Recent Commentary Distorts HHS IG's Gainsharing Bulletin

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The Analysis and Perspectives section of the August 11, 1999, Health Care Fraud Report, featured a commentary addressing the Office of Inspector General's ("OIG's") recent "Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries." (64 Fed. Reg. 37985 (July 14, 1999)). The commentary made a number of charges regarding the substance of, and the procedure used to issue, the Special Advisory Bulletin. In addition, the commentary contained a number of factual inaccuracies, some of which are now unfortunately being repeated in other trade publications.

Given the mischaracterizations and factual inaccuracies contained in the commentary, we are concerned that allowing the commentary to go unchallenged may create a false impression in the health industry. In an effort to forestall further misunderstandings and detrimental reliance on the commentary by those in the industry who want to avoid improper business relationships, we wish to make our position clear on the following points:

- The interpretation of section 1128A(b) of the Social Security Act (the "Act") proffered by the commentary is supported neither by the plain meaning nor the purposes of the statute.
- The OIG's 1994 Notice of Proposed Rulemaking on section 1128A(b) articulated a categorical prohibition on hospital payments to physicians that are based on reductions in costs for treatment of fee-for-service Medicare or Medicaid patients under the physicians' direct care -- a position wholly consistent with the Special Advisory Bulletin.
- The OIG issued the Special Advisory Bulletin in a manner that was fully consistent with congressional directives for greater industry guidance and did not subvert or otherwise improperly shortchange the advisory opinion process.
- The OIG's position on gainsharing arrangements is clearly stated in the Special Advisory Bulletin, and parties ignore the Special Advisory Bulletin at their own risk. Prompt unwinding of improper gainsharing arrangements will be taken into account in enforcement decisions.

Although in the interest of brevity we are limiting our response to three major points, we want to make clear that we believe the commentary contains other inaccuracies and mischaracterizations.

Interpretation of Section 1128A(b). A principal focus of both the Special Advisory Bulletin and the commentary is the proper interpretation of section 1128A(b)(1), the civil monetary penalty provision addressing hospital payments to physicians to induce the reduction or limitation of services to patients under the physicians' direct care.(1) The authors of the commentary contend that the "plain language" of the statute requires *both* that a violator have the specific intent to induce treating physicians to withhold *medically necessary* services from their patients and that the incentive plan *actually cause* a reduction or limitation of medically necessary services. In our view, this interpretation is plainly wrong. Simply put, the language of the statute refers to "services," not "medically necessary services," and requires a showing of an intent to induce a reduction of services, not an actual reduction.

The OIG interprets section 1128A(b) as prohibiting any physician incentive plan that conditions hospital payments to physicians or physician groups on savings attributable to reductions in hospital costs for treatment of fee-for-service Medicare or Medicaid patients under the physicians' clinical care. The legal basis for our interpretation is articulated in the Special Advisory Bulletin and need not be repeated here.

As to the commentary's authors' contention that our interpretation ignores the plain language of section 1128A(b), we believe that any honest reader of the broad, unqualified statutory language will concede that it clearly encompasses gainsharing arrangements involving monetary payments by hospitals to physicians conditioned on the physicians reducing their patients' hospital treatment costs.

More importantly, the authors' hyper-technical reading of the statute indicates a basic misapprehension of the purposes of the statute. The principal evil addressed by section 1128A(b) is not the actual reduction of services to beneficiaries, but rather the potential for hospital payments to corrupt a treating physician's medical judgment as to the provision of hospital services to his or her patients. In this respect, section 1128A(b) is an analog to the anti-kickback statute, section 1128B(b) of the Act. Thus, as is true with kickbacks, the gravamen of a violation is a knowing payment to a physician to influence his or her treatment of patients. While the physician's compromised judgment *may* result in the delivery of unnecessary services (in the case of kickbacks) or in "stinting" on services (in the case of a hospital gainsharing plan), proof of actual adverse effects on particular patients is not required under either section.

