JONES DAY

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COMMENTARY

Congress Amends Gainsharing Civil Monetary Penalties and Commissions Further Study of Gainsharing Arrangements

On April 16, 2015, President Obama signed into law the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). Most prominently, MACRA repealed the Sustainable Growth Rate formula, creating a permanent solution to threatened reductions in Medicare reimbursement rates for physicians and eliminating the need for Congress's annual "doc fix" ritual. But MACRA also contained significant changes related to gainsharing, including an amendment of the gainsharing civil money penalties ("CMPs") and the commissioning of a gainsharing study and report from the Secretary of Health and Human Services ("HHS"). The gainsharing provisions of MACRA, in conjunction with a recent proposed rulemaking from OIG in October 2014, should create significant new opportunities for aligning the financial interests of hospitals and physicians and bring added stability and certainty to existing gainsharing arrangements.

"Gainsharing" refers to arrangements where hospitals reward physicians with a percentage share of any reductions in the hospital's patient care costs attributable to the actions of the physician. Although gainsharing arrangements can align hospital and physician interests to reduce unnecessary costs and wasteful services, such arrangements also pose a risk of inducing physicians to stint on necessary care or discharge patients early. To address this risk, Section 1128A(b)(1) of the Social Security Act subjects hospitals or critical access hospitals that "knowingly [make] a payment, directly or indirectly, to a physician as an inducement to reduce or limit services" to Medicare beneficiaries to CMPs of up to $2,000 per individual, and Section 1128A(b)(2) of the Social Security Act subjects physicians to identical CMPs for accepting such payments (together, the "Gainsharing CMPs"). The Office of the Inspector General ("OIG") of HHS has consistently interpreted the Gainsharing CMPs to apply to any reduction in services, not just reductions in medically necessary services. OIG has acknowledged that this prohibition is broad and potentially includes beneficial gainsharing arrangements, but OIG has repeatedly stated that it could not read a "medically necessary" element into the Gainsharing CMPs.

Over time, old concerns about limiting care gave way to new concerns about growing health care costs and efficient use of resources. While OIG continues to assert that any gainsharing arrangement between hospitals and physicians is a violation of the Gainsharing CMPs, OIG has exercised its enforcement discretion to allow certain carefully crafted gainsharing arrangements.

Since 2002, OIG has approved 16 gainsharing arrangements via the advisory opinion process, and through these advisory opinions, OIG provided guidance on the key factors for structuring gainsharing agreements to avoid the risk of abuse. In October 2014, OIG took further steps to accommodate certain gainsharing arrangements by proposing to "interpret certain provisions [of the Gainsharing CMPs] in a manner that reflects today's health care landscape." Specifically, OIG proposed to codify the Gainsharing CMPs in its regulations and also solicited comments on whether, and how, to define the phrase "reduce or limit services." OIG noted they sought to "interpret the statutory prohibition [on gainsharing] broadly enough to protect beneficiaries and Federal health care programs, but narrowly enough to allow low risk programs that further the goal of delivering high quality health care at lower cost." Yet OIG also recognized that its options were somewhat restricted because, in spite of various developments that had made gainsharing more palatable and perhaps even beneficial, Congress had not amended the Gainsharing CMPs, and OIG had no statutory authority to create exceptions to the Gainsharing CMPs.

With the passage of MACRA, Congress has opened the door for precisely these sorts of exceptions. First, Congress specifically amended the Gainsharing CMPs by inserting the phrase "medically necessary." Going forward, hospitals and physicians will be subject to the Gainsharing CMP only if they "reduce or limit *medically necessary* services" to Medicare beneficiaries. Arrangements that induce reductions or limitations in unnecessary services to Medicare beneficiaries will not violate the Gainsharing CMPs, although providers should continue to carefully review such agreements with counsel to avoid violation of the Anti-Kickback Statute and Stark Law. Providers should also note that the amendment of the Gainsharing CMPs is prospective and does not apply retroactively to payments made before the effective date of MACRA; however, OIG noted in the October 2014 proposed rule that "pending further notice from OIG, gainsharing arrangements are not an enforcement priority for OIG unless the arrangement lacks significant patient and program safeguards."

