

Report to Congress

**Options for Potential Changes to Fraud and Abuse Laws Regarding Gainsharing or
Similar Arrangements between Physicians and Hospitals As Required by Section 512(b) of
the Medicare Access and CHIP Reauthorization Act of 2015**

United States Department of Health and Human Services
Centers for Medicare & Medicaid Services

EXECUTIVE SUMMARY

Section 512(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (P.L. 114-10) (MACRA) requires the Secretary of the Department of Health and Human Services (HHS), in consultation with the Inspector General of HHS, to submit to Congress “a report with options for amending existing fraud and abuse laws in, and regulations related to, titles XI and XVIII of the Social Security Act, through exceptions, safe harbors or other narrowly tailored provisions, to permit gainsharing arrangements that otherwise would be subject to the civil money penalties described in paragraphs (1) and (2) of section 1128A(b) of such Act, or similar arrangements between physicians and hospitals, and that improve care while reducing waste and increasing efficiency.” Pursuant to section 512(b), the report shall:

- Consider whether such provisions should apply to ownership interests, compensation arrangements, or other relationships;
- Describe how the recommendations address accountability, transparency, and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care; and
- Consider whether a portion of any savings generated by such arrangements (as compared to a historical benchmark or other metric specified by the Secretary to determine the impact of delivery and payment system changes under title XVIII on expenditures made under such title) should accrue to the Medicare program.

With respect to section 1877 of the Social Security Act (the Act), this report offers the following possible approaches:

- New statutory exceptions could be added for: (1) compensation paid to physicians under gainsharing arrangements that improve or maintain care while reducing waste and increasing efficiency; (2) incentive compensation arrangements for the provision of services or activities that achieve predetermined, appropriate quality, cost, or performance goals; and/or (3) addressing whether and, if so, how the “volume or value” and “other business generated” standards should apply to gainsharing and similar arrangements that contain appropriate accountability, transparency, and quality protections and do not induce care stinting, premature discharge of patients, or otherwise reduce or limit medically necessary care.
- The Secretary’s authority in section 1877(b)(4) of the Act could be amended to permit regulatory exceptions to the physician self-referral law that pose no undue risk of program or patient abuse. Amending this section of the Act could permit new exceptions to protect referrals for and the provision of designated health services under appropriately structured gainsharing and similar arrangements.

BACKGROUND

A. Section 512 of MACRA

Section 512(b) of MACRA requires the Secretary, in consultation with the Inspector General of HHS, to submit to Congress, “a report with options for amending existing fraud and abuse laws in, and regulations related to, titles XI and XVIII of the Social Security Act, through exceptions, safe harbors or other narrowly tailored provisions, to permit gainsharing arrangements that otherwise would be subject to the civil money penalties described in paragraphs (1) and (2) of section 1128A(b) of such Act, or similar arrangements between physicians and hospitals, and that improve care while reducing waste and increasing efficiency.” Pursuant to section 512(b), the report shall:

- Consider whether such provisions should apply to ownership interests, compensation arrangements, or other relationships;
- Describe how the recommendations address accountability, transparency, and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care; and
- Consider whether a portion of any savings generated by such arrangements (as compared to a historical benchmark or other metric specified by the Secretary to determine the impact of delivery and payment system changes under title XVIII on expenditures made under such title) should accrue to the Medicare program.

We interpret this mandate to require a report regarding: (1) gainsharing arrangements subject to sections 1128A(b)(1) and (2) of the Social Security Act (the Act) that improve or maintain care while reducing waste and increasing efficiency¹; and (2) arrangements between physicians and hospitals that are similar to gainsharing arrangements and that improve or maintain care while reducing waste and increasing efficiency.

B. Gainsharing and Similar Arrangements

In the health care context, gainsharing typically refers to an arrangement between entities and individuals that furnish health care services—often a hospital and the physicians who treat the hospital’s patients—that establishes a formal reward system wherein participants share in cost savings or increased profits resulting from the efforts or actions of the provider receiving the payment.² In contrast, shared savings arrangements include both providers³ and payors. Under a shared savings arrangement, a payor shares with a provider the savings that result when the payor’s expenditures on patient care services are lower than the expected amount. This report

¹ Section 512(a) of MACRA amended sections 1128A(b)(1) and (2) of the Act. We discuss the implications of the amendment in section C of this report.

