

200 C St. SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5)(21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 9B4672) has been filed by BP Amoco Chemicals, Inc., 28100 Torch Pkwy., Warrenville, IL 60555-4015. The petition proposes to amend the food additive regulations in part 177 (21 CFR part 177) by adding a section to provide for the safe use of poly(oxy[1,1'-biphenyl]-4,4'-diyl-oxy-1,4-phenylenesulfonyl-1,4-phenylene) prepared by the reaction of biphenol and 4,4'-dichlorodiphenylsulfone as articles or components of articles intended for contact with food.

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 25, 1999.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of the OIG Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: In its role of identifying and eliminating fraud, waste and abuse in the Department's health care programs, the OIG periodically develops and issues guidance, including Special Fraud Alerts and Advisory Bulletins, to alert and inform health care providers and program beneficiaries about potential problems or areas of special interest. This **Federal Register** notice sets forth the recently-issued OIG Special Advisory Bulletin addressing the civil money penalty (CMP) for hospital payments to physicians as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries, and its application to "gainsharing" arrangements involving hospitals and physicians.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Office of Counsel to the Inspector General, (202) 619-1306.

SUPPLEMENTARY INFORMATION:

I. Background

This Special Advisory Bulletin addresses the CMP for hospital payments to physicians to induce reductions or limitations in services to Medicare or Medicaid beneficiaries (section 1128A(b)(1) and (2) of the Social Security Act (the Act)), and its application to "gainsharing" arrangements and potentially to certain other hospital-physician clinical ventures. The OIG has concluded that section 1128A(b)(1) of the Act specifically prohibits any gainsharing arrangements that involve payments by or on behalf of a hospital, directly or indirectly, to induce physicians with clinical care responsibilities to reduce or limit services to Medicare or Medicaid patients.

II. Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries

A. Introduction

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse and waste in the Department's programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations and inspections.

The Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996, authorized the OIG to provide guidance to the health care industry to prevent fraud and abuse, and to promote the highest level of ethical and lawful conduct. To further these goals, the OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by the OIG.

This Special Advisory Bulletin addresses the application of sections 1128A(b)(1) and (2) of the Social Security Act (the Act) to gainsharing arrangements.¹ The civil money penalty (CMP) set forth in section 1128A(b)(1) of the Act prohibits any hospital or critical access hospital from knowingly making

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.

While the OIG recognizes that appropriately structured gainsharing arrangements may offer significant benefits where there is no adverse impact on the quality of care received by patients, section 1128A(b)(1) of the Act clearly prohibits such arrangements. Moreover, regulatory relief from the CMP prohibition will require statutory authorization.

Some hospitals and physicians may have already implemented programs that involve Medicare or Medicaid beneficiaries. In exercising its enforcement discretion, and in the absence of any evidence that a gainsharing arrangement has violated any other statutes or adversely affected patient care, the OIG will take into consideration whether a gainsharing arrangement was terminated expeditiously following publication of this Bulletin.

B. Prohibition on Hospital Payments to Physicians to Induce Reduction or Limitation of Services

Under section 1128A(b)(1) of the Act, a hospital is prohibited from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to \$2,000 per patient covered by the payments (section 1128A(b)(2) of the Act).

The statutory proscription is very broad. The payment need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. In short, any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute.

The breadth of the prohibition was intentional. As initially enacted by Congress, section 1128A(b)(1) of the Act prohibited payments by both hospitals and Medicare managed care plans to induce physicians to reduce clinical services.² Section 1128A(b)(1) of the Act was subsequently amended to delete the reference to Medicare managed care plans, and to add a new subsection to section 1876 of the Act that permitted

¹ Gainsharing arrangements may also implicate the anti-kickback statute (section 1128B(b) of the Act) and the physician self-referral prohibitions of the Act (section 1876 of the Act).

² Section 9313(c) of the Omnibus Budget Reconciliation Act (OBRA) of 1986 (P.L. 99-509).

Medicare managed care plans to implement physician incentive plans, provided the managed care plan did not induce the reduction of *medically necessary* care to *individual* patients and did not place the physician at substantial financial risk for services not provided by the physician.³ Further, Congress explicitly gave the Secretary authority to regulate physician incentive plans offered by Medicare risk managed care plans. Because the resulting two provisions address the same issues and were drafted together, the stark difference in otherwise parallel language reflects a congressional decision to prohibit any payment arrangement between hospitals and physicians that is intended to induce a reduction or limitation in services.

