

Dated: March 26, 2012.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information on Prescription Medication Adherence

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of the Surgeon General of the United States Public Health Service.

ACTION: Request for information.

SUMMARY: The Office of the Assistant Secretary for Health is seeking information about causes, impact and potential solutions associated with the public health problem of prescription medication non-adherence in adults with chronic conditions. The purpose of this notice is to provide individuals and organizations with the opportunity to identify issues relevant to all levels of government, as well as individuals, health care providers, and industry and private organizations in efforts to improve medication adherence in adults with chronic conditions. Comments that provide input on and evidence from interventions that improve adherence are particularly encouraged.

Comments must be in writing and should not exceed 500 words. All comments will receive careful consideration. However, persons and organizations submitting comments will not receive individual responses.

DATES: Individuals and organizations interested in providing information must submit their comments on or before May 7, 2012. Comments received after this date will not be considered.

ADDRESSES: Department of Health and Human Services, Office of the Surgeon General, Room 710-H, 200 Independence Ave., SW., Washington, DC 20201. Comments may also be sent via email to medadhere@hhs.gov.

FOR FURTHER INFORMATION CONTACT: Dawn Alley, Ph.D., Office of the Surgeon General, by telephone (202-205-9491) or email (Dawn.Alley@hhs.gov).

SUPPLEMENTARY INFORMATION: Many different factors can contribute to poor medication adherence, including copayments, difficulty remembering and managing complex regimens, and poor health literacy. Solutions to this

problem will need to involve both the health-care community and patients. This request for information is intended to solicit comments on both barriers to medication adherence and strategies for overcoming those barriers to improve public health.

Dated: March 29, 2012.

Boris Lushniak,

Deputy Surgeon General.

[FR Doc. 2012-8179 Filed 4-4-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Information Collection Activities; Proposed Collection; Comment Request; OAA Title III-C Evaluation

AGENCY: Administration on Aging, HHS.

ACTION: Notice

SUMMARY: The Administration on Aging (AoA) 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 information collection requirements relating to

OAA Title III-C Evaluation

DATES: Submit written or electronic comments on the collection of information by June 4, 2012.

ADDRESSES: Submit electronic comments on the collection of information to: *Jennifer.klocinski@aoa.hhs.gov*.

Submit written comments on the collection of information to Administration on Aging, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Jennifer Klocinski at 202-357-0146.

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 request 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, AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA's functions, including whether the information will have practical utility; (2) the accuracy of AoA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Describe Collection of Information

The mission of the Administration on Aging (AoA), operating through the Older Americans Act (OAA) programs, is to develop a comprehensive, coordinated and cost-effective system of home and community based services that helps elderly individuals to maintain their health and independence in their homes and communities and support family caregivers of older adults and grandparents caring for grandchildren, who are essential to making community living possible.

The OAA Title III-C Elderly Nutrition Services Program (statutory authority is contained in Title II section 205(a)(2)(A), and Title III sections 311, 331, 336 and 339 of the Older Americans Act (OAA) (42U.S.C. 3032), as amended by the Older Americans Act Amendments of 2006, P.L. 109-365) is part of these comprehensive home- and community-based services. It is intended to reduce hunger and food insecurity, reduce social isolation and improve the health and well-being of the older adult who participate.

The Older Americans Act requires AoA to conduct evaluations of OAA programs. The requirements stipulated under 206(a) of the OAA direct that "The Secretary shall measure and evaluate the impact of all programs authorized by this Act, their effectiveness in achieving stated goals in

general, and in relation to their cost, their impact on related programs, their effectiveness in targeting for services under this Act unserved older individuals with greatest economic need (including low-income minority individuals and older individuals residing in rural areas) and unserved older individuals with greatest social need (including low-income minority individuals and older individuals residing in rural areas), and their structure and mechanisms for delivery of services, including, where appropriate, comparisons with appropriate control groups composed of persons who have not participated in such programs. Evaluations shall be conducted by persons not immediately involved in the administration of the program or project evaluated”.