² *The Payment Reform Glossary*, Center for Healthcare Quality & Payment Reform, available at <http://www.chqpr.org/downloads/paymentreformglossary.pdf> (last visited Feb. 26, 2016).

³ For purposes of this report, the term “providers” includes both providers and physicians and other suppliers as defined in 42 CFR 400.202.

does not address shared savings programs or arrangements, including arrangements for the distribution of shared savings among providers.

Arrangements similar to gainsharing, which we refer to as “incentive compensation” arrangements may take many forms, including value-based purchasing (VBP) or “pay for performance” (P4P). Incentive compensation arrangements include a diverse set of arrangements used by either providers or payors that involve payment for performing certain actions or achieving quality, cost, or performance goals, regardless of whether cost savings are achieved. For instance, in addition to salary and productivity bonus payments, a physician group may pay incentive compensation to its members for their efforts to improve the quality of care provided to the group’s patients. Similarly, a hospital may pay incentive compensation to physicians who practice at the hospital for activities that support the hospital’s internal efforts in waste reduction or infection control. An incentive compensation program could also involve payments by payors to their participating providers. When sponsored by a payor, incentive compensation pays providers for high-value or low-cost care, with payments calculated by evaluating the provider’s performance relative to benchmarks on predetermined measures.

C. Fraud and Abuse Laws Affecting Gainsharing and Similar Arrangements

The Civil Monetary Penalty Law

Sections 1128A(b)(1) and (2) of the Act (the gainsharing CMP), as amended by section 512(a) of MACRA, prohibit a hospital or critical access hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit medically necessary services to Medicare or Medicaid beneficiaries under the physician’s care. Prior to the MACRA revision, the gainsharing CMP prohibited a hospital or critical access hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit *any* services to Medicare or Medicaid beneficiaries under the physician’s care. Hospitals that make (and physicians that receive) prohibited payments are liable for civil monetary penalties of up to \$2,000.00 per patient covered by the payments.

The Anti-kickback Statute

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services payable by a Federal health care program. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000.00,

imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid.

The anti-kickback statute itself includes a number of statutory exceptions to its general prohibition. See section 1128B(b)(3) of the Act. The same provision authorizes the Secretary to issue additional exceptions through regulation, known as “safe harbors.” The safe harbor regulations at 42 CFR 1001.952 describe various payment and business practices that, although they potentially implicate the anti-kickback statute, are not treated as offenses under the statute.

In accordance with section 1128(D)(b) of the Act and 42 CFR part 1008, OIG issues advisory opinions about the application of the anti-kickback statute (and other fraud and abuse authorities) to a requesting party's existing or proposed business arrangement. One purpose of the advisory opinion process is to provide meaningful advice on the application of the anti-kickback statute in specific factual situations. A party that receives a favorable advisory opinion is protected from OIG administrative sanctions based on the anti-kickback statute, so long as the arrangement at issue is conducted in accordance with the facts submitted to the OIG. A number of advisory opinions have approved of gainsharing arrangements. *See* OIG Advisory Opinions 01-01, 05-02, 05-03, 05-04, 05-05, 05-06, 06-22, 07-21, 07-22, 08-09, 08-15, 08-21, and 09-06.

The Physician Self-referral Law

1. General background

Unless the requirements of an applicable exception are satisfied, section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain “designated health services” (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation); and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse.

The provision of remuneration, whether in cash or in kind, by a hospital or other entity to a physician through a gainsharing or other incentive payment arrangement would constitute a compensation arrangement for purposes of the physician self-referral law, and the arrangement would need to satisfy the requirements of an applicable exception if the physician makes referrals to the entity for DHS that are billed to Medicare. This is true even if the arrangement relates only to the reduction or limitation of medically unnecessary services. Existing exceptions to the physician self-referral law, while useful, may not be sufficiently flexible to encourage a variety of nonabusive and beneficial gainsharing, P4P, and similar arrangements.⁴

Many of the statutory exceptions relating to compensation arrangements include a requirement that the compensation paid under the arrangement is not determined in a manner that takes into

⁴ See 73 FR 38502, 38548 (Jul. 7, 2008).

account the volume or value of referrals by the physician who is a party to the arrangement.⁵ Some exceptions also include a requirement that the compensation is not determined in a manner that takes into account other business generated between the parties. We refer to these as the “volume or value” and “other business generated” standards.

