

Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Community Living

Availability of Program Application Instructions for MIPPA Program Funds

AGENCY: Administration for Community Living, HHS.

Title: Medicare Improvements for Patients and Providers Act: State Plans for Medicare Savings Program, Low Income Subsidy & Prescription Drug Enrollment Outreach and Assistance.

Announcement Type: Initial.

Funding Opportunity Number: CIP-MI-18-001.

Statutory Authority: The Medicare Improvements for Patients and Providers Act of 2008—Section 119, Public Law (Pub. L.) 110-275 as amended by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), reauthorized by the American Taxpayer Relief Act of 2012 (ATRA), reauthorized by section 110 of the Protecting Access to Medicare Act of 2014 and reauthorized by the Medicare Access and CHIP Reauthorization Act of 2015, and was reauthorized for two years under the Bipartisan Budget Act of 2018 (Pub. L. 115-123, BBA of 2018).

Catalog of Federal Domestic Assistance (CFDA) Number: 93.071.

Dates: The deadline for the submission of MIPPA Program State Plans is 11:59 p.m. EST August 3, 2018.

I. Funding Opportunity Description

The purpose of MIPPA funding is to enhance state efforts to provide assistance to Medicare beneficiaries through statewide and local coalition building focused on intensified outreach activities to beneficiaries likely to be eligible for the Low Income Subsidy program (LIS) or the Medicare Savings Program (MSP) and in assisting those beneficiaries in applying for benefits. ACL will provide MIPPA program funding to State Health Insurance Assistance Programs (SHIPs), Area Agencies on Aging (AAAs), and Aging and Disability Resource Center programs (ADRCs), to inform Medicare beneficiaries about available Medicare program benefits. ACL seeks plans from states that will describe how the MIPPA

program funds will be used for beneficiary outreach, education, and one-on-one application assistance over the next two years.

ACL requests that states submit a two (2) year state plan with specific project strategies to expand, extend, or enhance their one-on-one assistance, education, and group outreach efforts to Medicare beneficiaries on Medicare and assistance programs for those with limited incomes. States should describe how the SHIP, AAA, and ADRC efforts will be coordinated to provide outreach to beneficiaries with limited incomes statewide. States that are eligible to apply are asked to review previous MIPPA plans and update these plans to reflect successes achieved to date and direct their efforts to enhance and expand their MIPPA outreach activities. State agencies may prepare either one statewide plan or separate plans for each eligible State agency. Program Instructions will be available to applicants through ACL. ACL will also host an applicant teleconference on Tuesday, June 19th, 2018 at 2:00 p.m. Eastern. Call in number: 202-774-2300. Meeting Number: 998 701 573.

II. Award Information

1. Funding Instrument Type

These awards will be made in the form of grants to State Agencies for each MIPPA Priority Area:

Priority Area 1—Grants to State Agencies (the State Unit on Aging or the State Department of Insurance) that administer the State Health Insurance Assistance Program (SHIP) to provide enhanced outreach to eligible Medicare beneficiaries regarding their benefits, enhanced outreach and application assistance to individuals who may be eligible for the Medicare Low Income Subsidy (LIS) or the Medicare Savings Program (MSP), and for the purposes of conducting outreach activities aimed at preventing disease and promoting wellness.

Priority Area 2—Grants to State Units on Aging for Area Agencies on Aging to provide enhanced outreach to eligible Medicare beneficiaries regarding their Medicare benefits, enhanced outreach and one-on-one application assistance to individuals who may be eligible for the LIS or the MSP, and for the purposes of conducting outreach activities aimed at preventing disease and promoting wellness.

Priority Area 3—Grants to State Units on Aging that administer the Aging and Disability Resource Centers to provide outreach to individuals regarding their Medicare Part D benefits, benefits available under the LIS and MSP, and

for the purposes of conducting outreach activities aimed at preventing disease and promoting wellness.

2. Anticipated Total Priority Area Funding per Budget Period

ACL intends to make available, under this program announcement, grant awards for the three MIPPA priority areas. Funding will be distributed through a formula as identified in statute. ACL will fund total project periods of up to two (2) years, contingent upon availability of federal funds.

Priority Area 1—SHIP: Up to \$13 million in Fiscal Year (FY) 2018 and \$13 million in FY 2019 for state agencies that administer the SHIP Program.