This reading of the statute is also consistent with the legislative history surrounding the enactment of section 1128A(b)(1) of the Act. The prohibition was prompted in part by a General Accounting Office (GAO) report for the Chairman of the Subcommittee on Health of the House Ways and Means Committee regarding the physician incentive plans being implemented by hospitals in response to the then-recently enacted diagnostic related group prospective payment system and their potential detrimental effects on quality of care for Medicare patients.⁴ The report analyzed four types of hospital-physician incentive plans, of which at least two bear strong similarities, and contain safeguards comparable, to the gainsharing arrangements currently being marketed by the healthcare consulting industry.⁵ While the GAO report discussed several features in these plans that reduced the incentive to give substandard care, it concluded that no combination of features could guarantee that such plans would not be subject to abuse.⁶

Congress concurred. The House Committee Report that accompanied the House provision that became section 1128A(b)(1) of the Act stated that "[t]he Committee believes that such incentive payments may create a conflict of interest that may limit the ability of the physician to exercise independent professional judgment in the best interest of his or her patients."⁷ In explaining the inclusion of the prohibition in the final budget

reconciliation bill that became OBRA 1986, the Chairman of the Subcommittee on Health of the House Ways and Means Committee, who was also a member of the Conference Committee, stated on the floor of the House that:

"[T]he House held firm in its insistence on outlawing certain physician incentive plans. We must not tolerate hospitals paying physicians to reduce or limit services to the elderly."⁸

In sum, we believe that section 1128A(b)(1) of the Act prohibits any hospital payments that induce physicians to reduce or limit clinical services to the physicians' patients.

C. Gainsharing Arrangements

While there is no fixed definition of a "gainsharing" arrangement, the term typically refers to an arrangement in which a hospital gives physicians a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physicians' efforts. In most arrangements, in order to receive any payment, the clinical care must not have been adversely affected as measured by selected quality and performance measures. In addition, many plans require a determination by an independent consultant that the payment represents "fair market value" for the collective physician efforts. Medicare Part B and Medicaid payments to physicians generally are unaffected by a gainsharing arrangement.

Gainsharing arrangements seek to align physician incentives with those of hospitals by offering physicians a share of the hospital's variable cost savings attributable to Medicare and Medicaid reimbursement. Since the institution of the Medicare Part A DRG system of hospital reimbursement and with the growth of managed care, hospitals have experienced significant financial pressures to reduce costs. However, because physicians are paid separately under Medicare Part B and Medicaid, physicians do not have the same incentive to save hospital costs. Gainsharing arrangements are designed to bridge this gap by offering physicians a portion of the hospital's cost savings in exchange for identifying and implementing cost saving strategies.

The OIG recognizes that hospitals have a legitimate interest in enlisting physicians in their efforts to eliminate unnecessary costs. Savings that do not affect the quality of patient care may be generated in many ways, including substituting lower cost but equally effective medical supplies, items or devices; re-engineering hospital surgical

and medical procedures; reducing utilization of medically unnecessary ancillary services; and reducing unnecessary lengths of stay. Achieving these savings may require substantial effort on the part of the participating physicians. Obviously, a reduction in health care costs that does not adversely affect the quality of the health care provided to patients is in the best interest of the nation's health care system. Nonetheless, the plain language of section 1128A(b)(1) of the Act prohibits tying the physicians' compensation for such services to reductions or limitations in items or services provided to patients under the physicians' clinical care.

D. Application of Section 1128A(b)(1) of the Act to Gainsharing Arrangements

Gainsharing arrangements that directly or indirectly provide physicians financial incentives to reduce or limit items or services to patients that are under the physicians' clinical care are precisely the kind of physician incentive plans that Congress prohibited when it enacted section 1128A(b)(1) of the Act. The language of the statute, the language of the companion statute on managed care physician incentive plans, and the legislative history compel the conclusion that section 1128A(b)(1) of the Act prohibits any hospital-physician incentive plan that compensates a physician directly or indirectly based on cost savings on items and services furnished to patients under the physician's clinical care. We can perceive no meaningful difference between the kinds of incentive plans proposed in 1986 at the time of enactment of section 1128A(b)(1) of the Act (as reflected in the GAO report) and the variants being promoted by hospitals and health care consultants today.

Moreover, given the clear statutory prohibition on hospital-physician incentive plans, the OIG cannot provide any regulatory relief absent further authorizing legislation. Where Congress intended the Department to regulate physician incentive plans, such as plans offered by risk-based Medicare managed care plans, it did so explicitly. Congress' omission of comparable regulatory authority for the Secretary over hospital-physician incentive plans represents its considered judgment that such plans are flatly prohibited.

We note, however, that hospitals may align incentives with physicians to achieve cost savings through means that do not violate section 1128A(b)(1) of the Act. For example, hospitals and physicians may enter into personal services contracts where hospitals pay

³ Sections 4204(a) and 4731 of the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) (codified at section 1876(i)(8) of the Act).

⁴ U.S. General Accounting Office, *Physician Incentive Payments by Hospitals Could Lead to Abuse*, GAO/HRD-86-103 (July 1986).

⁵ *Id.* at 14-21.

⁶ *Id.* at 23.

⁷ H.R. Rep. No. 99-727, at 441 (1986).

⁸ 144 Cong. Rec. H11,446 (October 17, 1986).

physicians based on a fixed fee that is fair market value for services rendered, rather than a percentage of cost savings. Such contracts must meet the requirements of the anti-kickback statute (section 1128B(b) of the Act).