The authors' claim that the OIG's interpretation of section 1128A(b) results in unfair discrimination against enrollees in Medicare managed care is equally groundless. Congress' disparate treatment of physician incentive plans offered by Medicare risk-based managed care plans (and their subcontractors) and physician incentive plans offered by hospitals treating Medicare or Medicaid fee-for-service beneficiaries is reasonable and equitable given the differences in the programs.(2) A basic premise of the Medicare risk-based managed care program is that beneficiaries who choose to enroll understand that their physicians will have economic incentives with respect to managing their care. In return, however, these managed care beneficiaries share in any savings through increased benefits, such as reduced copayments and outpatient prescription drug coverage. By contrast, fee-for-service beneficiaries incur substantial additional financial obligations (not borne by their managed care counterparts) in exchange for unfettered access to physicians of their choice. Moreover, unlike physician incentive programs under Medicare managed care plans, the entire benefit of the savings from hospital-based physician incentive plans for Medicare fee-for-service beneficiaries accrues solely to the hospital and the treating physicians; neither the fee-for-service enrollees, nor the Medicare Trust Fund, benefits in any way from these physician incentive programs. Given the substantial differences in the programs, Congress' disparate regulation of incentive plans is understandable.

The 1994 Notice of Proposed Rulemaking. The authors of the commentary mistakenly claim that the preamble to the 1994 Notice of Proposed Rulemaking ("NPRM") addressing section 1128A(b) (59 Fed. Reg. 61571 (Dec. 1, 1994)) is inconsistent with the OIG's position in the Special Advisory Bulletin.(3) Specifically, they allege that the preamble demonstrated that the OIG "understood that certain gainsharing agreements -- namely those that contain safeguards suggested in the GAO's 1986 report -- do indeed comply with section 1128A(b), and that a case-by-case analysis is required to determine whether a particular arrangement is legal." Those allegations are plainly wrong. Not only is the preamble to the NPRM completely consistent with the Special Advisory Bulletin, but the preamble language cited by the authors to support their argument has been quoted wholly out of context, creating a false impression.

Before discussing the substance of the preamble to the NPRM, it is useful to have a basic understanding of its structure. In particular, the section of the preamble that contains the discussion of the proposed rule is clearly divided into two subsections delineated by separate headings. The first subsection addresses the structure and nature of hospital physician incentive plans to be prohibited, while the second subsection discusses the application of the proposed rule to physician incentive plans *not relating to direct patient care responsibilities*. (59 Fed. Reg. 61573).

In the first subsection, the preamble made clear the OIG's view that incentive plans that are based on cost savings tied to the overall costs of patient treatment or lengths of stay are flatly prohibited, because they appear to be designed as inducements to reduce or limit services to patients admitted to hospitals and could also influence the type of patient admitted to the hospital. The *entire* discussion reads as follows:

"The precise structure and application of a physician incentive plan will ultimately determine whether CMPs would be assessed against a hospital or physician under this provision [section 1128A(b)]. There are certain incentive payments to physicians, based on cost savings, that are specifically designed to limit or reduce services normally provided by a hospital to a patient. Such incentive plans, tied to the overall costs of patient treatment or on a patient's length-of-stay without regard to how specific reductions are made, could be viewed as inducements to reduce patient services, and thus may be subject to CMPs under these regulations. Most DRG incentive plans, for example, under which payment to individual physicians is tied to DRG reimbursement, appear to be based on payments designed as inducements to reduce or limit services provided once a patient has been admitted. This type of incentive plan might also serve to influence the type of patient admitted to a particular hospital, thereby encouraging the physician to admit patients with less complicated conditions to a hospital offering incentives and directing patients with more complicated conditions elsewhere. *These types of incentive plans offered by hospitals to individual physicians related to the cost of services provided would be prohibited under this provision and subject to CMPs.*" (69 Fed. Reg. 61573) (emphasis added).

Thus, the preamble to the 1994 NPRM articulated a categorical prohibition on hospital payments to physicians that are based on reductions in costs for treatment of fee-for-service patients *under the physicians' direct care* -- a position wholly consistent with the Special Advisory Bulletin. Moreover, nowhere in the preamble discussion is there any basis for concluding (as does the commentary) that prohibited physician incentive plans could be immunized if they included some or all of the "safeguards" mentioned in the GAO report.(4)

Having concluded its discussion of prohibited plans involving *payments related to direct patient care*, the preamble to the NPRM continues with a new subsection addressing the application of section 1128A (b) to incentive plans that *do not involve payments for direct patient care*. In that subsection, the OIG recognized that incentive plans that do not involve direct patient care are not covered by section 1128A (b), but noted the difficulty in describing the entire universe of such plans in a regulation:

"We believe, for example, there may be certain types of hospital incentive plans to physicians, such as those designated to reward the timely review and completion of medical records which do not impact on direct patient care responsibilities or do not affect patient referral patterns, that may be acceptable and therefore not be subject to civil money penalties under this provision.

