

what are the practical and policy considerations associated with the various forms of inducements? Which kinds of inducements matter most to the efficient and successful completion of a clinical trial? What might be a reasonable cap on the value of inducements offered to particular patients?

- *Sources of benefits.* The OIG is aware that, in some cases, free items or services are offered to enrollees in a clinical trial by parties other than the trial sponsor. For example, a manufacturer might furnish patients with free or discounted products used in the course of the trial (but not the products that are the subject of the clinical trials). These kinds of arrangements raise concerns, as the benefits may induce enrollees to continue to use the manufacturer's products after completion of the trial.

3. Inducements of Low Value

As noted above, Congress indicated an intent to permit items and services of "nominal" value under section 1128A(a)(5) of the Act. Consistent with this intent, in the preamble to the final regulations governing section 1128A(a)(5), we indicated that items and services of nominal value are not prohibited by the statute and thus no exception would be necessary (65 FR 24410; April 6, 2000). We further interpreted "nominal" value to mean less the \$10 per item and \$50 in the aggregate on an annual basis (65 FR 24411; April 6, 2000).

We invite comments on whether, for the sake of clarity and bright-line guidance, we should codify an exception for inducements of low value, and, if so, what the value should be. Should the exception include a per item or service limitation on value or should it look solely to value on an annual (or other) aggregate basis?

4. Other Exceptions

The OIG welcomes suggestions for other possible exceptions to section 1128A(a)(5) of the Act. As noted above, comments are particularly useful if they address the legal and policy concerns raised by the application of section 1128A(a)(5) to particular business practices and offer specific suggestions for applicable criteria.

Dated: November 19, 2002.

Janet Rehnquist,

Inspector General.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Solicitation of New Safe Harbors and Special Fraud Alerts

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

ACTION: Notice of intent to develop regulations.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, this annual notice solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the anti-kickback statute (section 1128B(b) of the Social Security Act), as well as developing new OIG Special Fraud Alerts. In addition, this notice solicits public comments regarding the development of possible guidance addressing certain credentialing practices.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 7, 2003.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-71-N, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG-71-N. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619-0089, OIG Regulations Officer.

SUPPLEMENTARY INFORMATION:

I. Background

A. The OIG Safe Harbor Provisions

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a-7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce

or reward business reimbursable under the Federal health care programs. The offense is classified as a felony and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years. The OIG may also propose the imposition of civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a), or exclusions from the Federal health care programs, in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)).

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements may be subject to criminal prosecution or administrative sanction. In response to the above concern, the Medicare and Medicaid Patient and Program Protection Act of 1987, section 14 of Public Law 100-93, specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, specifying various payment and business practices which, although potentially capable of inducing referrals of business reimbursable under the Federal health care programs, would not be treated as criminal offenses under the anti-kickback statute and would not serve as a basis for administrative sanctions. The OIG safe harbor provisions have been developed "to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements" (56 FR 35952; July 29, 1991). Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement action under the anti-kickback statute or related administrative authorities. The safe harbor provisions are codified at 42 CFR 1001.952.

B. OIG Special Fraud Alerts and Special Advisory Bulletins

The OIG has also periodically issued Special Fraud Alerts and Special Advisory Bulletins to give continuing guidance to health care providers with respect to practices the OIG finds potentially fraudulent or abusive. The Special Fraud Alerts and Bulletins encourage industry compliance by giving providers guidance that can be applied to their own businesses. The OIG Special Fraud Alerts and Bulletins are intended for extensive distribution directly to the health care provider community, as well as those charged with administering the Federal health care programs. The OIG Special Fraud Alerts and Bulletins are available on the

OIG Web page at <http://oig.hhs.gov/fraud/fraudalerts.html>.

C. Section 205 of Public Law 104–191

Section 205 of Public Law 104–191 requires the Department to develop and publish an annual notice in the **Federal Register** formally soliciting proposals for modifying existing safe harbors to the anti-kickback statute and for developing new safe harbors and Special Fraud Alerts.

In developing safe harbors for a criminal statute, the OIG is required to engage in a thorough review of the range of factual circumstances that may fall within the proposed safe harbor subject area so as to uncover potential opportunities for fraud and abuse. Only then can the OIG determine, in consultation with the Department of Justice, whether it can effectively develop regulatory limitations and controls that will permit beneficial and innocuous arrangements within a subject area while, at the same time, protecting the Federal health care programs and their beneficiaries from abusive practices.

