DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

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TO: Jim R. Esquea
Assistant Secretary for Legislation

FROM: Andrew M. Slavitt
Acting Administrator

SUBJECT: Report to Congress: Options for Potential Changes to Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements between Physicians and Hospitals—**INFORMATION**

ISSUE

Section 512(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires the Secretary of the Department of Health and Human Services to submit, not later than April 16, 2016, a report to Congress with options for amending certain existing fraud and abuse laws to permit gainsharing or similar arrangements between physicians and hospitals that improve care while reducing waste and increasing efficiency.

BACKGROUND

Gainsharing typically refers to an arrangement between entities and individuals that furnish health care services 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. Arrangements similar to gainsharing, which we refer to as "incentive compensation" arrangements, include a diverse set of arrangements that involve payment for performing certain actions or achieving quality, cost, or performance goals, regardless of whether cost savings are achieved.

The fraud and abuse laws affecting gainsharing and similar arrangements include the civil monetary penalty (CMP) law, the anti-kickback statute, and the physician self-referral law.

- The gainsharing CMP prohibits 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.

- 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. The anti-kickback statute includes a number of statutory exceptions, and the statute authorizes the Secretary to issue additional exceptions through regulation, known as "safe harbors." The safe harbor regulations describe various payment and business practices that, although they potentially implicate

the anti-kickback statute, are not treated as offenses under the statute. The Office of Inspector General (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. 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.

- 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, unless the requirements of an applicable exception are satisfied; 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.

  Existing exceptions to the physician self-referral law may not be sufficiently flexible to encourage a variety of beneficial gainsharing and similar arrangements. 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 account the volume or value of referrals by the physician who is a party to the arrangement. 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. 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.

  Past attempts at issuing a regulatory exception to protect gainsharing and similar arrangement have been unsuccessful. We have determined that an exception that poses no risk of program or patient abuse could not provide sufficient flexibility to protect innovative and beneficial gainsharing and similar arrangements.

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 alternative payment models.

HIGHLIGHTS

Depending on the specific facts and circumstances, gainsharing and similar arrangements, including those that result in improvements in or maintenance of 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 this report we present the following possible approaches for the physician self-referral law:

- 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 statutory authority to establish regulatory exceptions to the physician self-referral law could be amended to permit exceptions 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 DHS under appropriately structured gainsharing and similar arrangements.

We have not included possible approaches for potential revisions to the anti-kickback statute. The Secretary has the authority to issue exceptions to this statute through regulations. Unlike in the physician self-referral law, 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. We also have not included possible approaches for potential revisions to the gainsharing CMP. As written, the law protects against stinting and otherwise limiting medically necessary care.

RECOMMENDATION

I recommend that you approve this Report to Congress on Options for Potential Changes to Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements between Physicians and Hospitals.

Attachments:
Tab A – Letter to President of the Senate
Tab B – Letter to Speaker of the House
Tab C – Report to Congress