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Incentive Payment and Shared Savings Programs—The New Gainsharing

By CATHERINE MARTIN

On July 7, 2008¹, the Centers for Medicare & Medicaid Services (CMS) issued the CY 2009 Medicare Physician Fee Schedule Proposed Rule (“Proposed Rule”)² which included a new exception to the physician self-referral law (commonly referred to as the Stark Law) for gainsharing programs and other quality-based initiatives. This proposal is especially timely, given the continued focus on the escalating cost of health care in the United States and the need for health care reform. It is widely recognized that health care costs are currently growing excessively and rapidly, such that at the current rate, the Medicare Hospital Insurance Trust Fund is expected to be depleted by 2019.³ In addition, concerns about quality of care and clinical waste in the system continue to be raised by patients, payers, and providers alike.

Hospitals are continually looking for creative ways to address these issues in the context of a health care system in which hospitals pay for products and services, while physicians determine which products and ser-

vices are used for each patient. Physicians control the vast majority of all spending—a phenomenon documented by numerous studies, including one recent study that identified 87 percent of all hospital costs as being under physician control.⁴ Moreover, physicians often know where the clinical waste exists, or could identify such places, if given better information regarding the specific types of care their colleagues have used successfully for particular patient populations. Physicians are in a unique position of being able to determine where costs can be decreased without compromising quality of care. Significantly, researchers have recognized physician control of these waste-reduction decisions as the “most careful, clinically effective, and humanly acceptable method of slowing U.S. health cost increases—and of doing so in a way that liberates the savings to finance coverage for all Americans.”⁵ Because physicians have both the power and knowledge to reduce health care costs in ways that are neutral or beneficial with respect to patients, physician cooperation is essential to hospitals’ efforts to contain costs.

Gainsharing provides a mechanism for aligning hospitals’ economic incentives with physicians’ interests and is a well-documented, viable method of facilitating this cooperation, to the benefit not only of hospitals, but also of patients and payers. Gainsharing is a term that is used to describe arrangements between hospitals and physicians whereby the hospital agrees to share with the physicians any reduction in the hospital’s costs for patient care attributable in part to the efforts of the physician. Typically, these payments are structured in a variety of ways, including hourly payments for services performed by the physician or as a percentage of the

¹ CMS will accept comments on the Physician Fee Schedule until Aug. 29, 2008.

² 73 Fed. Reg. 38502 (July 7, 2008), available at <http://edocket.access.gpo.gov/2008/pdf/E8-14949.pdf>.

³ 2008 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds, available at <http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2008.pdf>.

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⁴ Alan Sager and Deborah Socolar, “Health Costs Absorb One-Quarter of Economic Growth, 2000-2005,” Boston University School of Public Health (Feb. 2005), at 29.

⁵ *Id.* at 30.

cost savings realized under the arrangement. A recently published independent scientific analysis of some of the gainsharing programs approved by the Office of the Inspector General (OIG)⁶ through the OIG's formal advisory opinion process concluded that the gainsharing programs selected for the study controlled costs while maintaining both quality of care and access to new clinically useful but expensive devices.⁷ This independent study speaks to the benefits of properly structured gainsharing arrangements.

Despite the guidance from the OIG and support from the industry and research community, gainsharing programs' fate under the Stark Law had remained uncertain prior to CMS's proposal in the Proposed Rule. This proposed exception to the Stark Law, if finalized, would protect traditional gainsharing arrangements and, as explained below, broader quality-focused initiatives.

Physician Self-Referral Law

Gainsharing arrangements and other quality-focused initiatives may implicate the Stark Law, which prohibits referrals by physicians for certain designated health services (DHS)⁸ to an entity with which the physician or an immediate family member has a financial relationship. It also prohibits any person from billing a federal health care program for services provided as a result of a prohibited referral. The term "financial relationship" is defined very broadly and includes direct or indirect ownership or compensation relationships. Where a direct or indirect financial relationship exists between a physician and an entity, the Stark Law prohibits referrals of DHS unless an exception applies. The Stark Law essentially defines the entity furnishing the DHS to be the entity billing and receiving payment from Medicare for the service. Intent to violate the Stark Law is not required. Therefore, if an activity is prohibited by the lan-

