

device and is indicated for the disposal of standard plastic syringe-mounted hypodermic needles (19 through 28 gauge, up to 2 inches in length) in patient treatment and clinical laboratory settings.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the General Hospital and Personal Uses Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On September 26, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before March 2, 1998, file with the Dockets Management Branch (address

above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: January 5, 1998.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-2082]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

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: Revision of a currently approved collection; *Title of Information Collection:* Statistical Report on Medical Care: Eligibles, Recipients, Payments and Services; *Form No.:* HCFA-2082 (OMB# 0938-0345); *Use:* State data are reported either

on the hard copy HCFA-2082 or by the Federally mandated electronic process, known as the Medicaid Statistical Information System (MSIS). These data are the basis of actuarial forecasts for Medicaid service utilization, costs of analysis, cost savings estimates and responding to requests for information from HCFA components, the Department, Congress and other customers.; Frequency: Quarterly and Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 53; *Total Annual Responses:* 212; *Total Annual Hours:* 6,808.

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/reg/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. 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: Louis Blank, Room C2-26-17 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Date: January 22, 1998.

John P. Burke III,

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

[FR Doc. 98-2304 Filed 1-29-98; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4263-N-75]

Notice of Proposed Information Collection for Public Comments

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is

soliciting public comments on the subject proposal.

DATES: Comments due: March 31, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, S.W., Room 4238, Washington, D.C. 20410-5000.

FOR FURTHER INFORMATION CONTACT: Mildred M. Hamman, (202) 708-3642, extension 4128, for copies of the proposed forms and other available documents. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the

agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology; e.g. permitted electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Requisition for Partial Payment of Annual Contributions, Supporting Data for Annual Contributions, Voucher for Payment.

OMB Control Number: 2577-0149.

Description of the need for the information and proposed use: Housing Agencies (HAs) administering the Section 8 Rental Voucher, Rental Certificate and Moderate Rehabilitation Programs are required to maintain financial reports in accordance with accounting standards to permit timely and effective audits. The financial forms estimate the HA's annual contributions requirements; assure that program costs

do not exceed the amount of contract authority authorized in the Annual Contributions contract (ACC); requisition the advance of annual contributions; and report annual receipts and expenditures under the ACC. The authority for the collection of this information is the Housing and Community Development Act of 1987.

Agency form numbers, if applicable: HUD-52263, HUD-52672, HUD-52673, HUD-52681.

Members of affected public: State, Local or Tribal Governments.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: 6,200 respondents, seven responses per respondent, 1.4 hour average per response, 62,000 hours total reporting burden.

Status of the proposed information collection: Extension.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: January 23, 1998.

Kevin Emanuel Marchman,
Assistant Secretary for Public and Indian Housing.

BILLING CODE 4210-33-M

Suggested Format for Requisition for Partial Payment of Annual Contributions Section 8 Housing Assistance Payments Program

U.S. Department of Housing
and Urban Development
Office of Public and Indian Housing

OMB Approval No. 2577-0149 (Exp. 1/30/98)

Public reporting burden for this collection of information is estimated to average 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This agency may not conduct or sponsor, and you are not required to respond to, a collection of information unless that collection displays a valid OMB control number. Authority for this collection of information is the Housing and Community Development Act of 1987. Housing Agencies (HAs) required to maintain financial reports in accordance with accepted accounting standards too permit timely and effective audits. The financial records identify the amount of annual contributions that are received and disbursed by HAs. Responses to the collection of information are required to obtain a benefit or to retain a benefit. The information requested does not lend itself to confidentiality.

1. Date of Requisition		2. No. of Months in 1st FY		4. Public Housing Agency (HA) (Name and Address)		
3. Project No.						
5. Housing Program Type (Mark one) <input type="checkbox"/> (a) Moderate Rehabilitation <input type="checkbox"/> (c) Rental Vouchers <input type="checkbox"/> (b) Rental Certificates		6. HA Fiscal Year Ending Date (Mark one box and complete year) <input type="checkbox"/> (a) March 31, <input type="checkbox"/> (b) June 30, <input type="checkbox"/> (c) September 30, <input type="checkbox"/> (d) December 31, 19:				
7. Number of Units Under Lease to Eligible Families as of Date of Requisition	8. Average Monthly Housing Assistance Payment Per Unit as of Date of Requisition	9. Estimated Number of Units to be Under Lease at End of Requested Year	10. Unit Months Under Lease Year to Date	11. Average Monthly Housing Assistance Payment Per Unit Year to Date		
						Funds Required for Requested Year
12. Preliminary Administrative and General Expense						
13. Estimated Housing Assistance Payments (Account 4715)						
14. Estimated Ongoing Administrative Fee						
15. Estimated Hard-to-House Fee (Existing Housing Certificates and Housing Vouchers Only)						
16. Independent Public Accountant Audit Costs (Section 8 Only)						
17. Total Funds Required to End of Requested Year (Sum of Lines 12 through 16)						
18. Payments Previously Approved for the Fiscal Year (applicable only to revised requisition)						
19. Adjustment to Requisition (Difference of Line 17 and Line 18. Do not use brackets)						
20. Total Payment Requirement For Requested Year (Line 18 plus or minus adjustment on Line 19 if revised requisition. Total must equal Line 17)						
21. <input type="checkbox"/> Paid in Equal Installments (Original Requisition Only)			<input type="checkbox"/> Paid in Unequal Installments			
22. Installment	1	2	3	4	5	6
HA Total						
HUD Revision						
Installment	7	8	9	10	11	12
HA Total						
HUD Revision						
23a. Total (HA) \$		23b. Total (HUD) \$		24. Revised Monthly Installments Begin Month Of:		

