

In this data collection period, 85,000 households will be screened. After determining eligibility and consent, 12,500 respondents will complete the survey. The average burden per

screened respondent remains at 3 minutes, while the average burden per surveyed respondent is 25 minutes. The total estimated annualized burden hours are 9,458.

The survey will be conducted among English or Spanish speaking male and female adults (18 years and older) living in the United States. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Non-Participating Household (Screened)	NISVS Survey Instrument. First section non-participating.	85,000	1	3/60
Eligible Household (Completes Survey)	NISVS Survey Instrument. Section for participating.	12,500	1	25/60

Leroy A. Richardson,
*Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.*
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10398 and CMS-10529]

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. 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.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by November 19, 2014.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806, OR, Email: *OIRA_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Website address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies

to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Generic Clearance for Medicaid and CHIP State Plan, Waiver, and Program Submissions; *Use:* State Medicaid and CHIP agencies are responsible for developing submissions to CMS, including state plan amendments and requests for waivers and program demonstrations. States use templates when they are available and submit the forms to review for consistency with statutory and regulatory requirements (or in the case of waivers and demonstrations whether the proposal is likely to promote the objectives of the Medicaid program). If the requirements are met, we approve the states' submissions giving them the authority to implement the flexibilities. For a state to receive Medicaid Title XIX funding, there must be an approved Title XIX state plan.

The development of streamlined submissions forms enhances the collaboration and partnership between states and CMS by documenting our policy for states to use as they are developing program changes. Streamlined forms improve efficiency of administration by creating a common and user-friendly understanding of the information we need to quickly process requests for state plan amendments, waivers, and demonstration, as well as ongoing reporting.

Form Number: CMS-10398 (OMB control number: 0938-1148); *Frequency:* Collection-specific, but generally the

frequency is yearly, once, and occasionally; *Affected Public*: State, Local, or Tribal Governments; *Number of Respondents*: 56; *Total Responses*: 1,540 (3-year total); *Total Hours*: 86,240 (3-year total). (For policy questions regarding this collection contact Annette Pearson at 410-786-6858).

2. Type of Information Collection Request: New collection (Request for a new OMB control number); *Title of Information Collection*: Quarterly Medicaid and CHIP Budget and Expenditure Reporting for the Medical Assistance Program, Administration and CHIP; *Use*: At the request of OMB, this action would consolidate the following three OMB control numbers for forms CMS-21 and -21B (OMB control number: 0938-0731), CMS-37 (OMB control number: 0938-0101), and CMS-64 (OMB control number: 0938-0067) into a single control number that will be assigned upon OMB approval. It is important to emphasize that the consolidation of the control numbers does not consolidate any of the forms required for Medicaid and CHIP Budget and Expenditure Reporting.

While the overall package has been assigned a new CMS identification number (CMS-10529), the individual forms will retain their respective CMS-specific identification numbers, namely CMS-21, CMS-21B, CMS-37, and CMS-64. Supporting materials (see **ADDRESSES**) can be found under parent identification number, namely CMS-10529.

This action also revises CMS-37 and -64 while CMS-21 and -21B remain unchanged. Forms CMS-21 and -21B provide CMS with the information necessary to issue quarterly grant awards, monitor current year expenditure levels, determine the allowability of state claims for reimbursement, develop Children's Health Insurance Program (CHIP) financial management information, provide for state reporting of waiver expenditures, and ensure that the federally established allotment is not exceeded. They are also necessary in the redistribution and reallocation of unspent funds over the federally mandated timeframes.

Form CMS-37 due dates are November 15, February 15, May 15 and August 15 of each fiscal year. While all submissions represent equally important components of the grant award cycle, the May and November submissions are particularly significant for budget formulation. The November submission introduces a new fiscal year to the budget cycle and serves as the basis for the formulation of the Medicaid portion of the President's

Budget, which is presented to Congress in January. The February and August submissions are used primarily for budget execution in providing interim updates to our Office of Financial Management, the Department of Health and Human Services, the Office of Management and Budget and Congress depending on the scheduling of the national budget review process in a given fiscal year. The submissions provide us with base information necessary to track current year obligations and expenditures in relation to the current year appropriation and to notify senior managers of any impending surpluses or deficits.

Form CMS-64 is used to issue quarterly grant awards, monitor current year expenditure levels, determine the allowability of state claims for reimbursement, develop Medicaid financial management information provide for state reporting of waiver expenditures, ensure that the federally-established limit is not exceeded for HCBS waivers, and to allow for the implementation of the Assignment of Rights and Part A and Part B Premium (i.e., accounting for overdue Part A and Part B Premiums under state buy-in agreements)—Billing Offsets.

Form Number: CMS-10529 (OMB control number: 0938—New); *Frequency*: Quarterly; *Affected Public*: State, Local, or Tribal Governments; *Number of Respondents*: 56; *Total Annual Responses*: 672; *Total Annual Hours*: 17,920. (For policy questions regarding this collection contact Abraham John at 410-786-4519).

Dated: October 15, 2014.

Martique Jones,

*Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2005-N-0161]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and "Lookback"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information requirements relating to FDA's regulation of current good manufacturing practice (CGMP) and related regulations for blood and blood components; and requirements for donor testing, donor notification, and "lookback."

DATES: Submit either electronic or written comments on the collection of information by December 19, 2014.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in the brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.