The prohibition on compensation that takes into account the “volume or value” of referrals by a physician can pose impediments for the implementation of gainsharing arrangements, because compensation paid to a physician for reducing costs or increasing profits through changes to his or her patient care practices could be interpreted to take into account the volume or value of the physician’s referrals of DHS for Medicare beneficiaries. Similarly, depending on the nature and scope of the gainsharing arrangement, compensation in the form of gainsharing payments could be interpreted as taking into account the “other business generated” between the physician and the entity providing the payment.

2. Prior regulatory efforts with respect to gainsharing and similar arrangements

Section 1877(b)(4) of the Act grants the Secretary the ability to issue new exceptions for certain financial relationships. Specifically, the Act permits the Secretary to issue new regulations if “the Secretary determines, and specifies in regulations, [the new exception] does not pose a risk of program or patient abuse.” Thus, under section 1877(b)(4) of the Act, the Secretary may only issue exceptions where doing so would create no possible risk of program or patient abuse.

Recognizing the value to the Medicare program and its beneficiaries where the alignment of hospital and physician incentives results in improvements in quality care, in April 2008, we solicited comments regarding whether the Secretary should establish an exception specific to gainsharing arrangements and, if so, what safeguards should be included in the exception.⁶ Following this solicitation of comments, in July 2008, we proposed a new exception that would protect certain gainsharing and other arrangements that exist for the purpose of achieving quality standards, generating cost savings, and reducing waste.⁷ In order to address both “traditional” gainsharing arrangements as well as other innovative cost saving and waste reduction programs between and among entities and physicians, we referred to arrangements that could potentially fall within the scope of the proposed exception as “incentive compensation and shared savings arrangements.”⁸ Ultimately, we did not finalize the proposed exception.

Despite strong support for the establishment of an exception to the physician self-referral law for gainsharing and other incentive compensation arrangements, we were persuaded by commenters

⁵ For purposes of the physician self-referral law, “referral” is defined broadly and relates to DHS for which payment may be made under Medicare.

⁶ See 73 FR 23528, 23692-23694 (Apr. 30, 2008).

⁷ See 73 FR 38548-38558 (Jul. 7, 2008).

⁸ Since 2008, health care delivery and payment reform terminology has evolved. We now refer to arrangements exclusively between and among health care providers (including physicians and other suppliers) as “gainsharing” arrangements. In contrast, we now refer to payor-sponsored arrangements under which health care providers receive supplemental payments from the payor when lower-than-expected patient care expenditures are achieved as a “shared savings” arrangement. Despite its title, the July 2008 proposed exception did not address payor-sponsored “shared savings” arrangements.

that an exception that poses *no* risk of program or patient abuse could not provide sufficient flexibility for innovative, effective gainsharing and incentive compensation programs.⁹ Public comments on the proposed exception reinforced our initial concerns that “the variety and complexity of gainsharing and similar arrangements would make it difficult to craft a ‘one-size-fits-all’ set of conditions that are sufficiently ‘bright line’ to facilitate compliance and enforceability, yet sufficiently flexible to permit innovation without risk of program or patient abuse.”¹⁰

Waivers for the Medicare Shared Savings Program and Center for Medicare and Medicaid Innovation Initiatives

In January 2015, the Administration set a goal of tying 30 percent of traditional, fee-for-service Medicare payments to quality or value through alternative payment models (APMs), such as accountable care organizations (ACOs) or bundled payment arrangements, by the end of 2016 and 50 percent of payments to these models by the end of 2018.¹¹ The Secretary also set a goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016 and 90 percent of payments to quality or value by 2018, through programs such as the Hospital VBP Program and the Hospital Readmissions Reduction Program.¹² HHS met its 2016 APM goal ahead of schedule.¹³ As discussed below, the Secretary has found it necessary to waive the physician self-referral law and the anti-kickback statute to allow gainsharing and similar arrangements in connection with certain APMs.