MACRA also directs the Secretary of Health and Human Services to submit within 12 months a report to Congress containing options for statutory amendments, and related regulations such as exceptions and safe harbors, that would permit certain gainsharing arrangements otherwise subject to the Gainsharing CMPs. Congress specifically directed that the report (i) consider whether the Gainsharing CMPs should apply to ownership interests, compensation arrangements, and other relationships, (ii) describe how the recommendations address accountability, transparency, and quality, including how best to reduce incentives to improperly stint on care, and (iii) consider whether any savings generated by gainsharing arrangements should accrue to the Medicare Program. This report to Congress, and any related statutory amendments or regulatory interpretations and safe harbors, is likely to provide the foundation for the next generation of gainsharing arrangements. OIG has already developed a significant body of guidance regarding gainsharing arrangements through its advisory opinions, with a strong focus on accountability, quality control, and safeguards against payment for referrals. It is likely that HHS and OIG will use this existing body of guidance, along with the proposed regulations and comments from the October 2014 proposed rule, as the basis for their report.

At the moment, it is not clear how the gainsharing provisions of MACRA will affect the progress of OIG's October 2014 proposed rules related to gainsharing. OIG has not taken further action on the October 2014 proposed rule, or commented publicly on how the gainsharing report required by MACRA may alter or delay the progress of the October 2014 rulemaking. Believing at the time that it could not read "medically necessary" into the Gainsharing CMPs or craft regulatory exceptions to the statute, OIG's October 2014 rulemaking focused instead on soliciting comments regarding the definition of the phrase "reduce or limit services."

But even though Congress has now made precisely the amendment to the Gainsharing CMPs that OIG anticipated, the October 2014 proposal to define the phrase "reduce or limit services" remains important to future gainsharing arrangements. There is certainly potential to reduce wasteful spending via gainsharing arrangements that target medically unnecessary services, and MACRA makes such arrangements permissible. But there is also potential for gainsharing arrangements to use evidence-based approaches to promote shifts from more costly or inefficient services to cheaper and more efficient services.

Consider, for example, a gainsharing arrangement that seeks to promote, when appropriate, the less costly of two (or more) medically necessary services or items that are equally effective (e.g., a generic versus a name-brand drug, or a standard size versus uniquely sized item or device). The ability to pursue the latter type of arrangement, and the requirements for structuring them, may depend on the definition of "reduce or limit services." OIG may choose to address the definition of "reduce or limit services" as part of its report to Congress, or it may address the issue separately through continuation of the proposed rulemaking initiated in October 2014.

Providers who are interested in utilizing gainsharing arrangements are likely to have new options available in the future, and providers who have utilized certain limited gainsharing arrangements in the past based on guidance in OIG advisory opinions are likely to have more certainty regarding the risk of potential enforcement actions. Congress's action in MACRA comes on the heels of generally positive reports from the first round of Medicare accountable care organizations, which waived certain gainsharing restrictions and allowed for participants to share in cost savings in order to promote better coordinated care among providers. As such value-based payment programs continue to develop and spread, gainsharing arrangements may develop into a key tool for aligning provider incentives to reduce costs while maintaining high quality care. For now, providers can rely on the revised Gainsharing CMPs, which restrict only inducements to reduce medically necessary services, as well as prior OIG guidance on the structuring of gainsharing arrangements to present a low risk of abuse. However, certain questions regarding gainsharing remain unsettled, including how OIG will define the phrase "reduce or limit" services and what the scope of "medically necessary" will be.

HHS is required by MACRA to submit the gainsharing study and report to Congress by April 2016. Jones Day will monitor the development of this report, as well as actions related to the October 2014 proposed rules, and is available to provide assistance with gainsharing arrangements for parties interested in aligning the financial interest of hospitals and physicians.

Lawyer Contacts

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