ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total/annual burden (in hours)
Program director recruitment call protocol (Instrument 1)	6	1	0.50	3.0
Program staff interview protocol: Program director (Instrument 2) [a]	6	1	1.0	6.0
Program staff interview protocol ERSEA staff (Instrument 2) [a]	24	1	1.5	36
Head Start enrolled families focus group guide (Instrument 3)	60	1	1.5	90
Community partner recruitment call protocol (Instrument 4)	24	1	0.17	4.0
Community partner staff interview protocol (Instrument 5)	24	1	0.75	18
Community partner focus group coordination [b]	6	1	2.0	12
Families not enrolled in Head Start focus group guide (Instrument 6)	60	1	1.5	90

[a] There is one interview protocol for both the program director and the ERSEA staff and the interviewer will tailor it to the respondent(s).
[b] There is no instrument, only a document of duties associated with this activity.

Estimated Total Annual Burden Hours: 259

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Head Start Act Section 640 [42 U.S.C. 9835].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–11777 Filed 6–3–21; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Intent To Award 54 Single-Source Supplements for Current Senior Medicare Patrol (SMP) State Grantee

ACTION: Notice of single-source supplements.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award 54 administrative supplements in the form of cooperative agreements to existing SMP project grantees to further support SMP activities in each state, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands. The purpose of existing grantees' work is to empower and assist Medicare beneficiaries, their families, and caregivers to prevent, detect, and report health care fraud, errors, and abuse through outreach, counseling, and education with an emphasis on reaching Medicare beneficiaries with limited income and those residing in rural areas. The administrative supplements for FY 2021 will be distributed via formula to the existing 54 SMP state grantees, bringing the total for the supplement awards to $2,002,468. These current SMP grantees will use this funding to further enhance or expand existing and prior established plans to empower and assist Medicare beneficiaries, their families, and caregivers to prevent, detect, and report health care fraud, errors, and abuse through outreach, counseling, and education. This additional funding will be targeted to reach Medicare beneficiaries with limited income, and/or those residing in rural areas.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Marissa Whitehouse, U.S. Department of Health and Human Services, Administration for Community Living, Center for Integrated Programs, Office of Healthcare Information and Counseling; telephone (202) 795–7425; email *Marissa.Whitehouse@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Program Name: Senior Medicare Patrol (SMP).

Recipient: 54 current SMP grantees.

Current grantee	State	FY21 ACL recommended supplement amount
Alabama Dept of Senior Services	Alabama	$41,488
Alaska Department of Health and Social Services	Alaska	4,408
Arizona Department of Economic Security	Arizona	32,105
Arkansas Department of Human Services	Arkansas	36,963
California Health Advocates	California	170,823
Colorado Division of Insurance	Colorado	22,047
The Department of Rehabilitation Services	Connecticut	16,044
Delaware Division of Social Services	Delaware	4,199
Legal Counsel For The Elderly	District of Columbia	2,658
Florida Department of Elder Affairs	Florida	116,372
Eqhealth Solutions, Inc	Georgia	59,236
Guam Department of Public Health & Social Services	Guam	1,318
Hawaii Department of Health	Hawaii	10,665
Idaho Commission on Aging	Idaho	12,481
AgeOptions, Inc	Illinois	65,894