We believe, however, that it is impossible and impractical for the OIG to specifically indicate in regulations what specific criteria may make up an acceptable hospital physician incentive plan. In setting forth these proposed regulations, we are adopting a similar approach to that which we have used for other existing CMP authorities of closely following the statutory language. As with all CMP cases, the OIG will review and assess the nature and scope of each suspect incentive plan on a case-by-case basis to determine its specific intent and acceptability. An alternative approach would be to specify those kinds of incentive plans that may be exempt from CMP liability. We welcome comments on identifying those types of incentive plans that may not specifically affect direct patient care responsibilities, and thus would not be implicated by the statute." (59 Fed. Reg. 61573) (emphasis added).

The authors of the commentary cite the italicized language in the above passage to support their argument that the NPRM contradicts the Special Advisory Bulletin. However, in context, the cited language applies only to case-by-case determinations with respect to physician incentive plans *that do not involve direct patient care* -- an issue wholly irrelevant to the prohibited gainsharing arrangements discussed in the Special Advisory Bulletin.

The Special Advisory Bulletin and the Advisory Opinion Process. The authors of the commentary contend that the OIG issued the Special Advisory Bulletin in an improper manner that pre-empted the advisory opinion process and is in some fashion "suspect". The OIG's practice of issuing advisory bulletins, fraud alerts, and other general, industry-wide guidance is well-established and furthers OIG and congressional policy encouraging increased guidance to the industry on fraud and abuse issues. See, e.g., section 1128D of the Act. Given the widespread interest regarding gainsharing in the industry and the promotion of gainsharing arrangements by various parties, the OIG determined that the issuance of timely general guidance outlining our concerns with one of the most common gainsharing methodologies was the most efficient and appropriate way to communicate with the regulated community.

The contention that the use of a Special Advisory Bulletin improperly pre-empted the advisory opinion process is without merit. In response to requests for advisory opinions about gainsharing arrangements, the OIG and the Health Care Financing Administration examined and evaluated a number of these complex arrangements. The OIG afforded each arrangement individual and detailed consideration, including, in some cases, reviews by outside consultants and experts engaged both by the OIG and by the advisory opinion requesters themselves.

Given the clear prohibition in section 1128A(b), the only "favorable" treatment we could afford a gainsharing arrangement of the type described in the advisory opinion requests would be a determination that, notwithstanding the violation of section 1128A(b), we would exercise our prosecutorial discretion and decline to subject the arrangement to sanction. As noted in the Special Advisory Bulletin, such an opinion requires, as a threshold matter, a determination that the arrangement in question poses a minimal risk of fraud or abuse.

Thus, from the outset, the OIG made clear to the parties requesting the advisory opinions that, in order to be approved, any gainsharing arrangement would have to ensure that the quality of care for Medicare and Medicaid beneficiaries would not be adversely affected. Ultimately, the OIG determined that the quality measures proposed by the requesters were inadequate to guard against adverse effects on quality of care. Among our concerns were that the quality measures proffered (i) were more or less subjective, (ii) would be applied to patient volumes that were insufficient to yield statistically significant results, and (iii) were not subject to independent verification under the various gainsharing proposals.

Having concluded that none of the arrangements provided sufficient assurance that the care to Medicare and Medicaid beneficiaries would not be adversely affected, the OIG individually apprised the requesting parties of the OIG's conclusions, the pending issuance of the Special Advisory Bulletin, and the available options for handling the pending advisory opinion requests. These options included proceeding with their requests, in which case they would receive an individualized, reasoned -- albeit unfavorable -- opinion and incur the associated costs; withdrawing their requests, which would save them further expense; or revising their requests in light of the prohibition in section 1128A(b). Far from being short-circuited, the process has simply run its course. To date, two requesters have revised their requests, one has withdrawn its request, and the remainder are presumably still considering their choices.

