

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly

frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: August 19, 1996.
Michael A. Friedman,
Deputy Commissioner for Operations.
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Health Care Financing Administration [R-187]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and

Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* National Provider System (NPS); *Form No.:* HCFA-R-187; *Use:* HHS is consolidating provider enumeration across programs. The NPS will be used in program operations and management to assign provider identification numbers, i.e., billing numbers for claims processing and payment. It will replace the current Medicare Physician and Eligibility System (MPIES) and UPIN; it will replace the enumeration functions of the Medicare OSCAR, CLIA, and NSC provider numbering systems. *Frequency:* Annually; *Affected Public:* Federal Government, State, Local or Tribal Government, Individuals or Households, Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 88; *Total Annual Hours:* 23,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.hcfa.gov>, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 19, 1996.

Edwin J. Glatzel,

*Director, Management Planning and Analysis
Staff, Office of Financial and Human
Resources.*

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Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to 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 instruments, call the HRSA

Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Uncompensated Services Reporting and Recordkeeping—42 CFR 124, Subpart F (OMB No. 0915-0077)—Extension and Revision—Titles VI and XVI of the PHS Act, commonly known as the Hill-Burton Act, provide for government grants and loans for construction or renovation of health care facilities. As a condition of receiving this construction assistance,

facilities are required to provide a "reasonable volume" of services to persons unable to pay. Facilities are also required to provide assurances periodically that the required level of uncompensated care is being provided, and to follow certain notification and recordkeeping procedures. These requirements are referred to as the uncompensated services assurance.

The regulations contain provision for reporting to the government the amount of free care provided, as well as provisions for following certain notification and recordkeeping procedures. All of these regulations are included in this clearance request. The Uncompensated Services Assurance Report (USAR) (HRSA form 710) is one of the methods of reporting the amount of free care provided. There are no changes to the USAR form. There will be a significant reduction in the burden from the previous request for OMB approval. Fewer facilities are obligated to report since many have met their obligation. A new Charitable Facilities Compliance Alternative has been added. Burden estimates are as follows:

Requirement	Number of respondents	Responses per respondent	Burden per response	Total burden hours
Disclosure Requirements (42 CFR):				
Published Notices (124.504(a))	788	1	1	788
Individual Notices (124.504(c))	788	1	59	46,492
Determinations of Eligibility (124.507)	788	160	2	252,160
Reporting Requirements (42 CFR)—Uncompensated Services—HRSA Form 710 (USAR) (124.509(a))	678	1	14	9,492
Complaint Information (124.511(a)):				
Individuals	4	1	.25	1
Facilities	4	1	.50	2
Application for Compliance Alternative for Public Facilities (124.513(c))	5	1	6	30
Annual Certification for Public Facilities (124.509(b))	355	1	.5	178
Application for Compliance Alternative for Small Obligation Facilities (124.514(c))	0	0	2	0
Annual Certification for Small Obligation Facilities (124.509(c))	2	1	.5	1
Application for Compliance Alternative for Charitable Facilities (124.516(c))	2	1	6	12
Annual Certification for Charitable Facilities (124.516(c))	19	1	.5	10
Subtotal—Reporting and Disclosure—309,166				

Recordkeeping Burden is as follows:

Requirement (42 CFR)	Number of record-keepers	Hours/facility/year	Record-keeping burden
Nonalternative Facilities (124.510(a))	788	75	59,100
Small Obligation Facilities (124.510(b)) ¹	2	0	0
Public Facilities (124.510(b)) ¹	355	0	0
Subtotal—Recordkeeping—59,100			

¹ Requires facilities under the public facilities compliance alternative and the small obligation compliance alternative to maintain qualification documents. These are ordinarily retained by facilities, so there is no burden.