I Certify that (1) housing assistance payments have been or will be made only in accordance with Housing Assistance Payments Contracts or Housing Voucher contracts in the form prescribed by HUD and in accordance with HUD regulations and requirements; (2) units have been inspected by the HA in accordance with HUD regulations and requirements; and (3) this requisition for annual contributions has been examined by me and to the best of my knowledge and belief is true, correct and complete.

Warning: HUD will prosecute false claims and statements. Conviction may result in criminal and/or civil penalties. (18 U.S.C. 1001, 1010, 1012; 31 U.S.C. 3729, 3802)

Title of Authorized HA Official		Title of Authorized HUD Approving Official	
Signature	Date	Signature	Date

II. Maximum Annual Contributions	PHA Estimate (Housing Vouchers Only)		PHA Estimate Total	HUD Approved (Housing Vouchers Only)		HUD Approved Total
	Housing Payments	PHA Fee		Housing Payments	PHA Fee	
16. Estimated Annual Housing Assistance Payments (form HUD-52672, Line 15)						
17. Estimated Ongoing Administrative Fee (form HUD-52672, Line 18)						
18. Estimated Hard-to-House Fee (form HUD-52672, Line 19)						
19. Estimated Independent Public Accountant Audit Costs						
20. Estimated Preliminary Administrative and General Expense (form HUD-52672, Lines 27 and 36)						
21. Carryover of Preliminary Administrative and General Expense not Expended in the Previous FY Ending: (/ /)						
22. Estimated Non-Expendable Equipment Expense (form HUD-52672, Line 32)						
23. Carryover of Non-Expendable Equipment Expense not Expended in the Previous FY Ending: (/ /)						
24. Total Annual Contributions Required—Requested Fiscal Year (Lines 16 through 23)						
25. Deficit at End of Current Fiscal Year—Estimated or Actual						
26. Total Annual Contributions Required (Line 24 plus Line 25)						
27. Estimated Project Account Balance at End of Requested Fiscal Year (Line 15 minus Line 26)						
28. Provision for Project Account—Requested Fiscal Year Increase (decrease) (Line 27 minus Line 14)						
III. Annual Contributions Approved						
29. Total Annual Contributions Approved—Requested Fiscal Year (Line 26 plus increase, if any, on Line 28)						
30. Source of Total Contributions Approved—Requested Fiscal Year:						
(a) Requested Fiscal Year Maximum Annual Contributions Commitment (Line 13 or Line 29, whichever is smaller)						
(b) Project Account (Line 29 minus Line 30(a))						

Signature, Name and Title of PHA Approving Official (and date)

Signature, Name and Title of Approving HUD Field Office Official (and date)

Year-End Settlement Statement
Suggested Format

**U.S. Department of Housing
and Urban Development**
Office of Public and Indian Housing

OMB Approval No. 2577-0149 (Exp. 1/30/98)

Public reporting burden for this collection of information is estimated to average 3 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This agency may not conduct or sponsor, and you are not required to respond to, a collection of information unless that collection displays a valid OMB control number. Authority for this collection of information is the Housing and Community Development Act of 1987. Housing Agencies (HAs) required to maintain financial reports in accordance with accepted accounting standards too permit timely and effective audits. The financial records identify the amount of annual contributions that are received and disbursed by HAs. Responses to the collection of information are required to obtain a benefit or to retain a benefit. The information requested does not lend itself to confidentiality.

1. Public Housing Agency (HA) (name and address)	2. Project Number	3. Annual Contributions Contract Number			
4. Housing Program Type: <input type="checkbox"/> Rental Certificate <input type="checkbox"/> Rental Voucher <input type="checkbox"/> Moderate Rehab. <input type="checkbox"/> Section 23					
5. HA Fiscal Year Ending Date: (mark one and complete the year) <input type="checkbox"/> March 31, _____ <input type="checkbox"/> June 30, _____ <input type="checkbox"/> Sept. 30, _____ <input type="checkbox"/> December 31, _____					
6. Number of Unit Months under Lease by Bedroom Size: 1BR 2BR 3BR 4BR 5BR Other					
7. Average Tenant Contribution	8. Portability Accounts Payable _____ Accounts Receivable _____				

Request is hereby made for the payment of annual contributions pursuant to the terms and conditions of the above numbered Annual Contributions Contract for the project and fiscal year shown above.

