

document for industry will be on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. A copy of the draft guidance document will also be available on the Internet at "http://www.fda.gov/cder/guidance/index.htm".

On July 29, 1998, the committee will discuss effectiveness testing for final formulations of health-care antiseptic drug products relative to performance expectations for these OTC drug products. In the **Federal Register** of June 17, 1994 (59 FR 31402 through 31452), the agency published a proposed rule for OTC health-care antiseptic drug products, i.e., patient preoperative skin preparations, surgical hand scrubs, and health-care personnel and antiseptic handwashes. Included in the proposed rule are key characteristics for each drug product class of health-care antiseptic drug products (i.e., definitions), a requirement for final formulation testing, effectiveness standards, and labeling of each of the drug product categories. In response to the proposed rule, the agency received comments to consider six drug product categories (preoperative skin preparation, surgical hand scrub, health-care personnel handwash, food handler handwash, antimicrobial handwash, and antimicrobial bodywash). Comments also proposed alternate: (1) Testing requirements, (2) key characteristics, and (3) labeling for each of the categories. FDA is seeking the recommendations of the committee and experts on appropriate performance expectations for OTC health-care antiseptic drug products and how these final formulations should be tested.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 21, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on July 28 and 29, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 21, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 18, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration [HCFA-R-224]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

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 this 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:** Collection of Managed Care Data Using the Uniform Institutional Providers Form (HCFA-1450/UB-92) and Supporting Statute Section 1853(a)(3) of the Balanced Budget Act of 1997; **Form No.:** HCFA-R-224 (OMB No. 0938-0711); **Use:** Section 1853(a)(3) of the Balanced Budget Act (BBA) requires Medicare+Choice organizations, as well as eligible organizations with risk-sharing contracts under section 1876, to submit encounter data. Data regarding inpatient hospital services are required for periods beginning on or after July 1, 1997. These data may be collected starting January 1, 1998. Other data (as the Secretary deems necessary) may be required beginning July 1, 1998.

The BBA also requires the Secretary to implement a risk adjustment methodology that accounts for variation in per capita costs based on health

status. This payment method must be implemented no later than January 1, 2000. The encounter data are necessary to implement a risk adjustment methodology.

Hospital data from the period, July 1, 1997-June 30, 1998, will serve as the basis for plan-level estimates of risk adjusted payments. These estimates will be provided to plans by March, 1999. Encounter data collected from subsequent time periods will serve as the basis for actual payments to plans for CY 2000 and beyond.

In implementing the requirements of the BBA, hospitals will submit data to the managed care plan for enrollees who have a hospital discharge using the HCFA-1450 (UB-92), Uniform Institutional Provider Claim Form. Encounter data for hospital discharges occurring on or after July 1, 1997 are required. While submission from the hospital to the plan is required, plans are provided with an alternate submission route for the start-up year.

Special procedures have been identified to ensure that hospital encounter data are submitted for discharges occurring between July 1, 1997 and June 30, 1998, the start-up year. HCFA has identified three alternatives for the submission of hospital encounter data for discharges during the start-up year, including the following:

Option 1: The Plan will have a hospital submit UB-92s or Medicare Part A ANSI ASC X12 837 (ANSI 837) records using the traditional HMO "No Pay" bill method.

Option 2: The Plan can currently produce a complete UB-92/ANSI 837 and will hold the data until the fiscal intermediary (FI) can accept it.

Option 3: The Plan will submit an abbreviated UB-92 data set via an alternative route.

During the start up year, the plan is expected to establish an electronic data linkage to a FI to be determined by HCFA. HCFA will assist Plans in initiating discussions with their FI. By July 15, 1998, the Plan is expected to have completed this linkage, including testing of the linkage, and to be capable of transmitting hospital encounter data to a FI. Data for the start-up year must be transmitted to the plan's FI by September, 18, 1998. All data with discharge dates after July 1, 1998 will be transmitted using this linkage. (See Appendix III for additional information on the transmission of data to HCFA.) Each plan and/or contract will use a single FI. HCFA will establish a series of interim deadlines to ensure that plans are making sufficient progress toward

accomplishing this linkage no later than July 15, 1998.

After plans have established linkages to a FI, hospitals will submit HCFA-1450 (UB-92) forms to the managed care plan. The HCFA-1450 (UB-92) form is identical to the one used by hospitals in billing for Medicare fee-for-service claims. After receiving the pseudo claim from the hospital, the plan attaches the plan identifier, which is the HCFA assigned managed care organization (MCO) Contract Number, and submits the pseudo-claim electronically to the fiscal intermediary (FI). The data processing flow by the FI is very similar to current claims processing for the fee-for-service system, except that no payment is authorized to the plan. Pseudo claims will flow through the FI to our Common Working File (CWF) and will be retained by HCFA.; *Frequency*: On occasion; *Affected Public*: Business or other for-profit, Not-for-profit institutions, and Federal government; *Number of Respondents*: 1.9 million; *Total Annual Responses*: 1.9 million; *Total Annual Hours*: 32,833.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto: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 Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: June 16, 1998.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-243]

#### 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*: New Collection; *Title of Information Collection*: Medicare Agreement Application, Health Care Prepayment Plan; *Form No.*: HCFA-R-243; *Use*: An organization must meet certain requirements to be a Health Care Prepayment Plan that is eligible for a Medicare 1833 agreement. The application is the collection form used to obtain information from an organization that would allow HCFA staff to determine compliance with the regulations. This form includes requests for information about: the management of the applicant organization; arrangements for providing health care to beneficiaries; meeting Medicare requirements for appeals, hearings, advance directives, health benefits; risk sharing with other entities; the fiscal soundness of the applicant; the cost budget, which forms the basis for HCFA payment; prevention of duplicate payment; and the applicant's marketing strategy. *Frequency*: One time; *Affected Public*: Business or other for-profit institutions, Not-for-profit institutions, and State, Local or Tribal Governments.; *Number of Respondents*: 15; *Total Annual Responses*: 15; *Total Annual Hours*: 1,125.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or any

related forms, E-mail your request, including your address and phone number, to [Paperwork@hcfa.gov](mailto: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 Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: June 18, 1998.

**John P. Burke III,**

*HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

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, Pub. L. 104-13), 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 draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1891.

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.