Priority Area 2—AAA: Up to \$7.5 million in FY 2018 and \$7.5 million in FY 2019 for State Units on Aging for Area Agencies on Aging and for Native American programs. Funding for Native American Programs (\$270,000) is deducted from Priority 2 and is being allocated through a separate process.

Priority Area 3—ADRC: Up to \$5 million in FY 2018 and \$5 million in FY 2019 for State Agencies that received an ACL, CMS, VHA Aging and Disability Resource Center (ADRC)/No Wrong Door System (NWD) grant at any point in time to support the development of their ADRC/NWD Systems.

III. Eligibility Criteria and Other Requirements

1. Eligible Applicants MIPPA Priority Areas 1, 2 and 3: Awards made under this announcement, by statute, will be made only to agencies of State Governments.

Priority Area 1: Only existing SHIP grant recipients are eligible to apply.

Priority Area 2: Only State Units on Aging are eligible to apply.

Priority Area 3: Only State Agencies that received an ACL, CMS, VHA Aging and Disability Resource Center (ADRC)/No Wrong Door System (NWD) grant to support the development of their ADRC/NWD Systems at any point in time are eligible for MIPPA funding under this priority area.

Eligibility may change if future funding is made available.

2. Cost Sharing or Matching is not required.

3. DUNS Number

All grant applicants must obtain and keep current a D-U-N-S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D-U-N-S number can be obtained from: <https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm>.

4. Intergovernmental Review Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Reporting

1. MIPPA Grantees will be required to report data in the SHIP Tracking and Reporting System (STARS). STARS is the nationwide, web-based data system that facilitates reporting of activities completed by SHIP and MIPPA Grantees. All required data must be submitted accurately, completely, and on time, and in the format specified by ACL. All reports shall be completed according to instructions distributed by ACL for grantees. States using proprietary systems (and all proprietary agencies operating within a state) must submit data into a fully compliant data system reflecting STARS Data System specifications, with no unresolved errors as a condition of eligibility for continued MIPPA funding.

2. *Financial Reporting Requirements:* ACL requires the submission of the SF-425 (Federal Financial Report) semi-annually. The reporting cycle will be reflected in the Notice of Award. The annual SF-425 is due 30 days after the end of each semi-annual reporting period. The final SF-425 report is due 90 days after the end of the project period for each priority area. Grantees are required to complete the federal cash transactions portion of the SF-425 within the Payment Management System (PMS) for each priority area as identified in their award documents for the calendar quarters ending 3/31, 6/30, 9/30. And 12/31 through the life of their award. In addition, the fully completed SF-425 will be required as denoted in the Notice of Award terms and conditions.

3. *MIPPA Performance Reporting Requirements:* All successful applicants must submit a MIPPA narrative progress report twice a year to ACL. The reports shall include: A description of the progress made toward meeting each of the MIPPA objectives outlined in the funding opportunity announcement. As part of the narrative progress reports, the grantee must provide details of how the program expects to meet the goals described in their state plan submission. The narrative progress reports must be uploaded through www.grantsolutions.gov for each priority area. The narrative progress reports cover the following periods and due dates annually: (a) September 30 through March 31—due April 30; (b) April 1 through September 29—due October 31.

4. A final narrative report will be due at the end of the grant period. This final report will replace the last semi-annual narrative and must cover the entire life of the grant. The final narrative report is due 90 days after the end of the award (December 31, 2020).

V. Submission Information

1. Application Kits

Application kits/Program Instructions are available at www.grantsolutions.gov. Instructions for completing the application kit will be available on the site. For help in locating this information contact the ACL Agency Contact identified below. Note: Applicants must submit a separate SF-424 for each priority area with their application packages. Additional detailed instructions will be available in the Application Kit.

2. Submission Dates and Times

To receive consideration, applications must be submitted by 11:59 p.m. Eastern time on August 1, 2018, through www.GrantSolutions.gov.

VI. Agency Contacts

Direct inquiries regarding programmatic issues to U.S. Department of Health and Human Services, Administration for Community Living, Office of Healthcare Information and Counseling, Washington, DC 20201, attention: Katie Glendening or by calling 202-795-7350 or by email Katherine.Glendening@acl.hhs.gov.

Dated: May 30, 2018.

Mary Lazare,

Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1922]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA

Products.” This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar or interchangeable biological products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). The previous guidance for industry entitled “Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants,” issued on November 18, 2015, has been withdrawn.

DATES: Submit either electronic or written comments on the draft guidance by September 4, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for