

Information collected in the post-expenditure reports submitted by States is analyzed and described in an annual report on SSBG expenditures and recipients produced by the Office of Community Services (OCS), Administration for Children and Families (ACF). The information contained in this report is used for program planning and management. The data establish how SSBG funding is used for the provision of services in each State to each of the many specific populations of vulnerable children and adults.

The data is also analyzed to determine the performance of States' in meeting the SSBG program performance measures developed to meet the

requirements of the Government Performance and Results Act of 1993(GPRA), as amended by the GPRA Modernization Act of 2010.¹ GPRA requires all Federal agencies to develop measurable performance goals.

The SSBG program currently has an administrative costs efficiency measure which is intended to decrease the percentage of SSBG funds identified as administrative costs in the post-expenditure reports.² The SSBG program is also implementing a new performance measure designed to ensure that SSBG funds are spend effectively and efficiently while maintaining the program's intrinsic flexibility as a block grants. The performance measure will assess the

degree to which States spend SSBG funds in a manner consistent with their intended use, as required by Federal law.³ It will be used to determine how well States are doing overall in minimizing variance between projected and actual expenditures of SSBG funds. This program measure will be fully implemented for SSBG program data submitted for fiscal year 2013.

Respondents: The post-expenditure reporting form and intended use plan are completed once annually by a representative of the agency that administers the Social Services Block Grant at the State level in each State. Respondents include the 50 States, the District of Columbia, and Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents *	Number of responses per respondent	Average burden hours per response	Total burden hours
Post-Expenditure Reporting Form	56	1	110	6,160
Use of Post-Expenditure Reporting Form as Part of the Intended Use Plan	56	1	2	112
Estimated Total Annual Burden Hours:				6,272

* Respondents include the 50 States, the District of Columbia, Puerto Rico, Guam, American Samoa, Northern Mariana Islands, and Virgin Islands.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the

Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 8, 2014, from 8 a.m. to 6 p.m. and on October 9, 2014, from 8 a.m. to 12:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301-977-8900.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1611, Silver Spring, MD 20993-0002, 301-796-3063, Jamie.Waterhouse@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting

¹ Pub. L. 11-352; 31 U.S.C. 1115(b)(10).

² U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services. (2007, June). *Implementing a new performance measure to enhance efficiency* (Information Memorandum Transmittal No. 04-

2007). Available from http://archive.acf.hhs.gov/programs/ocs/ssbg/procedures/ssbg_im_04_2007.html.

³ 42. U.S.C. 1397e(a); U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services. (2012,

February). *Implementation of a new performance measure* (Information Memorandum Transmittal No. 01-2012). Available from <http://www.acf.hhs.gov/programs/ocs/resource/implementation-of-a-new-performance-measure>.

cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On October 8, the committee will discuss, make recommendations and vote on information related to the premarket approval application regarding the Boston Scientific Corporation's WATCHMAN Left Atrial Appendage (LAA) Closure Technology. FDA is seeking committee review and recommendations regarding new clinical data and associated additional adverse events including stroke that have become available since the previous advisory committee meeting on the WATCHMAN device, which was held December 11, 2013. The WATCHMAN LAA Closure Technology is a percutaneously delivered permanent cardiac implant placed in the left atrial appendage. This device is indicated to prevent thromboembolism (TE) from the left atrial appendage. It may be considered for use in patients with non-valvular atrial fibrillation who are eligible for warfarin therapy to reduce the risk of stroke and systemic embolism based on CHADS₂ (congestive heart failure, hypertension, age >75 years, diabetes, and prior stroke or transient ischemic attack (TIA)) or CHA₂DS₂-VASc (congestive heart failure, hypertension, age >75 years, diabetes mellitus, stroke/TIA/TE, vascular disease, age 65–74, and sex category) scores.

On October 9, the committee will discuss and make recommendations regarding the classification of more-than-minimally manipulated allograft heart valves (MMM Allograft HVs). A MMM Allograft HV is a human valve or valved conduit that has been aseptically recovered from qualified donors, dissected free from the human heart, and then subjected to a manufacturing process(es) that alters the original relevant characteristics of the tissue (21 CFR 1271.3(f), 21 CFR 1271.10(a)(1), and 21 CFR 1271.20). The valve is then stored until needed by a recipient. An example of such a manufacturing process is one that intentionally removes the cells and cellular debris with the goal of reducing in vivo antigenicity.

MMM Allograft HVs are considered preamendment devices because they were found substantially equivalent to devices in commercial distribution prior

to May 28, 1976, when the Medical Device Amendments became effective. MMM Allograft HVs are currently regulated under Product Code OHA, "Heart Valve, More than Minimally Manipulated Allograft," as unclassified devices and reviewed under the premarket notification, 510(k), authority (21 CFR part 807). FDA is seeking committee input on the safety and effectiveness of MMM Allograft HVs and the regulatory classification for MMM Allograft HVs.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

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 on or before September 30, 2014. On October 8, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. On October 9, oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before September 22, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 24, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to

accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, 301–796–5966, Annmarie.Williams@fda.hhs.gov at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: August 20, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 25, 2014.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the