DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

OIG Policy Statement Regarding Hospitals That Discount or Waive Amounts Owed by Medicare Beneficiaries for Self-Administered Drugs Dispensed in Outpatient Settings

The purpose of this Policy Statement is to assure hospitals that they will not be subject to Office of Inspector General (OIG) administrative sanctions for discounting or waiving amounts Medicare beneficiaries may owe for self-administered drugs (SADs) they receive in outpatient settings when those drugs are not covered by Medicare Part B, subject to the conditions specified herein. This Policy Statement is designed to address the question whether various guidance documents issued by the Centers for Medicare & Medicaid Services (CMS), including a Program Memorandum outlining changes in the Outpatient Prospective Payment System (OPPS) for calendar year 2003, require hospitals to bill and collect (or make good faith efforts to collect) their usual and customary charges for SADs that are not covered by Medicare Part B (Noncovered SADs) to comply with OIG's fraud and abuse authorities. That Program Memorandum stated that:

> [n]either the OPPS nor other Medicare payment rules regulate the provision or billing by hospitals of non-covered drugs to Medicare beneficiaries. However, a hospital's decision not to bill the beneficiary for non-covered drugs potentially implicates other statutory and regulatory provisions, including the prohibition on inducements to beneficiaries, section 1128A(a)(5) of the [Social Security] Act, or the anti-kickback statute, section 1128B(b) of the Act.[1]

Medicare Part B generally covers care that Medicare beneficiaries receive in hospital outpatient settings such as emergency departments and observation units; however, Medicare Part B covers only certain drugs in these settings. Specifically, Medicare Part B covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them.[2]

Although some or all of the SADs a Medicare beneficiary receives in an outpatient setting may be covered by Medicare Part D, most hospital pharmacies do not participate in Medicare Part D.[3] CMS has stated that only hospitals with pharmacies that dispense prescriptions to outpatients and have contracts with Medicare Part D plans should bill the contracted plans directly as in-network pharmacies; otherwise, the hospitals should bill the Medicare beneficiaries for any Noncovered

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[1] CMS, "2003 Update of the Hospital Outpatient Prospective Payment System (OPPS)," Program Memorandum Intermediaries, Transmittal A-02-129 (Change Request 2503, January 3, 2003).

[2] Section 1861(s)(2)(B) of the Social Security Act (the Act); *Medicare Benefit Policy Manual*, CMS, Pub. 100-02, Chapter 15, "Covered Medical and Other Health Services," Sections 50, 50.2.

[3] See, e.g., "How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings," CMS Product No. 11333, revised Feb. 2011, *available at* https://www.medicare.gov/Pubs/pdf/11333.pdf.

SADs that the hospitals dispense.[4] Consequently, Medicare beneficiaries may be billed for Noncovered SADs they received as outpatients—often at amounts much higher than they would have paid at retail pharmacies—even if those drugs are covered under their Medicare Part D plans.[5]

Ordinarily, routine discounts or waivers of costs owed by Medicare beneficiaries, including cost-sharing amounts, potentially implicate the Federal anti-kickback statute,[6] the civil monetary penalty and exclusion laws related to kickbacks,[7] and the Federal civil monetary penalty law prohibiting inducements to beneficiaries.[8] Nonetheless, in the limited circumstances described in this Policy Statement, hospitals will not be subject to OIG administrative sanctions if they discount or waive amounts that Medicare beneficiaries owe for Noncovered SADs (including Noncovered SADs that may be covered under Medicare Part D) the beneficiaries receive in outpatient settings, subject to the following conditions:

- This Policy Statement applies only to discounts on, or waivers of, amounts Medicare beneficiaries owe for Noncovered SADs that the beneficiaries receive for ingestion or administration in outpatient settings;[9]
- Hospitals must uniformly apply their policies regarding discounts or waivers on Noncovered SADs (e.g., without regard to a beneficiary's diagnosis or type of treatment);
- Hospitals must not market or advertise the discounts or waivers; and
- Hospitals must not claim the discounted or waived amounts as bad debt or otherwise shift the burden of these costs to the Medicare or Medicaid programs, other payers, or individuals.

Nothing in this Policy Statement requires hospitals to discount or waive amounts owed by Medicare beneficiaries for Noncovered SADs that the beneficiaries receive in outpatient settings.

Moreover, nothing in this Policy Statement affects the ability of a hospital to discount or waive any amounts owed by Medicare beneficiaries on the basis of a good-faith, individualized

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[4] See, e.g., "Information Partners Can Use On: Billing for Self-Administered Drugs Given in Outpatient Settings," CMS Product No. 11331-P, revised Feb. 2011, *available at* https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11331-P.pdf.

[5] If a self-administered drug is covered by a Medicare beneficiary's Part D plan, the beneficiary may submit a paper claim to the Medicare Part D plan for reimbursement; however, the beneficiary typically would remain liable for the difference between what the hospital charged and what the Medicare Part D plan paid. *See generally* MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System* (June 2015), *available at* http://www.medpac.gov/documents/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0.

[6] Section 1128B(b) of the Act, 42 U.S.C. § 1320a-7b(b).

[7] Sections 1128(b)(7) and 1128A(a)(7) of the Act, 42 U.S.C. §§ 1320a-7(b)(7) and 1320a-7a(a)(7).

[8] Section 1128A(a)(5) of the Act, 42 U.S.C. § 1320a-7a(a)(5).

[9] A beneficiary is not considered an outpatient if the only service received from the hospital is the dispensing of a drug for subsequent self-administration.

determination of a beneficiary's financial need. Further, nothing in this Policy Statement affects the operation of CMS's programmatic rules and regulations.

Finally, nothing in this Policy Statement affects a hospital's responsibility to bill only for services performed and to comply with Federal and State billing laws and guidance in effect at the time.

General guidance about the Federal anti-kickback statute and other fraud and abuse authorities is available on OIG's website at *http://oig.hhs.gov/*. This guidance includes the "Special Fraud Alert: Routine Waivers of Copayments or Deductibles Under Medicare Part B;" the "Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries;" safe harbor regulations (and the "preamble" discussions that include explanatory information); compliance program guidance documents for various industry sectors; and OIG advisory opinions.

OIG reserves the right to reconsider the issues raised in this Policy Statement and, where the public interest requires, to rescind, modify, or terminate this Policy Statement.

Questions regarding this Policy Statement may be directed to Jennifer Williams, Senior Counsel, Office of Counsel to the Inspector General, at (202) 401-4133.

/Daniel R Levinson/ October 29, 2015

Daniel R. Levinson Date
Inspector General