Estimated Total Annual Burden Hours: 1,104.

Authority: 42 U.S.C. 613.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–08495 Filed 4–20–22; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Availability of Program Application Instructions for MIPPA Program Funds

Title: Medicare Improvements for Patients and Providers Act: State Applications for Medicare Low-Income Benefit Programs Enrollment Outreach and Assistance.

Announcement Type: Initial.

Funding Opportunity Number: CIP–MI–22–001.

Statutory Authority: The Medicare Improvements for Patients and Providers Act of 2008, as amended by the Patient Protection and Affordable Care Act of 2010 and reauthorized by the American Taxpayer Relief Act of 2012 (ATRA), Protecting Access to Medicare Act of 2014, Medicare Access and CHIP Reauthorization Act of 2015, Bipartisan Budget Act of 2018, Coronavirus Aid, Relief, and Economic Security Act of 2020, and Consolidated Appropriations Act of 2021.

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

Dates: The deadline date for the submission of MIPPA Program State Plans is 11:59 p.m. ET on June 21, 2022.

I. Funding Opportunity Description

The Medicare Improvement for Patients and Providers Act (MIPPA) program supports states through grants to provide outreach and assistance to Medicare beneficiaries with limited incomes and assets to ensure the beneficiaries have access to all Medicare related benefits available to them. MIPPA state grantees help educate Medicare beneficiaries about benefit programs that help them pay for Medicare including the Low-Income Subsidy (LIS) program for Medicare Part D and the Medicare Savings Programs (MSPs). In addition, MIPPA grantees provide education on Medicare Preventive Services. MIPPA grantees provide education through public outreach while also providing one-on-one assistance to eligible Medicare beneficiaries to help them access and apply for benefit programs that help lower the costs of their Medicare premiums and deductibles.

MIPPA state funding is limited to agencies eligible for MIPPA funding:

- Priority Area 1—State Health Insurance Assistance Program (SHIP): SHIP grant recipients or (SHIP-designated state agencies)
- Priority Area 2—Area Agencies on Aging (AAAs): State Units on Aging (SUA) (or SUA-designated state agencies)
- Priority Area 3—Aging and Disability Resource Centers (ADRCs): Agencies that are established ADRCs who have received an ACL ADRC COVID grant (or designated state agency serving as the No Wrong Door lead)

ACL will accept only one application for each Priority Area per state. If an agency is eligible for more than one MIPPA Priority Area, the agency may combine their responses into one comprehensive application.

These funds will allow agencies to provide enhanced outreach to eligible Medicare beneficiaries regarding their preventive, wellness, and limited income benefits; application assistance to individuals who may be eligible for LIS or MSPs; and outreach activities covering LIS, MSP, or aimed at preventing disease and promoting wellness. Applicant plans should go above and beyond those regular activities planned in response to other funding sources.

II. Award Information

1. Funding Instrument Type

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

Priority Area 1—SHIP: Grants to state agencies (State Units on Aging or State Departments of Insurance) that administer the SHIP to provide enhanced outreach to eligible Medicare beneficiaries regarding their preventive, wellness, and limited income benefits; application assistance to individuals who may be eligible for LIS or MSPs; and outreach activities aimed at preventing disease and promoting wellness.

Priority Area 2—AAA: Grants to state agencies for AAA programs to provide enhanced outreach to eligible Medicare beneficiaries regarding their preventive, wellness, and limited income benefits; application assistance to individuals who may be eligible for LIS or MSPs; and outreach activities aimed at preventing disease and promoting wellness.

Priority Area 3—ADRC: Aging and Disability Resource Center Programs (ADRC): Grants to agencies that are established ADRCs to provide outreach regarding Medicare Part D benefits related to LIS and MSPs, and conduct 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. The amounts allocated are based upon factors defined in statute and will be distributed to each priority area based on the formula. ACL will fund total project periods of up to two (2) years contingent upon availability of federal funds.

Priority Area 1—SHIP: $15.8 million in FY 2022 for state agencies that administer the SHIP Program.

Priority Area 2—AAA: $13.4 million in FY 2022 for State Units on Aging for Area Agencies on Aging.

Priority Area 3—ADRC: $4.6 million in FY 2022 for agencies that are established ADRCs who have received an ACL ADRC COVID grant.

