



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

Action: Notice

Summary: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443-1984.

HRSA requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Drug Pricing Program Reporting Requirements

(OMB No. 0915-0176) – [Extension]

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act), “Limitation on Prices of Drugs Purchased by Covered Entities.” Section 340B provides that a manufacturer who participates in Medicaid must sign a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge enrolled covered entities a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Covered entities which choose to participate in the section 340B Drug Pricing Program must comply with the requirements of 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(5)(C) to permit the Secretary or manufacturers to conduct audits of covered entities and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Pharmacy Affairs (OPA) developed a dispute resolution process for manufacturers and covered entities, as well as manufacturer guidelines for audit of covered entities (Federal Register Final Notice, December 12, 1996 (Vol. 61, No. 240, pp. 65406-65413)).

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Reporting/ Notification Requirement	No. of Respondents	Responses per Respondent	Total Responses	Hours/ Response	Total Burden Hours
AUDITS					
Audit Notification to Entity ¹	10	1	10	4	40
Audit Workplan ¹	8	1	8	8	64
Audit Report ¹	6	1	6	8	48
Entity Response	6	1	6	8	48
DISPUTE RESOLUTION					
Mediation Request	10	4	40	10	400
Rebuttal	10	1	10	16	160

TOTAL	50		80		760
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¹ Prepared by the manufacturer

Recordkeeping Burden:

Recordkeeping requirement	Number of recordkeepers	Hours of recordkeeping	Total Burden
Dispute Records	50	0.5	25

Addresses: Submit your comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Deadline: Comments on this Information Collection Request must be received within 60 days of this notice.

Dated: October 22, 2012

Bahar Niakan

Director, Division of Policy and Information Coordination

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