Proposed 2009 Physician Fee Schedule Would Adopt Gainsharing Stark Exception

On June 30, the Centers for Medicare and Medicaid Services ("CMS") released the Proposed 2009 Medicare Physician Fee Schedule Update ("2009 PFS Update"), published in the *Federal Register* today. Among significant changes, including a 5.4 percent reduction in overall payments under the physician fee schedule (in addition to the reduction, if any, that ultimately takes effect for 2008), revisions to the Physician Quality Reporting Initiative, and amendments to the anti-markup rule that governs purchased diagnostic tests, CMS has proposed to add an explicit gainsharing exception to the Stark regulations.

Proposed Gainsharing Exception

History

Over the past decade, "gainsharing" programs adopted by certain hospitals have paid physicians for achieving identified quality measures (*e.g.*, reduction of infection rates), known as "quality-based gainsharing," or cost-saving benchmarks (*e.g.*, reduction of per-case orthopedic supply costs), known as "savings-based gainsharing." Some of the savings-based gainsharing programs have received favorable Advisory Opinions from the Office of the Inspector General of the Department of Health and Human Services ("OIG"), safeguarding them from challenge under the federal anti-kickback statute and the federal civil monetary penalties law. By statute, however, OIG Advisory Opinions cannot protect programs from potential exposure under the Stark law, which is subject to interpretation by CMS.

In July 2007, in the Proposed 2008 Medicare Physician Fee Schedule Update, CMS included a proposed rule that would have revised the "set in advance" requirement in the Stark regulations to require that percentage compensation arrangements (i) "be used only for paying for personally performed physician services" and (ii) "be based on revenues directly resulting from the physician services rather than based on some other factor such as percentage of the savings by a hospital department (which is not directly or indirectly related to the physician services provided)." Adoption of this rule, many feared, could prohibit gainsharing programs that pay physicians a percentage of cost savings.

In April 2008, in the Proposed 2009 Medicare Hospital Inpatient Prospective Payment System Update, CMS solicited comments "as to whether [it] should establish [a Stark] exception for gainsharing arrangements, and, if so, what safeguards should be included in the exception." The proposed exception contained in the 2009 PFS Update is the product of that process.

Proposed Stark Exception

The proposed exception addresses both "incentive payment" programs (*i.e.*, quality-based gainsharing) and "shared savings" programs (*i.e.*, savings-based gainsharing). In commentary, CMS indicated that the extremely detailed 16-element rule is intended to guard against the risks that gainsharing programs may lead to limiting costly services ("stinting"); favoring healthier and cheaper patients ("cherry picking") or disfavoring sicker and more expensive patients ("steering"); inappropriately limiting length of stay ("quicker and sicker discharge"); and generating abusive referrals by improperly increasing the percentage payments due to physicians or manipulating outcomes data.

Many of the requirements of the proposed exception mirror the characteristics of the gainsharing programs that have been the subject of favorable OIG Advisory Opinions. Key limitations in the exception include:

- *Hospital-Only.* The exception is available only for hospital-based programs, not programs undertaken by other entities, whether paid under the prospective payment system or on a fee-for-service basis.
- *Participation.* Programs must include a pool of at least five physicians, with all physicians participating in gainsharing payments on a *per capita* basis. Participating physicians must be on a hospital's medical staff at the commencement of the program—new members of a hospital's medical staff may not participate in preexisting gainsharing programs.
- *Measures.* Programs must include measures that are supported by an objective methodology, are verifiable, and are tracked individually. Quality (as opposed to cost-savings) measures must be listed in the CMS/JCAHO Specification Manual for National Hospital Quality Measures. Baselines must be reset each year, so that physicians are not paid in subsequent years for prior-year achievements. In commentary, CMS indicated that it ultimately may require that baselines be reset only for savings-based programs, not for quality-based programs. In addition, CMS indicated that, instead of requiring that baselines be reset annually, it may adopt an alternate approach that would prospectively reduce percentage payments in successive years.
- *Monitoring.* An independent monitor must review each program's impact on the quality of patient care services prior to a program's commencement and at least annually thereafter during the life of the program.
- *Payments.* Payments may not be based in whole or in part on reductions in length of stay, and amounts attributable to year-over-year increases in aggregate Medicare business must be carved out of the calculation of gainsharing payments. Additionally, physicians may not receive payments for the use of products with respect to which the physicians have an ownership or investment interest or a compensation arrangement. Finally, while not reflected in the rule itself, CMS indicated that it is considering a strict 50 percent cap on the portion of cost savings that hospitals may pay to physicians.
- *Duration.* Programs must have a term of at least one year and at most three years.
- *Notice to Patients.* Hospitals must give patients prior written notice describing gainsharing programs in place, including the performance measures to be used and identification of the participating physicians.

Issues to Watch

Preexisting Gainsharing Programs. The proposed rule does not require that the gainsharing exception would be the sole exception available for programs to comply with Stark. However, the CMS commentary accompanying the proposed rule, and commentary that would accompany any final rule, will be highly relevant to existing programs, which should be reviewed to ensure continuing compliance.

Other Percentage-Based Compensation. Adoption of a gainsharing exception could pave the way for CMS to implement its proposed restriction on percentage-based compensation. Hospitals, physician groups, and individual physicians that currently have or that are considering new percentage-based compensation arrangements should be prepared to analyze and, if necessary, revise such arrangements if CMS proceeds to adopt the July 2007 proposed rule.

Physician Interests in Device Manufacturers. In April 2008, CMS indicated that it was considering a rule that would deem device companies to be entities that furnish designated health services, and therefore subject relationships between physicians and device companies to the same Stark rules currently applicable to relationships between physicians and hospitals. The 2009 PFS Update did not address that proposal, but the requirement in the gainsharing exception that physicians

may not receive payments for the use of products with respect to which the physicians have an ownership or investment interest or a compensation arrangement confirms CMS's continued interest in physician–device company relationships. Physicians and device companies should watch for further developments and restrictions in this area.

Ask Ropes & Gray

If you have any questions about the proposed gainsharing exception, or other provisions of the proposed update to the physician fee schedule, please contact your Ropes & Gray attorney or one of the attorneys listed below.

Larry S. Gage
Washington Office
202-508-4761

Mitchell J. Olejko
San Francisco Office
415-315-6328

Daniel T. Roble
Boston Office
617-951-7476

Stephen A. Warnke
New York Office
212-841-0681

Click here for the Proposed 2009 Medicare Physician Fee Schedule Update as published in the Federal Register. Discussion of the proposed gainsharing exception begins on page 38548, and the text of the proposed gainsharing exception begins on page 38604.