⁶ In addition to the Stark Law, traditional gainsharing raises concerns under the Civil Monetary Penalty (CMP) law (42 U.S.C. § 1320a-7a(b)(1) and (2)) and the federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)). These laws fall under the purview of the OIG. Since as early as 1999, the OIG has issued guidance on gainsharing, including the approval of 10 individual gainsharing programs through its formal advisory opinion process. Of the 10 approved gainsharing arrangements, six involve cardiac surgery, three involve cardiology, and one involves anesthesiology services provided during cardiac surgery. These opinions are available on the OIG Web site at: www.oig.hhs.gov/fraud/advisoryopinions/opinions.html.

While the focus of this article is on the new proposed Stark exception, readers should be familiar with the OIG guidance which is particularly instructive and consistent in many respects with the CMS proposal. See also OIG Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July 1999), available on the OIG Web site at: <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>.

⁷ Jonathan D. Ketcham and Michael F. Furukawa, "Hospital-Physician Gain Sharing in Cardiology," *Health Affairs*, Vol. 27, No. 3 (May/June 2008), 808, 809.

⁸ The Stark Law regulations define the following categories of items and services as DHS when covered by Medicare/Medicaid: clinical laboratory services; physical therapy, occupational therapy, and speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. 42 C.F.R. § 411.351.

guage of the Stark Law, then the activity must meet all the requirements of a Stark exception in order not to violate the law.

It is important to keep in mind that this newly proposed exception is not the only available exception for these types of arrangements. Rather, in many instances, gainsharing and other quality-focused initiatives can be structured to comply with already-existing exceptions to the Stark Law—personal services arrangements⁹, bona fide employment¹⁰, fair market value compensation arrangements,¹¹ and indirect compensation arrangements.¹² In other instances, an exception may not be necessary—for example, in the case of an incentive payment paid directly from a payer at the payer's sole discretion to a physician for the physician's efforts in improving quality.

CMS's Approach to Gainsharing and Other Quality-Based Initiatives

Current Demonstrations

In addition to the recent proposal, CMS has been actively evaluating the benefits of properly structured gainsharing arrangements. CMS has initiated three new gainsharing demonstration projects over the past three years. One of these projects, the DRA 5007 Medicare Hospital Gainsharing Demonstration, responds to a mandate in the Deficit Reduction Act of 2005 (DRA) to study whether gainsharing can improve quality and efficiency of inpatient care, and also improve hospital operational and financial performance.¹³ This project, which is currently ongoing, is designed to review the short-term impact of gainsharing programs in six hospitals nationwide (including two rural hospitals). In addition, the Medicare Modernization Act (MMA) authorized a CMS demonstration project, the MMA Section 646 Physician Hospital Collaboration Demonstration.¹⁴ This project is open to up to 72 hospitals nationwide (including consortia of health care groups—with a maximum of 12 hospitals per consortium) and is designed to assess quality improvements and cost reductions in health delivery systems by tracking patients long-term for entire episodes of care. Most recently, CMS announced a new demonstration, the Medicare Acute Care Episode (ACE) Demonstration, which will provide bundled payments for acute care episodes involving cardiac and orthopedic inpatient surgical services in order to align incentives between hospitals and physicians, and thereby improve quality and efficiency of care.¹⁵

⁹ 42 C.F.R. § 411.357 (d).

¹⁰ 42 C.F.R. § 411.357 (c).

¹¹ 42 C.F.R. § 411.357 (l).

¹² 42 C.F.R. § 411.357 (p).

¹³ For more information, see [http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none & filterByDID=-99&sortByDID=3&sortOrder=ascending& itemID=CMS1186805&intNumPerPage=10](http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=ascending&itemID=CMS1186805&intNumPerPage=10).

¹⁴ This demonstration project is also known as the Medicare Health Care Quality (MHCQ) Demonstration Program. For more information, see [http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none & filterByDID=-99&sortByDID=3&sortOrder=ascending& itemID=CMS1186653&intNumPerPage=10](http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=ascending&itemID=CMS1186653&intNumPerPage=10).