II. Solicitation of Additional New Recommendations and Proposals

In accordance with the requirements of section 205 of Public Law 104–191, the OIG last published a **Federal Register** solicitation notice for developing new safe harbors and Special Fraud Alerts on December 19, 2001 (66 FR 65460). As required under section 205, a status report of the public comments received in response to that notice is set forth in Appendix G to the OIG's Semiannual Report covering the period April 1, 2002 through September, 30, 2002.¹ The OIG is not seeking additional public comment on the proposals listed in Appendix G at this time. Rather, this notice seeks additional recommendations regarding the development of proposed or modified safe harbor regulations and new Special Fraud Alerts beyond those summarized in Appendix G to the OIG Semiannual Report referenced above. A detailed explanation of justifications for a suggested safe harbor or Special Fraud Alert, as well as supporting empirical data if available, would be helpful and should, if possible, be included in any response to this solicitation.

A. Criteria for Modifying and Establishing Safe Harbor Provisions

In accordance with section 205 of HIPAA, we will consider a number of

factors in reviewing proposals for new or modified safe harbor provisions, such as the extent to which the proposals would effect an increase or decrease in—

- Access to health care services;
- The quality of care services;
- Patient freedom of choice among health care providers;
- Competition among health care providers;
- The cost to Federal health care programs;
- The potential overutilization of the health care services; and
- The ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

In addition, we will take into consideration other factors, including, for example, the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may vary based on their decisions to (1) order a health care item or service or (2) arrange for a referral for health care items or services to a particular practitioner or provider.

B. Criteria for Developing Special Fraud Alerts and Advisory Bulletins

In determining whether to issue Special Fraud Alerts and Special Advisory Bulletins, we will consider, among other factors, whether, and to what extent, the identified conduct may result in any of the consequences set forth above, as well as the potential volume and frequency of the identified conduct.

III. Solicitation of Public Comments on Certain Credentialing Practices

We have been asked by the American Medical Association (AMA) to issue guidance regarding the legality under the federal anti-kickback statute of certain practices in connection with the granting of hospital staff privileges. According to the AMA and other sources, an increasing number of hospitals are refusing to grant staff privileges to physicians who (1) own or have other financial interests in, or leadership positions with, competing healthcare entities, (2) refer to competing health care entities, or (3) fail to admit some specified percentage of their patients to the hospital. There may be other examples of restrictive credentialing.

In evaluating the propriety of these credentialing practices, the OIG has identified the following issues about which it is soliciting public comment in order to develop a better understanding of these practices and their potential for abuse:

A. Are hospital staff privileges “remuneration”? Historically, so long as a physician had privileges at one hospital, the denial of privileges at another hospital was rarely actionable, since the physician could admit his or her patients to the hospital at which the physician had privileges. With the growth of managed care networks, especially in combination with the growth of health care systems that substantially control local markets, access to patients may depend on having privileges at the proper hospital. What effect, if any, do these developments have on the determination whether staff privileges are remuneration? Should the determination whether staff privileges have monetary value turn on the particular factual circumstances (e.g., in a given market, does access to privileges have a demonstrable monetary value)? Under what circumstances do staff privileges have monetary value?

B. What are the implications of a hospital's denial of privileges to a physician who competes with the hospital? Increasingly, physicians invest in and own entities, such as ambulatory surgical centers, cardiac catheterization labs, and specialty hospitals, that compete with hospital services. These physicians may be in a position to steer profitable business or patients to their own competing business through their control of referrals. A credentialing policy that *categorically* refuses privileges to physicians with significant conflicts of interest would not appear to implicate that anti-kickback statute in most situations. How should such physicians be defined: ownership? employee or contractor? staff leadership position?

C. Should the exercise of discretion by the privilege-granting hospital affect the analysis under the anti-kickback statute? Several credentialing practices have been brought to our attention that give the privilege-granting hospital discretion to evaluate the “financial conflict” created by a physician's outside business interests and permit the physician to retain privileges subject to periodic review. Such discretionary decision-making appears to raise substantial risks under the anti-kickback statute (i.e., privileges are conditioned on a sufficient flow of referred business). What factors other than the amount of business still being generated for the hospital might be used as the basis for the hospital exercising discretion in these kinds of arrangements? From a policy perspective, are there bases for the hospital's review or exercise of discretion that should not implicate the

¹ The OIG Semiannual Report can be accessed through the OIG Web site at <http://oig.hhs.gov/publications/semiannual.html>.

anti-kickback statute? Are there limits on discretion that might provide sufficient safeguards under the anti-kickback statute?

D. Can privileges ever be conditioned on referrals, other than minimums necessary for clinical proficiency? Some hospitals have apparently attempted to condition privileges on a physician's referral of a predetermined level of his or her hospital business to the hospital. Assuming the privileges have monetary value, such conditions would appear to be suspect under the anti-kickback statute. Are there conditions under which such conditions might be justified? Failing financial health? Guaranteeing a patient volume sufficient to support offering a critical service not otherwise available (e.g., a cardiac service in a rural area)? Does the level of required referrals or business matter (e.g., is there a difference between a requirement of 25 percent of referrals compared to 75 percent)?

