

Healthy Communities activities that were part of the original information collection request.

CDC will continue to collect information about each awardee's tobacco control objectives, planning, activities, resources, partnerships, strategies, and progress toward meeting objectives. Awardees will use the information reported through the electronic MIS to manage and

coordinate their activities and to improve their efforts. CDC will use the information reported through the MIS to document and monitor each awardee's progress and to make adjustments, as needed, in the type and level of technical assistance provided to them. The information collection allows CDC to oversee the use of federal funds, and identify and disseminate information about successful strategies implemented

by awardees. CDC also uses the information to respond to Congressional and stakeholder inquiries about awardee activities, program implementation, and program impact.

Progress reporting through the MIS is required for DP09–901 awardees. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden
State Tobacco Control Program	53	2	6	636

Kimberly S. Lane,

Deputy Director, 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 Identifier: CMS–10493 and CMS–10495]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by September 20, 2013.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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' Web site 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:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10493 Nationwide Consumer Assessment of Healthcare Providers and Systems (DCAHPS) Survey for Adults in Medicaid

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 requires federal agencies to publish a 60-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.

Information Collections

1. *Type of Information Collection Request:* New collection (request for a new OMB control number); *Title of Information Collection:* Nationwide Consumer Assessment of Healthcare Providers and Systems (DCAHPS) Survey for Adults in Medicaid; *Use:* The goal of the survey is to attain national and state-by-state estimates of adult Medicaid beneficiaries' access and experiences and satisfaction with care

across different financing and delivery models (e.g., managed care and fee-for-service) and population groups (e.g., beneficiaries with physical, mental or both physical and mental disabilities, dually eligible beneficiaries, all other beneficiaries). The survey will serve as baseline information on the experiences of low-income adults during the early stages of implementation of the Affordable Care Act provision that permits states to expand eligibility to adults with income below 138 percent of the federal poverty level who were not previously eligible. Along with states, we can use the survey information as one indicator of the quality of care within and across states. It also will be used to assist us along with the states in efforts to provide better care and more affordable care to Medicaid beneficiaries. *Form Number:* CMS-10493 (OCN: 0938-New); *Frequency:* Once; *Affected Public:* Individuals and households; *Number of Respondents:* 1,500,000; *Total Annual Responses:* 510,000. *Total Annual Hours:* 170,000. (For policy questions regarding this collection contact Marsha Lillie-Blanton at 410-786-8856.).

2. *Type of Information Collection Request:* New collection (request for a new OMB control number); *Title of Information Collection:* Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments; *Use:* Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act (Act), which requires applicable manufacturers and applicable group purchasing organizations (GPOs) of covered drugs, devices, biologicals, or medical supplies to report annually to CMS certain payments or other transfers of value to physicians and teaching hospitals, as well as, certain information regarding the ownership or investment interests held by physicians or their immediate family members in applicable manufacturers or applicable GPOs.

Specifically, applicable manufacturers of covered drugs, devices, biologicals, and medical supplies are required to submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Similarly, section 1128G(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their

immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Applicable manufacturers must report the required payment and other transfer of value information annually to CMS in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to CMS the required information about physician ownership and investment interests, including information on any payments or other transfers of value provided to physician owners or investors, in an electronic format by the same date. Applicable manufacturers and applicable GPOs are subject to civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the statute. We are required by statute to publish the reported data on a public Web site. The data must be downloadable, easily searchable, and aggregated. In addition, we must submit annual reports to the Congress and each state summarizing the data reported. Finally, section 1128G of the Act generally preempts state laws that require disclosure of the same type of information by manufacturers.

We published a final rule in 2013 to implement this program, which included several information collections subject to the Paperwork Reduction Act. This information collection request is to inform the public about information collected that is necessary for registration, attestation, dispute resolution and corrections, record retention, and submitting an assumptions document within Open Payments. *Form Number:* CMS-10495 (OCN: 0938-New); *Frequency:* Once; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 451,582; *Total Annual Responses:* 451,582. *Total Annual Hours:* 949,005. (For policy questions regarding this collection contact Melissa Heesters at 410-786-0618.).

Dated: July 16, 2013.

Martique Jones,

Deputy 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-2013-D-0838]

Compliance Policy Guide Sec. 253.100—Use of Units of Plasma and Fresh Frozen Plasma Which Have Been Thawed; Withdrawal of Compliance Policy Guide

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the compliance policy guide (CPG) entitled “Sec. 253.100—Use of Units of Plasma and Fresh Frozen Plasma Which Have Been Thawed,” issued October 1, 1980, and revised in March 1995.

DATES: The withdrawal is effective July 22, 2013.

FOR FURTHER INFORMATION CONTACT: Robert L. Hummel, Medical Products and Tobacco Policy Staff, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301-796-4510.

SUPPLEMENTARY INFORMATION: FDA issued the CPG entitled “Sec. 253.100—Use of Units of Plasma and Fresh Frozen Plasma Which Have Been Thawed” on October 1, 1980, and revised it in March 1995. FDA originally issued CPG Sec. 253.100 to provide FDA’s current thinking regarding the time limits for when thawed frozen plasma should be used for transfusion. At the time of issuance of the CPG, 21 CFR 606.122(m)(3) provided that the instruction circular shall include, when applicable, instructions to begin administration of the product within 6 hours after thawing. The CPG noted a planned regulatory change that would allow greater flexibility in the time of administration requirements for frozen plasma products.

In a final rule published in the **Federal Register** on January 3, 2012 (77 FR 7), with an effective date of July 2, 2012, FDA modified the time limits contained in the instruction circular for when administration of thawed frozen plasma products begins, as required by 21 CFR 606.122(m)(3), to “within a specified time after thawing.” As noted in the preamble to the final rule, the change was made “to provide industry with increased flexibility for developing and specifying timeframes for which thawed plasma components can still be used for transfusion if stored at