Section 1899(f) of the Act authorizes the Secretary to waive certain fraud and abuse laws, including the physician self-referral law and the anti-kickback statute, as necessary to carry out the Medicare Shared Savings Program (Shared Savings Program) that establishes accountable care organizations (ACOs) in Medicare. On the basis of stakeholder input and experience with the Shared Savings Program, the OIG and CMS issued five waivers,¹⁴ including an “ACO pre-

⁹ See 73 FR 69726, 69793-69794 (Nov. 19, 2008). We determined that the initial public comment process following our proposed exception for “incentive compensation and shared savings” arrangements provided insufficient information or agreement among stakeholders regarding possible modifications to the proposal to allow us to finalize an exception that expanded the proposal in any meaningful way. Therefore, we re-opened the comment period to request additional information on more than 50 specific issues. See 73 FR 69795-69798.

¹⁰ 73 FR 38548.

¹¹ Press release titled “Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value,” U.S. Department of Health & Human Services (Jan. 26, 2015), <http://www.hhs.gov/news/press/2015pres/01/20150126a.html>.

¹² Press release titled “Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value,” U.S. Department of Health & Human Services (Jan. 26, 2015), <http://www.hhs.gov/news/press/2015pres/01/20150126a.html>.

¹³ Press release titled “HHS reaches goal of tying 30 percent of Medicare payments to quality ahead of schedule,” U.S. Department of Health & Human Services (Mar. 3, 2016), <http://www.hhs.gov/about/news/2016/03/03/hhs-reaches-goal-tying-30-percent-medicare-payments-quality-ahead-schedule.html>

¹⁴ The Secretary first issued waivers in an interim final rule. See 76 FR 67992 (Nov. 2, 2011). At that time, the Secretary found it necessary to waive the gainsharing CMP. OIG and CMS issued final waivers on Oct. 29, 2015. See 80 FR 66726. The Secretary determined that it was no longer necessary to waive the gainsharing CMP in the final waivers. At the time the Department published the interim final rule, hospitals were prohibited from knowingly paying physicians to induce them to reduce or limit services, including medically necessary services and medically unnecessary services. Section 512(a) of MACRA amended the statute to prohibit hospitals from

participation waiver” that applies to ACO-related start-up arrangements in anticipation of participating in the Shared Savings Program and an “ACO participation” waiver that applies broadly to ACO-related arrangements during the term of the ACO’s participation agreement under the Shared Savings Program and for a specified time thereafter. Provided that all waiver conditions are squarely met, these waivers provide protection under the physician self-referral law and the anti-kickback statute for, among other things, certain gainsharing and other performance-based payment arrangements that might be impermissible in the absence of such waivers.

Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain fraud and abuse laws, including the physician self-referral law and the anti-kickback statute, as necessary solely for purposes of testing payment and service delivery models developed by the Center for Medicare and Medicaid Innovation (the Innovation Center). As with the Shared Savings Program, CMS and OIG have issued specific waivers that protect gainsharing and similar arrangements for several Innovation Center models, subject to full compliance with conditions specified in the waivers. These waivers vary in content, scope and duration. Fraud and abuse waivers issued to date are available at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html> and on the OIG’s website.

POSSIBLE APPROACHES

Depending on the specific facts and circumstances, gainsharing and similar arrangements, including those that improve or maintain quality of care, reductions in waste, and increases in efficiency, may implicate the Federal fraud and abuse laws. Although we expect that some arrangements may be structured to satisfy the requirements of an applicable exception to the physician self-referral law and not violate the Federal anti-kickback statute or gainsharing CMP, the fraud and abuse laws may serve as an impediment to robust, innovative programs that align providers by using financial incentives to achieve quality standards, generate cost savings, and reduce waste. In fact, as discussed above, CMS and the OIG determined it necessary to waive the physician self-referral law’s prohibitions, the anti-kickback statute, and certain other fraud and abuse laws, in order to carry out or test effectively certain delivery and payment system reform models that have been incorporated into the Medicare program or are currently being tested by the Innovation Center. Because of the requirement in many exceptions to the physician self-referral law that compensation paid to a physician may not take into account the volume or value of a physician’s referrals or other business generated between the parties to a gainsharing or similar arrangement, the physician self-referral law presents a particularly difficult obstacle to structuring effective programs that do not run afoul of the fraud and abuse laws.¹⁵ With this in mind, we present the following possible approaches.