E. What is the effect of credentialing restrictions that apply only to members of a group practice? What are the implications of a hospital restricting privileges for some, but not all, members of a group practice? What about restricting privileges of the entire group?

Finally, we are interested in comments on other aspects of restrictive credentialing practices that should inform our review of these practices and development of possible guidance under the anti-kickback statute.

Dated: November 19, 2002.

Janet Rehnquist,

Inspector General.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1003

RIN 0991-AB04

Medicare and State Health Care Programs: Fraud and Abuse; Civil Money Penalty Exception To Protect Payment of Medicare Supplemental Insurance and Medigap Premiums for ESRD Beneficiaries

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

ACTION: Notice of withdrawal of proposed rulemaking.

SUMMARY: On May 2, 2000, we published a notice of proposed

rulemaking (65 FR 25460) soliciting public comments regarding a possible new exception under the OIG's civil money penalty provisions in 42 CFR part 1003 for independent dialysis facilities that pay, in whole or in part, premiums for Supplemental Medical Insurance (Medicare Part B) or Medicare Supplemental Health Insurance policies (Medigap) for financially needy Medicare beneficiaries with end-stage renal disease (ESRD). The exception would have established various standards and guidelines that, if met, would have resulted in the particular arrangement being protected from civil money sanctions under section 1128A(a)(5) of the Social Security Act (the Act). Having considered the public comments and for the reasons explained below, we are not promulgating an exception for these arrangements.

DATES: The NPRM published on May 2, 2000 at 65 FR 25460 is withdrawn as of December 9, 2002.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619-0089, Office of Counsel to the Inspector General.

SUPPLEMENTARY INFORMATION:

I. Background

A. Section 1128A(a)(5) of the Act

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, amended the Act to prohibit any person from offering Medicare or Medicaid beneficiaries remuneration that might influence them to order or receive from a particular provider, practitioner, or supplier items or services payable by Medicare or Medicaid. Specifically, section 231(h) of HIPAA established a new provision—section 1128A(a)(5) of the Act—for the imposition of a civil money penalty (CMP) against any person who:

Offers or transfers remuneration to any individual eligible for benefits under [Medicare or Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid].

Section 231(h) of HIPAA also created a new section 1128A(i)(6) of the Act to define the term “remuneration” for purposes of the new CMP. “Remuneration” is broadly defined to include any “waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value.” There are several narrow exceptions, including an exception for waivers of copayments based on financial need, if the waivers are neither

routine, nor advertised. No exception applies to the payment by providers of Medicare Part B or Medigap insurance premiums on behalf of Medicare or Medicaid beneficiaries.

B. Effects of Section 1128A(a)(5)

Following enactment of HIPAA, representatives of a number of ESRD providers informed the OIG that many providers had been paying for Medicare Part B premiums and Medigap policies for financially needy patients who could not afford to purchase such insurance. The OIG concluded that such premium subsidies could be unlawful under the new law, and providers subsequently suspended their purchases of Medigap policies and payments of Medicare Part B premiums for their patients. Alternatively, some providers entered into funding arrangements with unrelated, nonprofit organizations that pay premiums on behalf of needy ESRD patients without regard to the identity of the patient's provider.

To date, the OIG has approved three premium funding arrangements through advisory opinions. (OIG Advisory Opinions Nos. 97-1, 97-2, and 98-17.¹) OIG Advisory Opinion No. 97-1 is representative. In that instance, the American Kidney Fund (AKF)—a section 501(c)(3) charitable and educational organization—and a number of dialysis providers established an arrangement whereby the providers contribute funds to AKF, which, in turn, independently screens patients for financial need and pays Medicare Part B and Medigap premiums on behalf of qualifying patients. Under the arrangement, the providers do not make premium payments to, or on behalf of, particular patients; there is no “pass through” of payments from providers to specific patients; and payments do not tie patients in any way to particular providers. In short, the premium payments do not influence a patient's selection of any particular provider—the core prohibited conduct under section 1128A(a)(5). We understand that the AKF program now operates effectively and that contributions from ESRD providers have resulted in increasing numbers of needy patients receiving premium payment and other vital assistance. In the five years since AKF implemented its premium support program, we have received only a handful of letters from patients

¹ <http://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf>; <http://oig.hhs.gov/fraud/docs/advisoryopinions/1997/972ao.pdf> and http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_17.htm respectively.