

Q & A

HIPAA, Remuneration, and Medicaid Share of Cost

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Q. The hospital has been covering my client's Medicaid share of cost (aka spend down), thus allowing her to obtain outpatient coverage for her chronic condition early in the month. I understand that the facility has followed this policy for a number of beneficiaries. The provider is now telling my client that it cannot pay the share of cost because of HIPAA. Is this correct?

A. Medicaid-participating providers may be exposing themselves to the risk of a civil money penalty if they routinely pay their patients' spend down amounts so that the patients can qualify for Medicaid.

Discussion

The Medicaid medically needy option

Thirty-five states and the District of Columbia have medically needy programs. In these states, individuals qualify for Medicaid by spending down—incurring medical expenses that are sufficient to bring their incomes to a level at or below the state-set medically needy income level. See 42 C.F.R. § 435.811(a). Operationally, incurred medical expenses are deducted during the budget period—a period of between one month and six months as selected by the State. *Id.* at § 435.831(a). To apply a medical bill toward the spend down, it need only be incurred and not necessarily paid up front. 42 U.S.C. § 1396a(a)(17)(D). Medical expenses incurred by the applicant, family member, or financially responsible relative count toward the spend down if they are not subject to payment by a “liable third party.” 42 C.F.R. § 435.811(d). A liable third party is defined as “[a]ny individual, entity or program that is or may be liable to pay all or part of the cost of medical or remedial treatment for injury, disease, or disability of an applicant or recipient of Medicaid.” CMS, *State Medicaid Manual* § 3628. In this context, liability connotes a legal liability to pay all or part of the cost.

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OTHER OFFICES

HIPAA and improper inducements

Federal and State Medicaid authorities have instituted fraud and abuse programs since the early days of the Medicaid program. In 1976, Congress established the Office of Inspector General (OIG) within the U.S. Department of Health and Human Services as an independent unit responsible for conducting audits and investigations and developing fraud control policies. In addition to these federal responsibilities, the OIG works with State fraud control programs. 42 U.S.C. § 1396a(a)(61).

In 1996, the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191, was enacted, in part to “combat waste, fraud, and abuse in health insurance.” 104 CIS Legis. Hist. Pub. L. 191 (Dec. 1996). Among other things, HIPAA amended the Social Security Act (Act) to prohibit providers from offering patients any inducement in order to receive Medicaid (or Medicare) reimbursable items or services from a particular provider, practitioner, or supplier. Specifically, HIPAA provides for imposing a civil money penalty on:

[a]ny person (including an organization, agency, or other entity, but excluding a beneficiary, ...) that ... (5) offers to or transfers remuneration to any individual eligible for benefits under ... a State health care program [including 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 ... a State health care program....

HIPAA, § 231(h) (adding § 1128A(a)(5) to the Social Security Act, codified at 42 U.S.C. § 1320a-7a(a)(5)); *see also* 42 C.F.R. §§ 1003.100(b)(1)(xii), 1003.102(b)(13) (implementing regulations).

Thus, while the previously-existing anti-kickback provisions were intent-based (requiring specific intent to induce improper referrals), the HIPAA civil money penalty provision is not. Individuals and entities risk civil money penalties if they offer remuneration under circumstances where they know or should know that it is likely to influence the selection of health care provider or service. Violators are subject to a civil money penalty of up to \$10,000 for each item or service. The person can also be assessed up to three times the amount claimed for each item or service in lieu of damages sustained by the Federal government or State agency, and the Secretary of HHS can exclude the person from participation in Federal health care programs and direct the State agency to exclude the person from any State health care program. *Id.*²

² While this Q&A focuses on the civil money penalty provisions, the anti-kickback statute can also be implicated. That statute, section 1128B of the Act, makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. Even if legitimate services are provided, the statute has been interpreted to cover arrangements where *one* purpose of the remuneration is for the referral of services. *E.g., United States*

Section 1128A broadly defines remuneration to include “transfers of items or services for free or for other than fair market value” and includes the “waiver of coinsurance and deductible amounts (or any part thereof).” Social Security Act, § 1128A(i)(6). When enacting the HIPAA amendment, Congress said the “provision does not preclude the provision of items and services of nominal value, including, for example, refreshments, medical literature, complimentary local transportation services, or participation in free health fairs.” Joint Explanatory Statement of the Committee of Conference, § 231, HIPAA, Pub. L. 104-191.³

