

In its letter of disapproval, CMS responded to Maine's claim that *National Federation of Independent Business v. Sebelius*, 567 U.S. ___, 132 S. Ct. 2566 (2012), directed approval of the SPA. CMS pointed out that the Supreme Court did not strike down any provision of the Patient Protection and Affordable Care Act, including the MOE requirement, and that the MOE requirement is unrelated to the Medicaid eligibility expansion.

I am scheduling a hearing on your request for reconsideration to be held on May 23, 2013, at the CMS Boston Regional Office, JFK Federal Building, 15 N. Sudbury Street, Room 2050, Boston, Massachusetts 02203-0003 to reconsider CMS' decision to disapprove Maine SPA #12-010.

If this date is not acceptable, I would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by federal regulations at 42 CFR Part 430.

I am designating Mr. Benjamin Cohen as the presiding officer. If these arrangements present any problems, please contact Mr. Cohen at (410) 786-3169. In order to facilitate any communication that may be necessary between the parties prior to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the state at the hearing.

Sincerely,
Marilyn Tavenner
Acting Administrator

Section 1116 of the Social Security Act (42 U.S.C. 1316; 42 CFR 430.18)

(Catalog of Federal Domestic Assistance program No. 13.714, Medicaid Assistance Program.)

Dated: April 4, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013-08524 Filed 4-10-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Expansion Funds for the Support of the Senior Medicare Patrol (SMP) Program

ACTION: Notice of intent to provide expansion and capacity building funding to the incumbent Senior Medicare Patrol (SMP) grantees under limited competition.

SUMMARY: The Administration for Community Living is announcing the availability of expansion funds for the support of the Senior Medicare Patrol (SMP) Program. This additional funding opportunity will be used to expand the reach of the SMP program with the explicit purpose of expanding current program capacity to recruit, train, and support the SMP volunteer network. In addition, this funding opportunity will increase targeted collaborative efforts with the Centers for Medicare and Medicaid Services, Office of Inspector General and other law enforcement entities in identified high fraud states.

Funding Opportunity Title/Program Name: Health Care Fraud Prevention Program Expansion and SMP Capacity Building Grants.

Announcement Type: Health Care Fraud Prevention Program Expansion Capacity.

Funding Opportunity Number: Program Announcement No. HHS-2013-ACL-AoA-SP-0049

Statutory Authority: HIPAA of 1996 (Pub. L. 104-191).

Catalog of Federal Domestic Assistance (CFDA) Number: 93.048 Discretionary Projects

DATES: The deadline date for comments on this program announcement is May 13, 2013. Other important dates:

- The application due date May 27, 2013.
- The anticipated start date is September 30, 2013.

I. Funding Opportunity Description

During the past several years, the Department of Health and Human Services has increased efforts to fight Medicare and Medicaid fraud. The Administration for Community Living (ACL), Administration on Aging (AoA), through the SMP program, has worked in partnership with the Centers for Medicare and Medicaid Services (CMS), the Office of Inspector General (OIG), and the Department of Justice to expand strategies to eliminate waste, fraud, and abuse in these Federal programs. This additional funding opportunity will be used to expand the reach of the SMP program with the explicit purpose of expanding efforts to target collaborative efforts with CMS, OIG and other law enforcement entities in high fraud states and to expand current capacity to recruit, train, and support the SMP volunteer network.

Justification for the Exception to Competition

It is necessary to limit competition for this program to the current SMP grantees to expand their implementation

efforts. In order for the outcomes expected to be produced within the allotted timeframe of the program, the infrastructure for achieving these results must already be in place. This infrastructure includes:

- A proven SMP volunteer management, training, and recruiting program;
- Expertise in capturing data in the SMP management, tracking, and reporting system (SMART FACTS);
- Established partnership relationships between the SMP program and state and local fraud control partners, including CMS, OIG, Attorney General, and State Insurance Commissioners offices;
- Developed and tested SMP program public awareness materials, brochures, PSAs, and other resources to use in outreach and educational efforts;
- Expertise and experience in reaching targeted populations with the SMP message, among others.

The current SMP projects are uniquely qualified to address the requirements contained in this funding opportunity. Their established infrastructure and expertise will enable them to successfully meet the challenging and time-sensitive requirements of this program. It is essential that the infrastructure, foundation of expertise, and proven experience is in place to assure the grant objectives are achieved.

II. Award Information

A. Purpose of the Program: Health Care Fraud Prevention Program Expansion.

B. Amount of the Awards: \$20,000 to \$372,000 per budget period.

C. Project Period: September 30, 2013–September 29, 2015.

III. Eligible Applicants

Incumbent Senior Medicare Patrol (SMP) grantees.

IV. Evaluation Criteria

A. Project Relevance & Current Need—Weight: 5 points

B. Approach—Weight: 35 points

C. Budget—Weight: 10 points

D. Project Impact—Weight: 25 points

E. Organizational Capacity—Weight: 25 points

V. Application and Submission Requirements

A. SF 424—Application for Federal Assistance.

B. SF 424A—Budget Information.

C. Separate Budget Narrative/Justification.

D. SF 424B—Assurances. Note: Be sure to complete this form according to

instructions and have it signed and dated by the authorized representative (see item 18d of the SF 424).

E. Lobbying Certification.

F. Program narrative no more than twenty pages.

G. Work Plan.

H. The application should be submitted through grants.gov using the funding opportunity # HSS-2013-ACL-AoA-SP-0049.

VI. Application Review Information

Three field reviewers external to the Office of Elder Rights will be assigned to review and score each application.

VII. Agency Contact

For further information or comments regarding this program expansion supplement, contact Rebecca Kinney, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging, Office of Elder Rights, One Massachusetts Avenue NW., Washington, DC 20001; telephone (202) 357-3520; fax (202) 357-3560; email Rebecca.Kinney@acl.hhs.gov.

Dated: April 8, 2013.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2013-08485 Filed 4-10-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0620]

Guidance for Industry on Self-Selection Studies for Nonprescription Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Self-Selection Studies for Nonprescription Drug Products.” This guidance is intended to provide recommendations to industry involved in developing and conducting self-selection studies to support an application for nonprescription drug products. A self-selection study assesses the ability of consumers to apply drug labeling information to their personal health situation to make correct decisions about whether or not it is appropriate for them to use a drug product. This guidance finalizes the

draft guidance issued on September 19, 2011.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Barbara R. Cohen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5437, Silver Spring, MD 20993-0002, 301-796-2060.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Self-Selection Studies for Nonprescription Drug Products.” A self-selection study assesses the ability of consumers to apply drug labeling information to their personal health situation to make correct decisions about whether or not it is appropriate for them to use a drug product. The guidance provides recommendations to industry involved in developing and conducting self-selection studies to support an application for nonprescription drug products.

The guidance includes recommendations regarding study design, study conduct, and final reporting of self-selection studies. The guidance should not be considered a substitute for an FDA review of specific protocols. This guidance finalizes the draft guidance issued on September 19, 2011 (76 FR 58018). FDA has reviewed the docket comments submitted in response to the draft guidance and the guidance was revised based on that review. The guidance also incorporates advice obtained from the Nonprescription Drugs Advisory Committee at a meeting on September 25, 2006, at which the committee considered issues related to analysis and interpretation of consumer studies

conducted to support marketing of nonprescription drug products.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on self-selection studies for nonprescription drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: April 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-08443 Filed 4-10-13; 8:45 am]

BILLING CODE 4160-01-P