III. Eligibility Criteria and Other Requirements

1. Eligible Applicants for MIPPA State Grants:

Priority Area 1—SHIP: Only existing SHIP grant recipients or (SHIP-designated state agencies) are eligible to apply.

Priority Area 2—AAA: Only State Units on Aging (SUA) (or SUA-designated state agencies) are eligible to apply.

Priority Area 3—ADRC: Only agencies that are established ADRCs who have received an ACL ADRC COVID grant (or designated state agency serving as the No Wrong Door lead) are eligible to apply.

Eligibility may change if future funding is available.

2. Cost Sharing or Matching is not required.

3. Unique Entity ID: All grant applicants must obtain and keep current a Unique Entity ID (UEI). On April 4, 2022, the unique entity identifier used across the federal government changed from the DUNS Number to the Unique Entity ID (generated by *SAM.gov*). The Unique Entity ID is a 12-character alphanumeric ID assigned to an entity by *SAM.gov*. The UEI is viewable in your *SAM.gov* entity registration record.

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

IV. Submission Information

1. Application Kit

Application Kit/Program Instructions are available at *www.grantsolutions.gov.* Instructions for completing the application kit will be available on the site.

2. Submission Dates and Times

To receive consideration, applications must be submitted by 11:59 p.m. Eastern Time on June 21, 2022, through *www.GrantSolutions.gov.*

VII. Agency Contacts

Direct inquiries regarding programmatic issues to: Margaret Flowers, Phone: 202.795.7315, Email: *Margaret.Flowers@acl.hhs.gov*.

Dated: April 15, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2022–08511 Filed 4–20–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3771]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; 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 the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants have agreed, or are required, to conduct is on FDA's ''Postmarketing Requirements and Commitments: Reports'' web page (*https://www.fda.gov/drugs/postmarket-requirements-and-commitments/postmarketing-requirements-and-commitments-reports*).

FOR FURTHER INFORMATION CONTACT: Kathy Weil, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5367, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 506B(c) of the FD&C Act (21 U.S.C. 356b(c)) requires FDA to publish an annual report on the status of postmarketing studies that applicants have committed to, or are required to conduct, and for which annual status reports have been submitted.

Under §§ 314.81(b)(2)(vii) and 601.70 (21 CFR 314.81(b)(2)(vii) and 601.70), applicants of approved drugs and licensed biological products are required to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study or clinical trial either required by FDA (PMRs) or that they have committed to conduct (PMCs), either at the time of approval or after approval of their new drug application, abbreviated new drug application, or biologics license application. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies or clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. Furthermore, section 505(o)(3)(E) of the FD&C Act (21 U.S.C. 355(o)(3)(E)) requires that applicants report periodically on the status of each required study or clinical trial and each study or clinical trial ''otherwise undertaken . . . to investigate a safety issue . . .''

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval [1] until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information.

II. Fiscal Year 2020 Report

With this notice, FDA is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' [2] Information in this report covers any PMR/PMC that was established, in writing, at the time of approval or after approval of an application or a supplement to an application and summarizes the status of PMRs/PMCs in fiscal year (FY) 2020 (*i.e.,* as of September 30, 2020). Information summarized in the report reflects combined data from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and includes the following: (1) The number of applicants with open PMRs/PMCs; (2) the number of open PMRs/PMCs; (3) the timeliness of applicant submission of the annual status reports (ASRs); (4) FDA-verified status of open PMRs/PMCs reported in § 314.81(b)(2)(vii) or § 601.70 ASRs; (5) the status of closed PMRs/PMCs; and (6) the distribution of the status by fiscal year of establishment [3] (FY2014 to FY2020) for PMRs and PMCs open at the end of FY2020, or those closed within FY2020. Additional information about PMRs/PMCs is provided on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments.*

Dated: April 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08499 Filed 4–20–22; 8:45 am]

BILLING CODE 4164–01–P

[1] An applicant must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or on an alternate reporting date that was granted by FDA in writing. Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

[2] The ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments'' can be found on the FDA's Postmarketing Requirements and Commitments: Reports web page: *https://www.fda.gov/drugs/postmarket-requirements-and-commitments/postmarketing-requirements-and-commitments-reports.*

[3] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or requested (PMC) postmarketing study or clinical trial.