual provision, services billed “incident to” a physician’s professional services must be billed under the name of the physician who actually supervised the “incident to” service. If the ordering physician is not available in the office suite during the day and
CMS Overhauls “Incident To” Billing By Physicians

The new manual provision . . . . raises liability concerns since physicians will be verifying that they supervised the service to a particular patient, and that the service was medically reasonable and necessary, when in fact they may have never even met the patient, nor have any idea of the patient’s underlying medical condition. By participating in the patient’s care in this way, however, the supervising physicians open themselves up to being named in a malpractice suit if there is an unfortunate outcome for the patient.

The mechanics of billing by the supervising physician are difficult as well. The practice will have to maintain an accurate and timely physician log during each period of the day “incident to” services are furnished. For a service like chemotherapy, which can take 45 minutes to an hour to complete, the physician who is supervising the service at the beginning of the procedure may have to leave the office or otherwise not be present when the procedure is completed. Though other physicians in the practice are present when the procedure is completed, the new supervision requirement is not satisfied.

The new manual requirement could skew physician utilization patterns as well. Medicare carriers profile physician practices to determine if any physician bills an “excessive” number of a particular kind of procedure. Such Outliers often result in audits of that particular physician. If a practice chooses to comply with this new manual provision by always billing “incident to” services under one particular supervising physician, that physician’s profile will be skewed and could result in a Medicare audit.

Conclusion and Compliance

Despite the inherent flaws in CMS’s “incident to” billing requirements, practices must immediately begin to comply. They should maintain a log of physician presence in the office suite during all hours the clinic is open and “incident to” services are furnished. The practice must adopt and follow some kind of methodology for determining which physician should bill for “incident to” services. Failure to properly implement and comply with “incident to” billing requirements could result in recoupment of payments by Medicare, and, conceivably, also could be the subject of a false claim suit alleging the services were not furnished as claimed.

CMS Proposes 2.5 Percent Increase In Medicare Home Health Payment Rates

The Centers for Medicare & Medicaid Services (CMS) have announced a 2.5 percent increase in Medicare payment rates to home health agencies for 2005. The increase would bring an extra $270 million in payments to home health agencies next year. After annual double-digit increases in the 1990’s, payments for home health have dropped dramatically in the last 5 years.

To qualify for Medicare home health visits, a Medicare beneficiary must be under the care of a physician, have an intermittent need for skilled nursing care, or need physical therapy, or speech therapy or continue to need occupational therapy. The beneficiary must be home-bound and receive home health services from a Medicare-approved home health agency. Home health services, which in 2004 are expected to account for $10.7 billion in Medicare payments, often allow beneficiaries to avoid more costly inpatient care.

Medicare pays home health agencies under a prospective payment system. The payment system was moved to a calendar year update cycle as a result of the provisions of the Medicare Modernization Act. Under the prospective payment system, Medicare pays at higher rates to care for those beneficiaries with greater needs. Payment rates are based on relevant data from patient assessments conducted by clinicians as already required for all Medicare-participating home health agencies.

Growth in Federal Expenditures for Home Health Care ($ in billions)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.4</td>
<td>8.4</td>
<td>12.6</td>
<td>21.9</td>
<td>26.1</td>
<td>30.5</td>
<td>33.6</td>
<td>34.5</td>
<td>33.6</td>
<td>32.3</td>
<td>31.7</td>
<td>33.7</td>
<td>36.1</td>
</tr>
</tbody>
</table>

SOURCE: Centers for Medicare and Medicaid Services
MEDICARE ROLLS OUT PRESCRIPTION DRUG CARDS

The Centers for Medicare and Medicaid Services (CMS) predict that Medicare beneficiaries can save 46%-92% of the cost of many popular brand-name drugs by purchasing generic drugs through a Medicare drug discount card. The Medicare Modernization Act of 2003 authorized coverage of prescription drugs and also authorized the use of negotiated discounts by Medicare. Enrollees can apply for cards and benefit from saving because of two changes Medicare has made: first, as part of the Medicare-approved Drug Discount Card program, Medicare now provides personalized information to beneficiaries on the availability of less expensive generics for their prescription drug needs; and second, Medicare drug cards provide substantial new price discounts on generic drugs.

Medicare beneficiaries can learn more about the drug discount program at www.medicare.gov.

HIPAA BLOG

Are you finding that you can’t get enough HIPAA? Do you “blog” (or “blawg”)? JW Partner Jeff Drummond has been keeping up a weblog (or “blog”) on HIPAA issues for over 2 years (since it’s law-related, it’s sometimes called a “blawg”). It’s an archive of HIPAA thoughts and analysis, frequently updated, and loaded with HIPAA links. Visit the hip(aa) corner of Blogistan at www.hipaablog.blogspot.com