

and "Specific Instructions" in the application kit should be followed with the exception of the receipt dates and the mailing label address. Do not send applications to CSR, NIH. Applications from State and local Governments may be submitted on Form PHS 5161 (Rev. 7/92) or Form PHS 398 (Rev. 5/95).

The face page of the application should reflect the RFA number RFA-FDA-CVM-98-1.

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925-0001.

C. Legend

Unless disclosure is required by FOIA as amended as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: April 10, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Form #HCFA-R-224]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 (DHHS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an

emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, part 1320. The Agency cannot reasonably comply with the normal clearance procedures because of a statutory deadline imposed by section 1853(a)(3) of the Balanced Budget Act of 1997. Without this information, HCFA would not be able to properly implement the requirements set forth in the statute.

HCFA is requesting OMB review and approval of this collection by 5/8/98, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individual designated below, by 5/6/98.

During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 CFR 1320.5.

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;

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 a start-up period during which time an alternate submission route is permitted.

The six month start up period, beginning January 1, 1998 will enable plans to accomplish the requirements of the BBA by the end of the start-up period, or June 30, 1998. Special procedures have been identified to ensure that hospital encounter data are submitted for discharges occurring on or after July 1, 1997 and before June 30, 1998. The special procedures for the start up period include the following:

1. In order to provide plans with an estimate of their Average Payment Rate (APR) by March, 1999, HCFA must receive data on hospital discharges that occurred on or after July 1, 1997 and before December 31, 1997, as well as encounter data on discharges that occur during the start up period, or January 1, 1998 through June 30, 1998. Currently, most plans do not have the capacity to submit data electronically to a fiscal intermediary (FI), and the FIs are not capable of receiving these data. Therefore, during this period only, unless an alternative approach is approved by HCFA, hospitals must submit completed UB-92s for the Plan's enrollees. These pseudo-claims must be submitted to the hospital's regular fiscal intermediary. This is a current requirement for hospitals, and they are expected to comply with this requirement throughout this period. Plans must provide hospitals with the Medicare identification number of all enrollees admitted who have Medicare coverage.

If hospitals are unable to submit these data on behalf of the plan during the start-up period, an alternate method of submitting the data may be developed by HCFA. If such a method is developed, it would require the plans to submit a subset of data elements that are found on the UB-92. Possible data elements include the following: Plan Contract Number; HIC (or Medicare Identification Number); enrollee's name; enrollee's state and county of residence; enrollee's birthdate and gender; Medicare Provider Number for the Hospital; claim from and thru date; admission date; and principal and secondary diagnoses codes. HCFA will specify the data elements, submission route, and format for these data.

2. During the start up period, the plan is expected to establish an electronic data linkage to a FI to be determined by HCFA. By June 30, 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 an FI. All data submitted after July 1, 1998 will be transmitted using this linkage. (See Attachment 1 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 June 30, 1998. HCFA will assist plans in initiating discussions with their FI.

After plans have established linkages to a FI, hospitals will submit HCFA-1450 (UB-92) forms to the managed care plan. The HCFA-1450 (UB92) 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: 13,310.

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, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designee referenced below, by 5/6/98:

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395-6974 or (202) 395-5167, Attn: Allison Herron Eydt, HCFA Desk Officer.

Dated: April 9, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-8005.

Proposed Project: Community Mental Health Services (CMHS) Block Grant Application—Revision—The ADAMHA

Reorganization Act 42 USC 300x1-9 established the Community Mental Health Services Block Grant program which authorized block grants to States to provide community based mental health services. The name of the program was changed in the Spring of 1997 to The Performance Partnership Block Grants (PPBG) for Community Mental Health Services. Under provision of the law, States may receive allotments only after an application is approved by the Secretary. Further, the Act requires States to submit to the Secretary a plan for providing comprehensive community mental health services to adults with a serious mental illness and to children with a serious emotional disturbance and an annual implementation report on the block grant fund activities for the previous year.

This block grant program is administered by SAMHSA's Center for Mental Health Services (CMHS). Through an iterative process of consultation with State mental health planners, representatives of the National Association of State Mental Health Program Directors, and the National Governors Association, CMHS revised the recommended voluntary format and content. The proposed application for FY 1999-2001 reflects the criteria, assurances, and requirements set forth in Public Law 102-321. The proposed application provides maximum flexibility to the States while providing performance measures as required by the Government Performance and Results Act. It includes a multi-year option for the State Plan, the option for consolidation of the 12 criteria for application to 5 criteria, and reduced respondent burden. Based on feedback from States that might exercise the multi-year planning option and the consolidation of the criteria, the annual burden estimates are as follows:

ESTIMATES OF ANNUALIZED BURDEN

	Number of States responding	Responses per respondent (over 3 year period)	Hours per response	Annualized response burden (hours)
State Plan:				
12 Criteria:				
1 year	7	3	210	1470
2 year	3	2	180	360
3 year	4	1	150	200
5 Criteria:				
1 year	15	3	180	2700
2 year	15	2	150	1500
3 year	15	1	110	550
Implementation Report	59	3	80	4720