Part I. Request for Payment	Approved Budget Estimates (a)	HA Actuals Total (b)	HUD Approved Total (c)
Maximum Annual Contributions Available			
9. Maximum Annual Contributions Commitment (per ACC)			
10. Prorata Maximum Annual Contributions applicable to a Period of less than Twelve Months			
11. Contingency Reserve, ACC Program Reserve			
12. Total Annual Contributions Available (sum of lines 9, 10, and 11)			
Annual Contributions Required			
13. 4715 Housing Assistance Payments			
14. Security and Utility Deposit Fund (Section 23 Only)			
15. Ongoing Administrative Fees Earned			
16. Hard-to-House Fees Earned (Rental Certificates, Rental Vouchers, and Moderate Rehabilitation units converted to Rental Certificates)			
17. Actual Independent Public Accountant Audit Costs			
18. Total Preliminary Fees Earned			
19. Total Funds Required (sum of lines 13 thru 18)			
20. Deficit at End of Preceding Fiscal Year			
21. Program Receipts Other than Annual Contributions (3610, 3690, 7530, and Section 23 Security and Utility Deposits Repaid)			
22. Ongoing Fee Reduction			
23. Total Annual Contributions Required (line 19 plus line 20 minus line 21 minus line 22)			

	Approved Budget Estimates (a)	HA Actuals Total (b)	HUD Approved Total (c)
Balance of Annual Contributions Available			
24. ACC Program Reserve Balance (Amount by which line 12 exceeds line 23)			
25. Deficit (amount by which line 23 exceeds line 12)			
26. Provision for ACC Program Reserve			
a) Increase (Amount by which line 24 exceeds line 11)			
b) Decrease (amount by which line 11 exceeds line 24)			
Year End Settlement			
27. Annual Contributions due for Fiscal Year (line 23 minus line 25)			
28. Total Partial Payments Approved by HUD for Fiscal Year			
29. Underpayment due HA (amount by which line 27 exceeds line 28)			
30. Overpayment due HUD (amount by which line 28 exceeds line 27)			
Part II. Operating Receipts			
31. 3300 Interest Earned on Operating Reserve			
32. 3300P Administrative Fee Income - Portable Certificates and Vouchers			
33. 3610 Interest Earned on General Fund Investment			
34. 3690 Other Income			
35. 7530 Receipts from Non-Expendable Equipment not Replaced			
36. Total Annual Contributions Required (line 23)			
37. Total Receipts (sum of lines 31 thru 36)			
Part III. Operating Expenditures			
38. 4715 Housing Assistance Payments			
39. Independent Public Accountant Costs (Section 8 only)			
40. Total Ongoing Administrative Expenses			
41. Total Preliminary Fees Earned			
42. Total Expenditures (sum of lines 38 thru 41)			
Prior Year Adjustments			
43. Affecting Residual Receipts (or Deficit) for Debit (Credit)			
44. Total Operating Expenses (line 42 plus line 43)			
45. Net Income (or Deficit) before Provision for Operating Reserve (line 37 minus line 44)			

	Approved Budget Estimates (a)	HA Actuals Total (b)	HUD Approved Total (c)
Part IV. Analysis of Operating Reserve			
46. Operating Reserve - Balance at Beginning of FY Covered by this Statement			
47. Cash Deposits to (or Withdrawals from) Operating Reserve During Fiscal Year			
48. Net Income (or Deficit) before Provision for Operating Reserve (line 45)			
Provision for Operating Reserve (Acct. 7016/Sec. 8; Acct. 7016.1/Rental Vouchers)			
49. Addition (The amount of income, if any, on line 48)			
50. Deduction (The amount of deficit, if any, on line 48)			
51. Operating Reserve - Balance at End of Fiscal Year Covered by this Statement (line 46 plus or minus line 47 plus line 49 or minus line 50)			

I Certify that: (1) housing assistance payments have been or will be made only in accordance with Housing Assistance Payments Contracts or Rental Voucher Contracts in the form prescribed by HUD and in accordance with HUD regulations and requirements; (2) units have been inspected by the HA in accordance with HUD regulations and requirements; and (3) this voucher for annual contributions has been examined by me and to the best of my knowledge and belief is true, correct and complete.

Warning: HUD will prosecute false claims and statements. Conviction may result in criminal and/or civil penalties. (18 U.S.C. 1001, 1010, 1012; 31 U.S.C. 3729, 3802)

Name of Public Housing Agency	Title of Authorized HA Official	
	Signature of Authorized HA Official	Date

The Field Office has reviewed calculations of the Ongoing Administrative Fee. The HUD approved totals are the official totals as reported in HUD CAPs.

Name of Office	Signature of Director, Office of Public Housing	Date
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Overpayment to be offset \$ _____ Underpayment certified for payment to the HA \$ _____