Current grantee	State	FY21 ACL recommended supplement amount
IAAAA Education Institute, Inc	Indiana	45,349
Iowa Department of Commerce	Iowa	26,115
Kansas Department for Aging and Disability Services	Kansas	18,494
Louisville-Jefferson County Metro Government	Kentucky	46,755
Eqhealth Solutions, Inc	Louisiana	34,011
Maine Department of Health and Human Services	Maine	13,962
Aging, Maryland Department of	Maryland	21,364
Elder Services of The Merrimack Valley Inc	Massachusetts	32,656
MMAP Inc	Michigan	63,145
Minnesota Department of Human Services	Minnesota	33,924
Eqhealth Solutions, Inc	Mississippi	34,405
District III Area Agency on Aging	Missouri	45,870
Missoula Aging Services	Montana	12,067
Insurance, Nebraska Department of	Nebraska	13,080
State of Nevada Aging and Disability Services Division	Nevada	14,798
New Hampshire Dept of Health and Human Services	New Hampshire	10,893
Jewish Family & Vocational Service of Middlesex County, Inc	New Jersey	34,929
Aging & Long-Term Services Department, New Mexico	New Mexico	16,806
NY Statewide Senior Action Council, Inc	New York	122,593
North Carolina Department of Insurance	North Carolina	78,824
Minot State University	North Dakota	5,558
Pro Seniors Inc	Ohio	76,984
Oklahoma State Insurance Department	Oklahoma	29,996
DHS Office of Financial Services	Oregon	23,257
Center for Advocacy for the Rights and Interests of the Elderly	Pennsylvania	80,868
Hispanic-American Institute, Inc	Puerto Rico	69,909
Rhode Island Dept of Elderly Affairs	Rhode Island	5,334
South Carolina Department on Aging	South Carolina	38,362
South Dakota Department of Human Services	South Dakota	7,419
Upper Cumberland Development District	Tennessee	54,777
Better Business Bureau Educational Foundation	Texas	134,139
Legal Services of Virgin Islands Inc	U.S. Virgin Islands	1,980
Human Services, Utah Department of	Utah	10,035
Community of Vermont Elders	Vermont	7,973
Virginia Association of Area Agencies on Aging	Virginia	45,083
Washington State Insurance Commissioner	Washington	30,651
Senior Services West Virginia Bureau	West Virginia	20,356
Greater Wisconsin Agency on Aging Resources, Inc	Wisconsin	37,286
Wyoming Senior Citizens, Inc	Wyoming	5,760

Period of Performance: The award will be issued for the Fiscal Year 2021 project period of June 1, 2021 through May 31, 2022.

Total Award Amount: $2,002,468 total in FY 2021.

Award Type: Cooperative Agreement.

Statutory Authority: The statutory authority is contained in the HIPAA of 1996 (Pub. L. 104–191).

Basis for Award: With the final FY 2021 appropriation, Congress established the new baseline for the SMP program, setting the minimum ACL will receive to support this program to $20 million annually. This is an increase of $2 million over the amount ACL received for SMP historically. The additional funding is intended to expand and enhance current SMP activities with the purpose of reaching more Medicare beneficiaries. As such, OHIC is proposing to distribute the additional funding to the existing SMP state grantees to establish new baseline funding amounts for each of the state projects.

The current SMP state grantees are funded to carry out the SMP Project mission for the period of June 1, 2018 through May 31, 2023. Much work has already been completed and further tasks are currently being accomplished. It would be unnecessarily time consuming and disruptive to the SMP program, and the beneficiaries being served, for ACL to establish new grantees at this time. The current grantees are providing critical services in an efficient and successful manner. These administrative supplements will allow the SMP state grantees to expand their current work in empowering Medicare beneficiaries, their families, and caregivers to prevent, detect, and report health care fraud, errors, and abuse through outreach, counseling, and education with a particular emphasis on reaching Medicare beneficiaries with limited income and those residing in rural areas. The existing SMP state grantees are uniquely placed to continue and expand this work. Since 2018, and for years before for many repeat grantees, current grantees have been the proven state and community presence for preventing, detecting, and reporting Medicare fraud. There is one SMP state grantee project in each of the 50 States, the District of Columbia, Puerto Rico, Guam, and the U.S. Virgin Islands. In 2019, the most up-to-date complete year of data, the 54 SMP projects had a total of 6,875 active team members who conducted a total of 28,146 group outreach and education events, reaching an estimated 1.6 million people. In addition, the projects had 320,590 individual interactions with, or on behalf of, a Medicare beneficiary. For 2019, the SMP projects reported $2.4 million in expected Medicare recoveries. This program has successfully operated since its inception 23 years ago. Current grantees are closely monitored and are successfully

meeting all programmatic goals under the current SMP grant.

Dated: May 26, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2021–11779 Filed 6–3–21; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2024]

Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act; 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 ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act.'' The Drug Supply Chain Security Act (DSCSA) outlines critical enhanced drug distribution security requirements for building an electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs at the package level as they are distributed within the United States. This draft guidance clarifies these requirements and provides recommendations on the system attributes necessary to enable the secure tracing of product at the package level, including allowing for the use of verification, inference, and aggregation, as necessary.

DATES: Submit either electronic or written comments on the draft guidance by August 3, 2021 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 information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–2024 for ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Abha Kundi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov* 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

FDA is announcing the availability of a draft guidance for industry entitled ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act.''