Notwithstanding the statutory prohibition, the OIG has given extensive consideration to whether it would be appropriate to protect individual gainsharing arrangements from OIG administrative sanctions through the issuance of favorable advisory opinions. Based on our review of a number of requests, we have concluded that they contain common elements that preclude our issuance of any favorable opinion. First, to date, the OIG has exercised its discretion to protect various arrangements from sanction only where such arrangements pose a minimal risk of fraud or abuse. By contrast, gainsharing arrangements pose a high risk of abuse. In order to retain or attract high-referring physicians, hospitals will be under pressure from competitors and physicians to increase the percentage of savings shared with the physicians, manipulate the hospital accounts to generate phantom savings, or otherwise game the arrangement to generate income for referring physicians. Given these pressures and the potential adverse impact on patient care from gainsharing arrangements, the OIG believes that immunizing such arrangements from sanction would be imprudent and inappropriate.

Second, gainsharing arrangements will require ongoing oversight both as to quality of care and fraud that is not available through the advisory opinion process. Apart from the potential for fraud and abuse, a critical inquiry is whether the arrangements have adequate and accurate measures of quality of care that would provide assurance that there is no adverse impact on patient care. Based on discussions with experts both within and without the Federal Government, the OIG has determined that any performance measures would require extensive verification through audits or review by an independent party on a continuing basis. The Office of Counsel to the Inspector General, which issues advisory opinions, has neither the resources nor the expertise to police a multitude of such arrangements on an ongoing basis.

Third, case by case determinations by advisory opinions are an inadequate and inequitable substitute for comprehensive and uniform regulation in this area. Were the OIG to issue a favorable opinion to one provider, that provider would have a significant competitive advantage in recruiting and

attracting physicians to admit patients to its facility, since the physicians would have the opportunity to earn significant additional income not available at other institutions. The consequences would be that every hospital in the country would request an advisory opinion for its own program, and many would implement their own programs in the hope that their programs were close enough. Given the potentially serious adverse effects on patient care from improperly designed or implemented gainsharing arrangements, regulation of gainsharing arrangements requires clear, uniform, enforceable and independently verifiable standards applicable to all affected providers and not case by case decision-making.

E. Application to Other Arrangements

We are aware of reports that hospitals and physicians are engaging in a number of clinical joint ventures, including both freestanding specialty hospitals (e.g., heart, orthopedic, or maternity hospitals), and arrangements in which a high revenue generating unit or service (e.g., cardiology or cardiac surgery) of an existing hospital is restructured and legally incorporated as a separate hospital.

Typically marketed only to physicians in a position to refer patients to the venture and structured to take advantage of the exception in the physician self-referral law for physician investments in "whole hospitals", these ventures may induce investor-physicians to reduce services to patients through participation in profits generated by cost savings in clinical care. Accordingly, we believe such arrangements may also violate section 1128A(b)(1) of the Act, in at least some circumstances. In addition, such arrangements may implicate the anti-kickback statute (section 1128B(b) of the Act).

F. Conclusion

Absent legislative relief, section 1128A(b)(1) of the Act prohibits any gainsharing arrangements that involve payments by or on behalf of a hospital to physicians with clinical care responsibilities, directly or indirectly, to induce a reduction or limitation of services to Medicare or Medicaid patients. Parties interested in pursuing gainsharing arrangements that are currently prohibited by section 1128A(b)(1) of the Act should seek legislative relief. In the light of reports that some hospitals may already have such arrangements in place, the OIG will, in the absence of any evidence that an arrangement has violated any other

statutes or adversely affected patient care, take into consideration in exercising its enforcement discretion whether a gainsharing arrangement was terminated expeditiously following publication of this Bulletin in the **Federal Register**.

Dated: July 6, 1999.

June Gibbs Brown,

Inspector General.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request, Survey of National Cancer Organizations Served by the NCI Office of Liaison Activities (OLA)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: Title: Survey of National Cancer Organizations Served by the NCI Office of Liaison Activities. Type of Information Collection Request: New. Need and Use of Information Collection: The information to be collected in this survey is of vital importance to the National Cancer Institute's Office of Liaison Activities in determining the communication needs of the national cancer advocacy and voluntary organizations it serves and the desirability and usefulness of NCI's products and services. Information collected in this survey will be used to improve program services and make appropriate programmatic decisions. The respondents are leaders of organizations served by OLA and have a deep commitment to cancer advocacy in areas of cancer prevention, detection, treatment, control, and survivorship. They seek to improve the communication and collaboration between their organizations and the NCI. Frequency of Response: one time. Affected Public: Not-for-profit organizations. Type of Respondents: Organization leaders. The annual reporting burden is as follows: Estimated Number of Respondents: 150; Estimated Number of Responses per Respondent: 1; Average Burden Hours Per Response: .3841 and Estimated Total