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.

[FR Doc. 02–31039 Filed 12–6–02; 8:45 am]

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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.

concerned abut mistakes made in connection with their AKF funding.

C. The Proposed Exception

On October 21, 1998, Congress enacted the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), Public Law 105–277. Section 5201 of OCESAA authorized, but did not require, the Secretary to issue regulations establishing exceptions under section 1128A(a)(5) of the Act for payment practices that would otherwise violate the statute. (Additionally, OCESSA vested the Secretary with authority to issue advisory opinions approving such arrangements on a case-by-case basis.) Congress provided no guidance as to acceptable bases for protecting or approving an otherwise unlawful arrangement. Under OCESAA, if a regulatory exception is promulgated for premium support payments by ESRD providers, (i) the exception must be limited to two years, and (ii) the Comptroller General of the United States must study any disproportionate impact on specific Medigap insurers due to adverse selection in enrolling Medicare ESRD beneficiaries and recommend whether to extend the exception past two years.

We construed OCESSA as evidencing Congress' intent that we consider, but not necessarily establish, an exception for premium payments made by ESRD providers. To that end, we issued an NPRM soliciting public comment regarding a proposed exception that would have applied to independent dialysis facilities (as defined in 42 CFR 413.174) that have no hospital, physician, or other provider or supplier ownership and that pay for Medicare Part B or Medigap premiums for financially needy ESRD patients when (i) the payment is not advertised, (ii) the dialysis facility does not routinely make payments for such premiums, and (iii) the dialysis facility makes a good faith determination that the individual is financially needy. The proposed exception would not have covered the payment of Medicare Part B or Medigap premiums on behalf of any other beneficiaries or by any other type of provider. We specifically solicited comments on the potential impact of adverse selection on the Medigap insurance market.

We received 72 timely comments to the proposed rule from a cross-section of interested parties. Many commenters considered the proposed rule too narrow and advocated a broader rule that would apply to dialysis providers owned or operated by hospitals, physicians, or other providers. Other commenters thought the rule was unnecessary. Commenters representing insurers opposed the rule.

Commenters favoring a broader rule believed that OCESSA demonstrated Congress' support for an ESRD premium payment exception. They pointed out that many ESRD facilities had paid premiums for financially needy patients prior to the enactment of HIPAA and that the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) had a separate line on the ESRD cost report for such payments. They also noted that dialysis patients traditionally have very high copayments and, thus, have a particular need for supplemental insurance. A substantial amount of care provided to these patients is covered under Medicare Part B and requires a 20% copayment. According to these commenters, premium payments do not influence a patient's choice of an ESRD facility, since the availability of premium support is not typically advertised and an ESRD patient typically picks a dialysis facility based on proximity to the patient's home or the recommendation of the patient's nephrologist. Commenters also asserted that there is little risk of overutilization because both ESRD facilities and nephrologists are paid by Medicare primarily on a composite rate basis that does not vary with the amount of services provided.

Commenters opposing the proposed rule emphasized the potential effects of adverse selection on the insurance market, noting that the claims costs of Medigap subscribers with ESRD are significantly higher than those of non-ESRD subscribers. Commenters also observed, among other things, that the proposed safe harbor would give ESRD facilities an incentive to pay Medicare Part B and Medigap premiums in order to maintain their revenue streams; would benefit nephrologists who may be influenced to steer patients to facilities providing premium support; and would influence beneficiaries to select particular facilities. In sum, commenters opposing the proposal believed it would have detrimental effects on insurers, the Medicare program, and beneficiaries.

D. Determination Not To Promulgate an Exception

We have reviewed the public comments and considered the issues raised by an exception to section 1128A(a)(5) for ESRD premium payments. For the following reasons, we decline to promulgate such an exception.

First, the direct payment of supplemental premiums by ESRD providers for financially needy patients carries the same potential for abuse as the provision of free or below market rate goods or services by any other health care provider. (*See OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries* (65 FR 55844; August 30, 2002). The statute targets corruption of the provider selection process. Since any exception would be permissive, any ESRD facility that did not pay premiums for financially needy patients would likely lose business. In short, the exception would promote the very conduct the statute prohibits: the offering of remuneration to influence the selection of a provider. Moreover, patients would not only be influenced to select ESRD facilities that buy them supplemental health insurance, but would be ''locked in'' to those facilities, since changing facilities would jeopardize their supplemental insurance for all services, including substantial non-ESRD services.

Second, creating an exception for direct premium payments by ESRD providers would create demands for additional exceptions for comparable payments by other health care providers and would potentially increase federal expenditures and Medigap premiums. We can discern no rational basis—and Congress has provided no guidance—for distinguishing between providers paying premiums for ESRD patients and providers paying premiums for other chronically ill, financially needy patients, such as patients with cancer, diabetes, or congestive heart disease. Nor can we discern any rational bases for distinguishing among types of benefits provided to Medicare and Medicaid beneficiaries or among categories of sick beneficiaries. Absent congressional guidance, attempting to draw such distinctions would necessarily result in arbitrary standards and would undermine the statute.

It is to a provider's financial advantage (i) to pay the Medigap premium whenever the premium is less than the expected copayments and (ii) to pay the Part B premium whenever the premium is less than the expected Part B payments. Thus, the insurer will always lose money on these policies, as the amount paid out to the provider will always exceed the premiums received. This phenomenon—adverse selection—will likely cause insurers to raise premiums for all other enrollees to cover the losses. For this reason, the health insurance industry objected to the proposed exception.

Finally, we are not persuaded that a special exception for ESRD premium payments is needed. Financially needy dialysis patients are already receiving, and will continue to receive, supplemental health insurance support through funding arrangements with AKF or comparable independent nonprofit organizations. These arrangements are lawful, are apparently efficient, and minimize the potential for abuse.

In sum, in the absence of specific guidance from Congress on the standards to apply, we are not promulgating an exception for ESRD premium payments under section 1128A(a)(5) of the Act. This approach reflects our determination—articulated in the OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (67 FR 55855; August 30, 2002)—that any exceptions to section 1128A(a)(5) must be closely aligned with the existing language of the statute.

II. Withdrawal of Notice of Proposed Rulemaking

Accordingly, the notice of proposed rulemaking that was published in the **Federal Register** on May 2, 2000 (65 FR 25460) is withdrawn.

III. Regulatory Impact

Since the action only withdraws a notice of proposed rulemaking, it is neither a proposed or a final rule and, therefore, is not covered under Executive Order 12866 or the Regulatory Flexibility Act (5 U.S.C. 601–612).

List of Subjects in 42 CFR Part 1003

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Penalties.

Dated: October 25, 2002.

Janet Rehnquist,

Inspector General.

Approved: December 2, 2002.

Tommy G. Thompson,

Secretary.

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