



By Messenger

February 17, 2009

Daniel R. Levinson
Inspector General
Department of Health and Human Services
Room 5541, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

RE: OIG-113-N, Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Reduce or Limit Services to Beneficiaries and Response to Annual Solicitation for Safe Harbors and Special Fraud Alerts

Dear Mr. Levinson:

On behalf of the American Hospital Association's (AHA) more than 5,000 member hospitals, health systems and other health care organizations; the Association of American Medical Colleges' (AAMC) nearly 400 major teaching hospital and health system members and 125,000 faculty members; and the Federation of American Hospitals' (FAH) more than 1,000 investor-owned and -managed hospital members, we request that the 1999 Office of Inspector General (OIG) Special Advisory Bulletin (Bulletin) concerning "Gainsharing Arrangements and Civil Monetary Penalties (CMP) for Hospital Payment to Physicians to Reduce or Limit Services to Beneficiaries" be formally withdrawn. We also are using your annual solicitation for safe harbors to request promulgation of a safe harbor for incentive-payment and shared-savings arrangements under the Antikickback statute.

THE OIG SHOULD WITHDRAW THE 1999 SPECIAL ADVISORY BULLETIN

Much has changed in the delivery of care and the OIG's interpretation of the CMP provision since the 1999 Bulletin was released. The use of incentives has become an increasingly important factor in the ability of hospital leaders and physicians to work together to efficiently bring patients the right care, at the right time, in the right setting. The use of incentives to foster improvement in quality and efficiency is embedded in many current federal health care initiatives – from the Institute of Medicine's reports on quality to the Centers for Medicare and Medicaid Services' (CMS) Medicare pay-for-reporting and value-based purchasing proposals, to many of the delivery reform proposals recommended by the Medicare Payment Advisory Commission.

In the 1999 Bulletin, the OIG concluded that it could not envision any individual gainsharing arrangements that would merit a favorable advisory opinion. But less than two years later, the office issued the first of several advisory opinions on gainsharing arrangements and the ability of hospitals and physicians to include financial incentives in their arrangements intended to improve efficiency and quality in providing care. The more recent favorable review of 14

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gainsharing arrangements and a quality improvement incentive arrangement indicates that the OIG's analysis of the CMP standard also has changed. We agree with the OIG's implicit acknowledgment that the experiences and context that gave rise to the 1999 Bulletin have changed significantly. We believe that the interpretation of the CMP standard as set forth in the 1999 Bulletin is no longer consistent with your office's thinking on the statute.

The Bulletin should be withdrawn for two primary reasons. First, it fails to distinguish between incentives to reduce medically necessary and reasonable services (those services covered by Medicare) from medically unnecessary or unreasonable services (those services not covered by Medicare). Second, the OIG's more recent Advisory Opinions recognize that appropriate safeguards can prevent quality and efficiency programs from becoming conduits for fraud and abuse.

In the Bulletin, the OIG expressed a literal view of the statute that failed to account for the context in which it was enacted. On its face, for example, the statute provides that penalties shall be assessed if a hospital knowingly makes a payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's care. The only services with which the Medicare and Medicaid programs are concerned are those that meet the statutory definition of covered services. However, those services are medically necessary and reasonable. The Bulletin is written as if Congress prohibited the use of incentives to reduce the delivery of "any" item or service, including medically unnecessary or unreasonable services. This could not have been something Congress intended.

The CMP provision was devised at a time when Congress wanted to offset pressures hospitals might experience under the then new prospective payment system (PPS) – pressure to reduce medically necessary care in an attempt to bring down costs. For example, in its 1986 report, "Physician Incentive Payments by Hospitals Could Lead to Abuse," the Government Accountability Office found that under the old cost-based system, hospitals arguably had incentives to encourage physicians to "admit more patients, leave them in the hospital longer, and use more services while they were there." In contrast, under the PPS, the incentives could lead hospitals to, among other things, "underprovide services [and] discharge patients too early." Reading the CMP provision as prohibiting incentives to reduce unnecessary or unreasonable services would be at odds with Congress' intent to control rising health care costs through enactment of the PPS.

Today, it is clear that OIG believes hospitals and others have developed tools to prevent financial incentives from causing harm to patients by reducing covered – i.e., reasonable and necessary – items or services. The "common elements" of the programs the OIG reviewed and that led it to conclude in the 1999 Bulletin that *all* gainsharing arrangements pose a high risk of fraud and abuse, as opposed to a minimal risk, simply are no longer common in this new era of health care delivery. The concerns underlying the CMP provision have been overcome by a near singular focus, led by the Institute of Medicine among others, on the need to improve patient safety and quality performance. While in 1999 the OIG may have struggled to find "[a]dequate and accurate measures of quality of care" to allay its concerns regarding the adverse effects these arrangements would have on the quality of care, the OIG's more recent favorable advisory

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opinions demonstrate that this is no longer the case. There are many well-established and nationally recognized practices of safe, effective, efficient, patient-centered, timely and equitable care. The many current and well-founded practices that foster quality improvement and more efficient delivery of care should support the OIG's revisiting of its interpretation of what Congress was trying to achieve.

As a consequence of its interpretation, the OIG has faced repeated requests for advisory opinions for gainsharing programs that differ very little from each other, and is likely to see similar requests for incentive programs. Hospitals have been unreasonably constrained in their efforts to design and implement programs to improve quality and reduce inefficiencies without adversely affecting the quality of care. If the CMP provision were restated in the way we believe it was intended – to prohibit only payments intended to reduce reasonable and medically necessary services – these quality-improvement and shared-savings programs, which contain sufficient safeguards against this risk, would be able to proceed. We urge the OIG to withdraw the Bulletin and revisit its interpretation of the statute.

THE OIG AND CMS SHOULD COORDINATE ENFORCEMENT POLICY ON HOSPITAL INCENTIVE-PAYMENT AND SHARED-SAVINGS PROGRAMS

Currently, CMS is considering exceptions to the physician self-referral law to protect incentive-payment and shared-savings programs. We are enclosing a copy of the letter we submitted today commenting on CMS' proposed exception. A companion safe harbor from the OIG would provide hospitals and physicians the benefit of coordinated guidance that would facilitate the development of these programs. We believe our recommendations to CMS would provide an appropriate basis for an Antikickback statute safe harbor to be issued by the OIG.

It is essential that the OIG guidance adapt to enable hospitals and physicians to work together to achieve the quality improvement and efficiency goals that public policy demands. We would welcome the opportunity to discuss these issues with you. In the interim, you may contact Maureen Mudron, the AHA's deputy general counsel, at 202-626-2301 or mmudron@aha.org; or Ivy Baer, AAMC's director and regulatory counsel at 202-828-0499 or ibaer@aamc.org; or Jeffrey Micklos, FAH's executive vice president, management, compliance and general counsel at 202-624-1521 or jmicklos@fah.org.

Sincerely,

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Attachment