

(Comment 4) One comment states that Medication Guides increasingly become accessible online for download and print and the costs for printing, including paper, toner, administrative, and software costs, have shifted from the manufacturers to the pharmacies.

(Response) While Medication Guides are increasingly available online for download and printing, the FDA does not agree that a financial and acquisition burden has shifted to or been created for dispensers. The comment mischaracterizes the cost to dispensers associated with the distribution of Medication Guides. For

purposes of information collection requests under the PRA, capital costs are costs for equipment, machinery, and construction that, if not for FDA's request or requirement, the respondent would not incur. Capital costs do not include costs to achieve regulatory compliance. The costs presented by the comment are not capital costs because they are costs associated with achieving regulatory compliance with requirements of the FD&C Act, not costs associated specifically with equipment, machinery, and construction needed to retain appropriate substantiating evidence.

(Comment 5) One comment states that the length of Medication Guides continues to be burdensome and hinders a pharmacist from utilizing a potentially effective tool. The comment stresses the need for a succinct, one-page document that can be easily integrated into current pharmacy practice workflow.

(Response) FDA generally agrees with the comment and is currently in the process of evaluating whether a one-page solution can be implemented.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
208.20 .....	25	1	25	320	8,000
314.70(b)(3)(ii), 601.12(f) .....	5	1	5	72	360
208.24(e) .....	59,000	5,000	295 million	3 minutes	14,750,000
208.26(a) .....	1	1	1	4	4
Total .....					14,758,364

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 20, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443-1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Assessing Factors That Impact AIDS Drug Assistance Program (ADAP) Enrollment and Management in the Face of ADAP Waiting Lists (OMB No. 0915-xxxx)—[New]**

HRSA's AIDS Drug Assistance Program (ADAP) provides assistance to help low-income, uninsured and underinsured individuals living with HIV/AIDS get access to life-saving medications. As part of the Ryan White HIV/AIDS Program, ADAP is the payer of last resort. Clients enrolled in ADAP have exhausted all other resources to obtain necessary medications and care. In recent years, ADAP has experienced an increase in enrollment while funding resources have decreased.

This study will use case study methods to identify and examine factors that contribute to the rising enrollments in ADAP and States' abilities to meet demands for ADAP services. Data

collection will include interviews with up to eight respondents in each of eight selected states, for a maximum of 64 total respondents. Each interview will last approximately one and a half hours. The respondents fall into three general categories—ADAP personnel, State HIV/AIDS program leads, and personnel from related State and local programs such as Medicaid and pharmacy assistance programs. Interviews will be conducted over a period of two and a half months.

The proposed study will assess factors that may contribute to the rise in ADAP enrollment and costs such as new HIV cases, earlier use of antiretroviral medications, lower attrition of existing clients, unemployment and loss of insurance, or increasing drug costs. In addition, the study will examine factors that may decrease ADAP costs such as health care reform and cost containment strategies. Findings from the study will be used to develop policy and to recommend promising practices for managing ADAPs.

The annual estimate of burden is as follows:

Activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
ADAP Site Visit Coordination .....	8	1	8	1	8
Instrument:					
ADAP Personnel Interview .....	32	1	32	1.5	48
State HIV/AIDS Lead Interview .....	8	1	8	1.5	12

Activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Alternative State/Local Program Informant Interview .....	24	1	24	1.5	36
Total .....	72	.....	.....	.....	104

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: April 19, 2012.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

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The following request has been submitted to the Office of Management

and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Uncompensated Services Assurance Report (OMB No. 0915-0077)—[Revision]**

Under the Hill-Burton Act, the Government provides grants and loans for construction or renovation of health care facilities. As a condition of receiving this construction assistance, facilities are required to provide services to persons unable to pay. A condition of receiving this assistance requires facilities to provide assurances periodically that the required level of uncompensated care is being provided, and that certain notification and record keeping procedures are being followed. These standard requirements are referred to as the uncompensated services assurance.

The annual estimate of burden is as follows:

**ESTIMATE OF INFORMATION COLLECTION BURDEN**

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
<b>Disclosure Burden (42 CFR)</b>					
Published Notices (124.504(c)) .....	63	1	63	0.75	47.25
Individual Notices (124.504(c)) .....	63	1	63	43.60	2,746.80
Determinations of Eligibility (124.507) .....	63	99	6,237	0.75	4,677.75
Subtotal Disclosure Burden .....	.....	.....	.....	.....	7,471.80
<b>Reporting</b>					
Uncompensated Services Report—HRSA-710 Form (124.509(a)) .....	10	1	10	11.00	110.00
<b>Application for Compliance Alternatives</b>					
Public Facilities (124.513) .....	4	1	4	6.00	24.00
Small Obligation Facilities (124.514(c)) .....	0	.....	.....	.....	.....
Charitable Facilities (124.516(c)) .....	0	.....	.....	.....	.....
<b>Annual Certification for Compliance Alternatives</b>					
Public Facilities (124.509(b)) .....	32	1	32	0.50	16.00
Charitable Facilities (124.509(b)) .....	13	1	13	0.50	6.50
Small Obligation Facilities (124.509(c)) .....	0	.....	0	.....	.....
<b>Complaint Information (124.511(a))</b>					
Individuals .....	10	1	10	0.25	2.50
Facilities .....	10	1	10	0.50	5.00
Subtotal Reporting Burden .....	.....	.....	.....	.....	164.00