The commentary further suggests that the OIG's issuance of the Special Advisory Bulletin somehow

circumvented the consultation with the Department of Justice that is integral to the advisory opinion process. The authors' implication that the OIG's issuance of the Special Advisory Bulletin was an "end-run" around our Department of Justice partners is simply untrue. The OIG had ongoing discussions with its relevant counterparts at the Department of Justice's Criminal and Civil Divisions with respect to both the pending advisory opinion requests involving gainsharing arrangements and the Special Advisory Bulletin, a fact that the authors could readily have established with a telephone call to the OIG.

Rather than subverting the advisory opinion process, the Special Advisory Bulletin was a logical outgrowth of the process -- a synthesis of the lessons learned from the study of specific advisory opinion requests. The OIG has long used special industry-wide alerts and guidance to disseminate its views of specific industry-wide practices. Nothing in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which established the OIG's advisory opinion process, remotely suggests that Congress intended to preclude the use of these more generalized means of providing guidance to the industry. To the contrary, the same sections of HIPAA that gave the OIG authority to issue advisory opinions also refer to more general guidance, including fraud alerts and safe harbor regulations. See section 1128D of the Act. In short, the use of the advisory opinion process to inform the development and issuance of general guidance is sensible, consistent with congressional policy, and responsive to the industry's expressed desire for OIG guidance on the fraud and abuse laws.

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In conclusion, we believe that hospitals and physicians involved in or contemplating gainsharing arrangements are well-advised to heed the guidance offered in the Special Advisory Bulletin. As explained there, the OIG interprets section 1128A(b) as prohibiting any physician incentive plan that conditions hospital payments to physicians or physician groups on savings attributable to reductions in hospital costs for treatment of fee-for-service Medicare or Medicaid patients under their clinical care. To the extent that parties may have entered into improper arrangements in the mistaken belief that they were lawful, the OIG has indicated that it will take into account the prompt unwinding of such arrangements in its enforcement decisions. Parties seeking assurance that their arrangements do not run afoul of section 1128A(b) or other OIG anti-fraud and abuse authorities are encouraged to request an advisory opinion.

FOOTNOTES:

1. Section 1128A(b)(1) of the Act reads:

"(b)(1) If a hospital or critical access hospital knowingly makes a payment, directly or indirect, to a physician as an inducement to reduce or limit services provided with respect to individuals who --

(A) are entitled to benefits under part A or part B of title XVIII or to medical assistance under a State plan approved under Title XIX, and

(B) are under the direct care of the physician,

the hospital or a critical access hospital shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $2,000 for each such individual with respect to whom the payment is made."

2. Medicare risk-based managed care plans are regulated by section 1876(i)(8) of the Act and the corresponding regulations at 42 C.F.R. § 417.479. (Medicaid managed care plans and Medicare+Choice

coordinated care plans are regulated under comparable provisions. See, as to Medicaid, section 1903(m)(2)(A)(x) of the Act and 42 C.F.R. § 434.70, and as to Medicare+Choice, section 1852(j)(4) of the Act and 63 Fed. Reg. 34968, 35002 (June 26, 1998) (interim final rule)). To the extent that hospitals have physician incentive plans that make payments that are based on treatment of both managed care (whether Medicare risk-based, Medicaid, or Medicare+Choice coordinated care plans) beneficiaries and Medicare or Medicaid fee-for-service beneficiaries, any payments that relate to, or potentially affect, the provision of clinical care services for the fee-for-service beneficiaries would implicate section 1128A(b).

3. A final rule has not been promulgated.

4. Indeed, the only references to the GAO report in the NPRM are contained in the initial, descriptive background section. That discussion summarizes the report and concludes:

"The GAO recommended that physician incentive plans that do not include these characteristics should be prohibited. However, the GAO also noted that no combination of characteristics in a physician incentive plan could guarantee that the plan would not be abusive." (59 Fed. Reg. 61572).

There is no other reference to the GAO report in the entire NPRM, and nowhere in the NPRM does the OIG state or imply that physician incentive plans that contained the safeguards would be deemed in compliance with section 1128A(b). In addition, the suggestion in the commentary that a GAO staff report issued *prior* to enactment of section 1128A(b) could give rise to "settled law" is most peculiar.