The purpose of this data collection is to fulfill this requirement and understand how well this program is meeting its goals and mission through the conduct of a process and outcome evaluation that is a rigorous and independent assessment of the Program’s progress, efficiency and effectiveness. This information collection will enable AoA to effectively report its results to the President, to Congress, to the Department of Health and Human Services and to the public. The information will also aid in program refinement and continuous improvement.

The evaluation design is comprised of three primary components:

1. *A process study*, which examines the strategies, activities, and resources of the program at each level of the Aging Network—State Unit on Aging (SUA), Area Agency on Aging (AAA), and Local Service Provider (LSP);

2. *A cost study*, which determines the cost per meal by cost category and program type at the local service provider level; and

3. *A client outcome study*, which examines the health and social effects of the program on participants compared to non-participants. Included is an analysis of the nutrient quality of the meals provided.

The process study will include all 56 SUAs, a sample of AAAs (N=300), a sample of local service providers (N=200), and a sample of program participants and non-participants (N=2400). The SUA process component includes a short faxable data verification survey which asks the SUA to verify basic information on topics such as organization structure, staff and volunteers and population served and a survey that covers a variety of topics. The AAA process component includes a short faxable survey that focuses on

program funding, staffing, and client characteristics and a web-based survey that covers a range of topics. The local service provider process component includes a short faxable survey that is comparable to the AAA faxable survey and a web-based survey that covers a range of topics. The cost study will be conducted with a sample of local service providers (including AAAs that provide direct nutrition services) and includes a data collection tool that asks about the component costs associated with meal production and delivery.

The client outcome study includes subcomponents: (1) A survey of a matched sample of program participants and non-participants and consists of an assessment of health and well-being outcomes, individual level characteristics, and program service use and quality assessments; (2) an assessment of diet quality using a 24-Hour Recall of nutrient intake; (3) a study of healthcare utilization using linked Medicare files with client data collected via the initial survey described above and brief, follow-up interviews to measure service use over the year following the initial survey; and (4) an analysis of the nutrient quality of the meals provided to program participants collected from the local service providers. Data will be collected via face-to-face interviews with the aid of Computer Assisted Personal Interview (CAPI) software. Respondents’ diet quality and the nutrient content of the meals provided through the program will be measured using the USDA’s Automated Multiple Pass Method (AMPM) software. Respondents will be re-contacted at 6 and 12 months via telephone with a brief survey to measure frequency of participation in the Program since the previous interview.

This information will be used by AoA to measure how well and under what circumstances does the OAA Title III-C Elderly Nutrition Services Program meet its legislative intent and goals. The proposed data collection tools may be found on the AoA Web site at http://www.aoa.gov/AoARoot/Program_Results/Program_Evaluation.aspx.

AoA estimates the burden of this collection of information as follows: 1,432.08 hours for organizations and 3,336.00 hours for individuals for a total of 4,768.08 hours.

Dated: April 2, 2012.

Kathy Greenlee,

Assistant Secretary for Aging.

[FR Doc. 2012-8241 Filed 4-4-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0330]

Ashish Macwan: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarment Ashish Macwan for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Macwan was convicted of one count of conspiracy to commit an offense against the United States for conduct relating to the development and approval, including the process for development and approval, of a drug product and to the regulation of drug products under the FD&C Act. In addition, the type of conduct underlying the conviction undermined the process for the regulation of drugs. Mr. Macwan was given notice of the proposed debarment and an opportunity to request a hearing within the time frame prescribed by regulation. Mr. Macwan failed to request a hearing, which constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective April 5, 2012.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs (HFC-230), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg, Rm. 4144, Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(II) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(II)) permits FDA to debar an individual if it finds that the individual has been convicted of a conspiracy to commit a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or relating to the regulation of any drug product under the FD&C Act and if FDA finds that the type of conduct that