With respect to section 1877 of the Act, possible approaches could include:

knowingly paying physicians to induce them to reduce or limit medically *necessary* services. The amended statute obviates the need to waive this provision to carry out the Shared Savings Program.

¹⁵ While certain safe harbors under the anti-kickback statute issued through regulations include similar language (for example, 42 CFR 1001.952(b), (c) and (d)), the statutory exceptions do not.

- New statutory exceptions could be added for: (1) compensation paid to physicians under gainsharing arrangements that improve or maintain care while reducing waste and increasing efficiency; (2) incentive compensation arrangements for the provision of services or activities that achieve predetermined, appropriate quality, cost, or performance goals; and/or (3) addressing whether and, if so, how the “volume or value” and “other business generated” standards should apply to gainsharing and similar arrangements that contain appropriate accountability, transparency, and quality protections and do not induce care stinting, premature discharge of patients, or otherwise reduce or limit medically necessary care.
- The Secretary’s authority in section 1877(b)(4) of the Act could be amended to permit regulatory exceptions to the physician self-referral law that pose no undue risk of program or patient abuse. Amending this section of the Act could permit new exceptions to protect referrals for and the provision of designated health services under appropriately structured gainsharing and similar arrangements.

We have not included possible approaches for revisions to the anti-kickback statute. The Secretary has the authority to issue exceptions to this statute through regulations. Unlike in the case of section 1877 of the Act, this authority is not constrained either by existing statutory exceptions that apply a standard tied to the “volume or value” of referrals, or by a requirement that exceptions pose “no risk” of patient or program abuse. If either statutory or regulatory exceptions to section 1877 of the Act were to permit gainsharing or shared savings arrangements, the Secretary has the authority to issue regulations to protect the same arrangements from sanctions under the anti-kickback statute.

We also have not included possible approaches for revisions to sections 1128A(b)(1) or (2) of the Act. As written, these sections protect against stinting and otherwise limiting medically necessary care.

ACCRUAL OF A PORTION OF POTENTIAL SAVINGS GENERATED TO THE MEDICARE PROGRAM

It is not clear whether implementing a requirement that a portion of savings generated by gainsharing or similar arrangements permitted as a result of changes to the fraud and abuse laws should accrue to the Medicare program is appropriate. As discussed above, gainsharing arrangements typically are arrangements between providers of health care services where participants share in cost savings or increased profits resulting from the efforts of the provider receiving the payment. Such “gains” (or savings) are generally not tied to the care of individual patients. Moreover, gainsharing and similar arrangements commonly relate to the care furnished to a diverse cohort of patients that is not limited only to patients whose care is paid for by a specific payor. Requiring providers who sponsor gainsharing and similar programs to track the savings attributable to the care of Medicare beneficiaries in order to share such savings with the Medicare program could present potential challenges with respect to the growth of and innovation in valuable programs that improve care, reduce waste, and increase efficiency.

In the absence of direct accrual of the savings generated from provider-sponsored gainsharing and similar arrangements that improve care while reducing waste and increasing efficiency, the Medicare program could still benefit from such programs. For example, a successfully implemented gainsharing program that achieves cost savings for a hospital would potentially result in lower total costs reported to Medicare on the hospital's cost report. Cost report data used in determining future payments under the Hospital Inpatient Prospective Payment System would potentially include lower overall costs, which would result in changes in the amount of payment made to hospitals—and the potential to generate savings to the Medicare program—over time.

CONCLUSION

Gainsharing and similar arrangements, when properly structured, could improve or maintain care while reducing waste and increasing efficiency. Currently, the physician self-referral law may deter physicians and hospitals from entering into these arrangements even if the arrangements present little risk of abuse. Possible approaches could consider the potential utility of gainsharing and similar arrangements as tools to help transform our healthcare system as indicated by the information and options presented in this report.