¹⁵ For more information, see <http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none &>

Regulatory Activity

Aside from the CMS demonstration projects, guidance on gainsharing has come primarily from the OIG, with the question of “What about Stark?” going unanswered. On April 14, 2008 CMS issued its FY 2009 Hospital Inpatient Prospective Payment System proposed rule (2009 IPPS proposed rule)¹⁶ that included a solicitation of comments requesting industry input on whether an exception to the Stark Law was warranted for gainsharing arrangements. Specifically, CMS sought comments on (1) whether CMS should establish an exception to the Stark Law for gainsharing arrangements; (2) what safeguards should be included in an exception for gainsharing arrangements; and (3) whether certain services, clinical protocols or other arrangements should not qualify for an exception, if one is ultimately proposed by CMS.

This solicitation came on the heels of the CY 2008 Proposed Medicare Physician Fee Schedule (2008 PFS proposed rule)¹⁷, where CMS expressed 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 Stark Law. In the 2008 PFS proposed rule, CMS indicated that it may revise the special rules on compensation to clarify that percentage-based compensation arrangements (1) may be used only for paying for personally performed physician services; and (2) must be based on the revenues resulting directly from the physician services and not based on “some other factor such as a percentage of the savings by the hospital department.”¹⁸ If those changes are finalized—and an adequate gainsharing exception is not finalized—the ability of hospitals and physicians to participate in gainsharing arrangements will be significantly impaired. In the 2009 IPPS proposed rule, CMS acknowledges this result and, more importantly, acknowledges the value to the Medicare program and its beneficiaries when properly structured gainsharing arrangements result in improvements in quality of care.

Most recently, CMS proposed a new exception to the Stark Law for gainsharing programs and other quality-based initiatives. The following is an overview of the proposed exception and some practical considerations.

Proposed Stark Law Exception: Incentive Payment and Shared Savings Programs

CMS proposes a new exception (to be located at § 411.357(x)) for a variety of programs, including gainsharing, pay-for-performance (P4P), value-based purchasing, and other programs seeking to foster improvements in health care quality and efficiency through financial incentives.¹⁹ As noted above, the CMS solicitation of comments in the FY 2009 IPPS proposed rule was limited to gainsharing. The Proposed Rule goes beyond traditional gainsharing and includes other quality-focused initiatives. Still, CMS notes in the Proposed Rule that its proposed exception is relatively nar-

row and that the agency is soliciting comments on ways to expand the exception to include other types of innovative, beneficial arrangements without exposing the Medicare program and its beneficiaries to an undue risk of fraud and abuse. The CMS proposal contains many similar, if not the same, safeguards and protections included in the favorable gainsharing opinions issued by the OIG—namely, criteria designed to establish transparency, quality controls and safeguards against payments for referrals.

CMS refers to the proposed exception as relating to “incentive payment and shared savings programs” but requests comments on whether the proposal is too limited or too expansive. CMS also welcomes suggestions of alternative terminology to describe the scope of programs that should be included in the revised exception. The proposed regulation would apply to both incentive payment (i.e., P4P and quality-focused programs) and shared savings programs (i.e., gainsharing and other economic models), though CMS requests comments on whether separate exceptions should be proposed and, if so, which requirements should be included in each. For most of the proposed requirements and safeguards, CMS provides regulation text as well as commentary, though in a few cases, CMS describes its proposal and requests comments on appropriate ways to incorporate the proposal into the regulations.

As a general matter, CMS notes that the proposed exception would protect payments made to physicians participating in the programs as individuals or to physician organizations composed wholly of participating physicians, provided that such “qualified physician organizations” distributed payments on a per capita basis to participating physicians. CMS registers its concern with programs that led physicians to (1) limit their use of quality-improving but expensive devices, tests, or treatments (stinting); (2) treat only relatively healthier patients (cherry-picking); (3) avoid relatively sicker patients (steering); (4) or discharge patients to home or post-acute care settings earlier than clinically indicated (quicker-sicker discharge). Further, CMS expresses concern with programs that directly or indirectly provide for payments in exchange for patient referrals or that result in unfair competition among hospitals. All of CMS’s identified concerns are shared by the OIG.

The proposed requirements fall into three categories: (1) Design of incentive payment and shared savings programs; (2) limitations and conditions for payments to physicians under the programs; and (3) requirements for the arrangements between the hospitals and the physicians participating in the programs.