There are statutory safe harbor exceptions for practices that would otherwise be considered remuneration and, thus, run afoul of the statute:

- Waivers of coinsurance or deductible amounts that are not offered as part of an advertisement or solicitation, are made on a case-by-case basis and are not routine, and are made either after a good faith, individualized determination of financial need or after reasonable collection efforts have failed;⁴
- Waivers of coinsurance or deductible amounts made in accordance with a safe harbor to the anti-kickback statute, § 1128B, or other regulations issued by the Secretary;
- Differentials in coinsurance and deductible amounts as part of a benefit plan design where the differentials have been fully disclosed in writing and meet standards set forth by the Secretary; and
- Incentives given to individuals to promote the delivery of preventive care. Preventive care is a prenatal or a post-natal well-baby visit or a specific clinical service described in the U.S. Preventive Services Task Force *Guide to Clinical Preventive Services*. 42 C.F.R. § 1003.101; 65 Fed.

v. Kats, 871 F.2d 105 (9th Cir. 1989). Violation of section 1128B constitutes a felony and is punishable by a fine up to \$25,000, imprisonment up to five years, or both. Automatic exclusion from Federal health care programs follows a conviction.

³ According to the OIG, the gifts must be inexpensive—having a retail value of no more than \$10 individually and no more than \$50 in the aggregate annually per patient. 67 Fed. Reg. 55,855 (Aug. 30, 2002) (OIG Special Advisory Bulletin); *see also, e.g.*, 63 Fed. Reg. 14, 393, 14,396 (Mar. 25, 1998) (proposed rule).

⁴ Hospitals have flexibility in taking relevant variables into account; factors can include the local cost of living, a patient’s income, assets, and expenses, a patient’s family size, and the scope of a patient’s medical bills. 70 Fed. Reg. 4858, 4871 (Jan. 31, 2005) (Supplemental Compliance Program Guidance for Hospitals).

Reg. 24,400, 24,408-9 (Apr. 26, 2000) (preamble discussion of incentives for preventive care).⁵

Notably, in giving the Secretary (through OIG) the authority to create additional regulatory exceptions, Congress provided no guidance on how the criteria are to be applied. In regulations and advisory statements, the OIG has consistently read the prohibition broadly and the exceptions narrowly. For example, the OIG has stated that “remuneration” includes “anything of value.” For example, “hospitals may not offer valuable items or services to Medicare or Medicaid beneficiaries to attract their business.” 70 Fed. Reg. 4858, 4871 (Jan. 31, 2005) (Supplemental Compliance Program Guidance for Hospitals).

With respect to defining safe harbor exceptions to the remuneration prohibition, the OIG has been similarly restrictive. In December of 2002, the agency stated:

In the absence of statutory guidance, attempting to distinguish among types of benefits or categories of beneficiaries necessarily results in arbitrary standards. In these circumstance, the OIG has determined to exercise its regulatory authority cautiously by limiting exceptions to areas in which Congress has indicated a desire for flexibility in the provision [of] remuneration to beneficiaries or where the provision of such remuneration serves a governmental interest.

67 Fed. Reg. 72,892, 72,893 (Dec. 9, 2002); see also, e.g., Office of Inspector General, Special Advisory Bulletin: *Offering Gifts and Other Inducements to Beneficiaries* (Aug. 2002), reprinted in 67 Fed. Reg. 55,855 (Aug. 30, 2002) (OIG Special Advisory Bulletin) (stating that “given the difficulty in drawing principled distinctions between categories of beneficiaries or types of inducements,” favorable advisory opinions have been, and are expected to be, limited to situations involving conduct that is very close to an existing exception).

The payment practices that the clinic has applied to your client appear to fit within the definition of remuneration (“transfers of items or services for free or for other than fair market value,” including the “waiver of coinsurance and deductible amounts”). The safe harbor exceptions, set forth above, do not include routine payment of patients’ spend down amounts by Medicaid-participating health care providers. Thus, under current laws and the OIG’s narrow application of these laws, your client’s provider does indeed appear to be exposing itself to the risk of a civil money penalty if it routinely pays patients’ spend down amounts so that the patients can qualify for Medicaid.⁶

⁵ The Guide is available at <http://www.ahrq.gov/clinic/cps3dix.htm> and can be reviewed to determine the extent to which services are included as preventive. Any tie between provision of an exempt preventive care service and a Medicaid service that is not preventive would violate the preventive care exception and could constitute a violation. See 65 Fed. Reg. at 24,408. “An expansion of the preventive care exception to include tertiary preventive care (that is, preventive care that is part of the treatment and management of persons with clinical illnesses), ... would create an exception that would swallow the general prohibition.” *Id.* at 24,409.

