

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS-1229-P]

RIN 0938-AM12

Medicare Program; Payment Reform for Part B Drugs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise, based on one of four approaches, the current payment methodology for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis. We are seeking comments on which of these proposed approaches we should implement. This proposed rule would also make changes to Medicare payment for furnishing or administering certain drugs and biologicals.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 14, 2003.

ADDRESSES: In commenting, please refer to file code CMS-1229-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail. Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1229-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850. (Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Marjorie Baldo, (410) 786-0548.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please call (410) 786-7197.

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To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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Alphabetical List of Acronyms in the Proposed Rule

AMP Average Manufacturer's Price
 APC Ambulatory Payment Classification
 ASCO American Society of Clinical Oncology

ASP Average Sale Price
 AWP Average Wholesale Price
 BBA Balanced Budget Act of 1997
 BBRA Balanced Budget Refinement Act of 1999
 BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
 CMS Centers for Medicare & Medicaid Services
 DHHS Department of Health and Human Services
 DME Durable Medical Equipment
 DMERC Durable Medical Equipment Regional Carrier
 DOJ Department of Justice
 EAC Estimated Acquisition Cost
 EPO Erythropoietin
 ESRD End-Stage Renal Disease
 FSS Federal Supply Schedule
 GAO General Accounting Office
 MEDPAC Medicare Payment Advisory Commission
 NDC National Drug Code
 NOC Not Otherwise Classified
 OIG Department of Health and Human Services Office of Inspector General
 OMB Office of Management and Budget
 OPPTS Outpatient Prospective Payment System
 PPO Preferred Provider Organization
 PRA Paperwork Reduction Act of 1995
 SDP Single Drug Pricer
 VA Department of Veterans Affairs
 WAMP Widely Available Market Price

I. Background

A. Covered Drugs and Biologicals

Medicare Part B currently covers a limited number of prescription drugs. For the purposes of this proposed rule, the term "drugs" will hereafter refer to both drugs and biologicals. Currently covered Medicare drugs generally fall into three categories: drugs furnished incident to a physician's service, durable medical equipment (DME) drugs, and statutorily covered drugs and other drugs.

1. Drugs Furnished Incident to a Physician's Service

These are injectable or intravenous drugs that are administered incident to a physician's service (section 1861(s)(2) of the Social Security Act (the Act)). The Act limits coverage to drugs that are not usually self-administered. Under the "incident-to" provision, the physician must incur a cost for the drug, and must bill for it. Examples include injectable prostate cancer drugs (lupron acetate for depot suspension, goserelin acetate implant), injectable drugs used in connection with treatment of cancer (epoetin alpha), intravenous drugs used to treat cancer (paclitaxel and docetaxel).