Design and Structure of the Program

With respect to program design, CMS proposes to require programs to include patient care quality or cost savings measures (or both) that are supported by objective, verifiable, independent medical evidence indicating that the measures would not negatively impact patient care. The proposal is applicable only to hospital-sponsored programs, but CMS is soliciting comments on whether the exception should be expanded to include programs sponsored by nonhospital providers.

Specific to quality of care measures, the proposal would require that the selected measures be including in CMS’s Specification Manual for National Hospital Quality Measures (NHQM). CMS is also considering an alternative proposal, whereby inclusion of measures on

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¹⁶ 73 Fed. Reg. 23528 (April 30, 2008). The 2009 IPPS proposed rule comment period closed on June 13, 2008.

¹⁷ 72 Fed. Reg. 38122 (July 12, 2007).

¹⁸ *Id.* at 38184.

¹⁹ 73 Fed. Reg. 23528, 23694 (April 30, 2008).

the NHQM list would be deemed to satisfy this requirement of the exception but other measures would be permitted, subject to CMS approval on a case-by-case basis. CMS also proposes to require that the programs be reviewed by an independent person or organization with relevant clinical expertise before the program is implemented, and at least annually thereafter, to determine the program's impact on the quality of patient care services provided by the hospital. Appropriate corrective action would need to be taken depending on the outcome of these reviews, and CMS will consider comments on appropriate types of corrective action and on how to incorporate this requirement into the regulation text.

CMS proposes to require physicians participating in the program to do so in "pools" of at least five participating physicians, among whom the payments will be divided on a per capita basis. Participating physicians must be members of the sponsoring hospital's medical staff at the commencement of the program. CMS is soliciting comments on how to handle physicians who join the medical staff after commencement of the program as part of the normal cycle of the work force. The hospitals would be required to continue permitting participating physicians to access the same sets of items, supplies and devices that were available prior to the physicians' participation in the program. The hospitals would be prohibited from restricting the availability of items, supplies or devices (including new technology linked by objective evidence to improved outcomes) that meet Federal regulatory standards and are determined to be medically necessary for the patient's care.

Of note, CMS proposes to prohibit payments under product standardization programs to physicians or physician organizations for the use of items, supplies or devices, if the physician or organization has an ownership or investment interest in, or a compensation relationship with, (1) the manufacturer or distributor or the item, supply, or device; or (2) a group purchasing organization (GPO) that arranges for the purchase of the item, supply or device. This restriction would apply to any compensation relationship—even a physician serving as a clinical research principal investigator. CMS appears concerned with these types of companies and is questioning the impact on medical decision-making. Additionally, CMS is seeking comments on whether programs that include product standardization measures disadvantage small manufacturers of items, supplies and devices, and on how product standardization could be achieved without restricting patient access to items, supplies and devices beneficial to patient care.

Limitations and Conditions on Payments

In addition to the requirement for per capita-based payment distribution (mentioned above), another proposed payment requirement is that payment must be made directly to the physician or to the qualified physician organization.²⁰ The proposal includes a prohibition on including in payments to physicians or physician organizations any amounts that take into account the provision of an increased volume of services to federal health care program beneficiaries, when compared with the volume provided during a period of equal length immediately preceding implementation of the program.

²⁰ The phrase "qualified physician organization" is defined in the proposed regulations at 42 C.F.R. § 411.351.

CMS is soliciting comments on how to address volume increases due to market dynamics or physician practice expansion. CMS also proposes to limit program duration to at least one, but no more than three, years, which is a welcome expansion to the limited scope and duration of the gainsharing programs approved by the OIG.

CMS proposes two types of limitations on payments, which could be adopted independently or together: (1) A limit on payments calculated as a defined percentage of the savings available to hospitals generated by participating physicians' changes in clinical or administrative practices (e.g., a 50 percent cap for programs of any length, or a reduced percentage cap each year for multi-year programs); and (2) for multi-year programs, a limit on payments that takes into account payments already made under the program to physicians for achieving performance measures (re-basing). What should not come as a surprise to the industry—and what is wholly consistent with OIG guidance—is CMS's explicit statement that payments may not be based in whole, or in part, on a reduction in the length of stay for a particular patient or in the aggregate.