⁶ Section 1128A applies to an “individual eligible for benefits,” so there is a potential argument that “remuneration” has not occurred if the State treats individuals with a spend down as ineligible for

Recommendations

You can meet with the provider to suggest strategies for assuring that patients are able to obtain the insurance coverage as early as possible. Strategies could include:

- Making sure that the facility is taking full advantage of the safe harbor provisions that OIG does recognize. For example, in making case-by-case decisions for forgive spend downs/deductibles are they considering the full range of factors, such as the local cost of living; the patient's income, assets, and expenses; the patient's family size; and the scope of a patient's medical bills? Is the facility taking full advantage of its ability to offer incentives for preventive care, as defined by the U.S. Preventive Services Task Force *Guide to Clinical Preventive Services*?
- Discussing whether the provider would consider donating funds to a non-profit community-based organization that would use these funds to pay individuals' spend down amounts. The OIG Special Advisory Bulletin has recognized that "nothing in section 1128A(a)(5) prevents" this type of arrangement if certain conditions are met: (1) the entity receiving donations must be independent; (2) the entity must make independent determinations of whether an individual needs financial assistance; and (3) the receipt of assistance cannot depend, directly or indirectly, on the use of any particular provider. A number of previous OIG Opinion Letters have sanctioned similar arrangements, for example:
 - Opinion Letter No. 06-09 (Aug. 18, 2006): discussing nonprofit, charitable organization's proposal to subsidize Medicare Part D prescription drug premiums and cost sharing obligations owed by financially-needy patients with end-stage renal disease and chronic kidney disease and stating that neither the nonprofit nor donating providers would be subject to sanctions because, among other things: (1) all applicants would complete a grant application and be processed on a first-come, first-served basis to the extent funding is available; (2) each patient would have selected his provider and have a treatment regimen in place before applying for assistance; (3) objective and verifiable criteria would be used to decide eligibility, and assistance would be provided for a specified period after which reapplication would be necessary; (4) eligibility for assistance would be decided by the organization without regard to any donor, the amount of the donor's contribution, or the applicant's choice of provider; (5) the

Medicaid pending spend down, as opposed to treating these individuals as Medicaid eligible with a spend down. The anti-kickback provision would still be implicated, however. See note 1, *supra*.

⁷ For OIG opinion letters, go to <http://oig.hhs.gov/fraud/advisoryopinions/opinions.html>. These opinions must be relied on with caution. The OIG limits its opinions to the precise facts presented by the requester and says its opinions cannot be introduced into evidence in any matter by an entity other than the requester. Nevertheless, these letters are instructive.

organization would not recommend any specific provider, and recipients would have complete freedom regarding selection of provider; (6) donors could change or discontinue their contributions at any time; (7) on request, donors would be informed using aggregate, non-personally identifiable information; (8) no donor would exert direct or indirect control over the organization or its programs; (9) the organization certified that “its discretion as to the use of contributions will be absolute, independent, and autonomous.” See *also, e.g.*, Opinion Letter No. 02-1 (Apr. 4, 2002) (similar opinion affecting financially-needy Medicare patients suffering from specific chronic illnesses and rare disorders).

- Opinion Letter No. 97-1 (undated): regarding donations by renal providers to an independent charitable organization (American Kidney Fund), for the purpose of funding a program to pay Part B and Medigap cost sharing for financially-needy Medicare beneficiaries with end-stage renal disease where such beneficiaries may be receiving treatment from a donor dialysis provider. Neither the AKF nor the donating companies would be subject to sanctions because, among other things: (1) AKF will not advertise the availability of possible assistance or disclose directly or indirectly to individual patients that companies had contributed to AKF to fund the grants; (2) determinations of eligibility for assistance will be made solely on AKF’s good faith assessment of a patient’s need, and AKF will not take the identity of a donor into account when assessing an applicant; (3) dialysis facilities will be free to decide whether and how much to contribute to AKF and will not track the amount that AKF pays on behalf of their patients; (4) dialysis facilities will not disclose to each other or other dialysis providers the amount or method of calculating their respective contributions; (5) contributions will be made without any restriction or conditions placed on the donation.