CMS is considering whether to allow the exception to cover payments from hospitals to physician organizations that include both participating and nonparticipating physicians (e.g., multi-specialty practices when the program includes only certain specialties), where the organization would be responsible for passing through payments to participating physicians. CMS identifies one benefit of an appropriately structured pass-through proposal as avoiding confusion that could otherwise be created in relation to the "stand in the shoes" provisions in 42 C.F.R. § 411.354(c)(2).

Requirements for Hospital-Physician Arrangements

With respect to the requirements for hospital-physician arrangements, CMS proposes to include the criteria common to most Stark Law exceptions for compensation arrangements. Included among these are the requirements that the arrangement (1) be set out in writing, signed by the parties, and specify compensation (or formula) that is set in advance, does not vary during the term of the arrangement, and is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties; (2) be disclosed in writing to patients affected by the program; and (3) not violate the federal anti-kickback statute. The disclosure to patients affected by the program would be required to identify the physicians participating in the program, disclose that physicians receive payment under the program and describe the performance measures. In addition, the proposal includes substantial documentation requirements that must be made available to the secretary of the Department of Health and Human Services upon request. Required documentation includes a basis for the selection of performance measures, selection and qualification of independent medical reviewer, written findings of the independent medical review and any corrective actions, and the amount and calculation of payment.

CMS also proposes to require monitoring by an independent outside party, or an internal committee of the patient population treated by participating physicians, in order to identify any significant changes from the hospital's historical measures. Significant changes re-

lating to one physician would require that physician's termination from the program, and significant changes spread across all participating physicians would require the termination of the entire program.

Practical Considerations

While the proposed exception provides much-needed guidance and insight into CMS's thinking with respect to gainsharing and quality-focused programs, the exception as currently drafted is very narrow and presents some practical concerns worth mentioning. Here are a few items for consideration:

- **Required Patient Disclosures:** The required patient disclosures are significant, and it is unclear how the disclosures would work with respect to quality-focused measures. For example, if a quality measure requires the physician to document the patient encounter in the patient's electronic health record within 24 hours of the encounter, what disclosure to the patient would be required and is such a disclosure even feasible?
- **Pooling of Five or More Physicians:** This provision corresponds with the "group practice" definition under the Stark Law and the rules related to payment of productivity bonuses and profit shares. This requirement, however, may prove difficult to satisfy for hospitals that have fewer than five physicians practicing in certain specialties and may limit the ability of some hospitals to utilize the exception.
- **Independent Medical Review:** While everyone would agree that ensuring quality of care is of paramount importance, the requirement related to independent medical review—by an individual not affiliated with the sponsoring hospital nor with any participating physician or physician organization to which any participating physician belongs, and not participating in an incentive payment or shared

savings program in the hospital—may prove difficult to satisfy. Hopefully, the comment period will lead CMS to soften this requirement to avoid the creation of a new cottage industry of medical experts, and to permit hospitals to tap into their already-existing internal quality oversight programs.

- **Audit Requirements:** CMS is proposing to require auditing of the incentive payment or shared savings program, but has not proposed specific regulatory text. Rather, CMS is soliciting comments regarding the formality of the audit requirements. It is unclear why CMS did not propose regulatory text for this requirement. Depending on the scope, timing and frequency of any audit requirements, a concern exists that such a requirement would create another cottage industry for a function that could be appropriately managed internally at the sponsoring hospital.

Conclusion

We are clearly entering a new era of thinking about improving health care quality, controlling cost, and using collaboration among the health care provider community to achieve these goals. Gainsharing and quality-focused initiatives continue to gain momentum offering hospitals and other providers a real opportunity to contain costs, reduce waste, and maintain or improve quality. Thankfully, CMS has recently proposed a new exception to the Stark Law for incentive payment and shared savings programs, which provides further guidance on gainsharing and other quality-focused efforts and may ultimately help to answer the question, "What about Stark?" While the proposal is narrow in scope, CMS is soliciting comments on numerous facets of the proposed exception, and has indicated a willingness to expand or modify this proposal if finalized.