

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual total number of respondents	Annual total number of responses per respondent	Average burden hours per response	Annual total burden hours
Appointment of Representative for Risk Determination Hearing (Form RDH–3)	1740	1	0.17	290
Risk Determination Hearing Transcript Request (Form RDH–4)	16	1	0.17	3
Request for Appeal of Risk Determination Hearing (Form RDH–5)	3	1	0.17	.5

Estimated Total Annual Burden Hours: 438.5

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: 6 U.S.C. 279; 8 U.S.C. 1232

Mary C. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2024–03018 Filed 2–9–24; 4:15 pm]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Availability of Program Application Instructions for Adult Protective Services Funding

Title: Elder Justice Act—Adult Protective Services.

Announcement Type: Initial.

Statutory Authority: 42 U.S.C 1397m–1.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.698.

DATES: Letters of Assurance and the Initial Spend Plan must be submitted electronically by 11:59 p.m. (EST) March 15, 2024.

I. Funding Opportunity Description

The Administration for Community Living (ACL) is establishing the “Elder Justice Act—Adult Protective Services” funding opportunity in accordance with section 2042(b) of subtitle B of title XX of the Social Security Act, otherwise known as the Elder Justice Act (EJA) as

authorized and funded through the Further Additional Continuing Appropriations and Other Extensions Act, 2024, Public Law 118–35. In accordance with these statutes, the purpose of this opportunity is to enhance and improve adult protective services provided by States, the District of Columbia, and the Territories.

Funds awarded to States and Territories under this opportunity will provide Adult Protective Services (APS) programs in the States, District of Columbia, and Territories with resources to enhance, improve, and expand the ability of APS to investigate allegations of abuse, neglect, and exploitation. Examples of activities consistent with the purposes of the statute include:

- Costs and salaries for hiring permanent or temporary staff members, extended hours/over-time for current staff, and associated personnel costs;
- Costs associated with providing goods and services to APS clients;
- Costs associated with community outreach, including public awareness campaigns and other resources designed to increase the public's awareness and understanding of APS' role in the community;
- Training costs, including state-wide training conferences for APS staff;
- Acquiring personal protection equipment and supplies;
- Improving and enhancing technology systems, including supporting remote work, such as the purchase of communications and technology hardware, software, or infrastructure in order to provide adult protective services;
- Improving data collection and reporting at the case worker, local-, and State-levels in a manner that is consistent with the National Adult Maltreatment Reporting System (NAMRS);
- Improving or enhancing existing APS processes for receiving reports, conducting intakes and investigations, planning/providing for services, making case determinations, documenting and closing cases, and continuous quality improvement;

- Working with tribal adult protective services efforts, such as conducting demonstrations on State-Tribal APS partnerships to better serve tribal elders who experience abuse, neglect, and exploitation, partnering with Tribes within the State to include tribal elder abuse data in the State's NAMRS reporting, and undertaking demonstrations to better understand elder abuse experienced by tribal individuals living in non-tribal communities and served by State APS programs;

- Establishing or enhancing the availability for elder shelters and other emergency, short-term housing and accompanying “wrap-around” services for APS clients;
- Establishing, expanding, or enhancing state-wide and local-level elder justice networks for the purpose of removing bureaucratic obstacles and improving coordination across the many State and local agencies interacting with APS clients who have experienced abuse, neglect, or exploitation;
- Costs associated with establishing new, or improving existing processes for responding to alleged scams and frauds;
- Costs associated with assisting APS clients secure the least restrictive option for emergency or alternative housing, and with obtaining, providing, or coordinating with care transitions as appropriate;
- Costs associated with transporting APS clients to necessary appointments, such as medical visits; and
- Costs associated with establishing grants or contracts to address gaps in the APS program identified in the environmental scan previously completed.

Awards authorized under the EJA section 2042(b) shall be provided to the agency or unit of State government having the legal responsibility for providing adult protective services within the State, District of Columbia, or Territory. Funding under this opportunity may be used to serve any APS client who meets their State's statutory or regulatory criteria for client eligibility for APS services. This funding must supplement and not supplant existing funding for APS

provided by States and local units of government. Additionally, award recipients will be required to submit Federal financial reports and annual program reports related to the activities performed.

II. Award Information

A. Eligible Entity

The eligible entity for these awards is the agency or unit of State government legally responsible for providing adult protective services in each State, the District of Columbia, or Territory (EJA section 2042(b)(3)(B)).

B. Funding Instrument Type

These awards will be made in the form of formula grants to the agencies and units of State government with the legal responsibility to provide adult protective services.

C. Anticipated Total Funding per Budget Period

Under this program, ACL intends to make grant awards to each State, Territory, and the District of Columbia. Funding will be distributed through the formula identified in section 2042(b) of the Elder Justice Act. The amounts allocated are based upon the proportion of elders living in each State and Territory, as defined in statute, and will be distributed based on the formula. There are no cost-sharing nor match requirements.

The project period for awards made under this announcement have an estimated start date of April 1, 2024 and an estimated end date of March 30, 2028. These awards have a 24-month budget period. Projected available funding for FY 2024 is \$13,766,829. The projected available funding is based on the FY23 appropriation levels, as described in the Further Additional Continuing Appropriations and Other Extensions Act, 2024, Public Law 118–35. Availability of funding and Notices of Award are contingent upon final Congressional appropriations, and this Notice will be updated accordingly.

Below are the projected award amounts for FY 2024:

Alabama	\$202,092
Alaska	103,251
Arizona	295,966
Arkansas	118,929
California	1,370,306
Colorado	204,579
Connecticut	148,885
Delaware	103,251
District of Columbia	19,193
Florida	1,020,937
Georgia	371,308
Hawaii	103,251
Idaho	103,251
Illinois	481,263
Indiana	257,455

Iowa	128,721
Kansas	111,431
Kentucky	176,257
Louisiana	174,021
Maine	103,251
Maryland	234,760
Massachusetts	280,653
Michigan	416,921
Minnesota	223,065
Mississippi	112,707
Missouri	247,579
Montana	103,251
Nebraska	103,251
Nevada	118,427
New Hampshire	103,251
New Jersey	361,336
New Mexico	103,251
New York	788,096
North Carolina	411,823
North Dakota	103,251
Ohio	478,682
Oklahoma	146,670
Oregon	175,035
Pennsylvania	557,851
Rhode Island	103,251
South Carolina	220,397
South Dakota	103,251
Tennessee	271,006
Texas	914,609
Utah	103,251
Vermont	103,251
Virginia	326,196
Washington	288,664
West Virginia	103,251
Wisconsin	246,152
Wyoming	103,251
American Samoa	13,767
Guam	13,767
Northern Marianas	13,767
Puerto Rico	157,773
Virgin Islands	13,767

III. Submission Requirements

A. Letter of Assurance

A *Letter of Assurance* is required to be submitted by the eligible entity in order to receive an award. The Letter of Assurance must include the following:

1. Assurance that the award recipient is the agency or unit of State government legally responsible for providing adult protective services in each State and Territory.
2. Assurance that funds will supplement and not supplant existing APS funding.
3. Assurance that the award recipient has included an initial spend plan for the FY 2024 funds, that a spend plan will be submitted prior to awards for each new budget period, and that the initial spend plans will be regularly maintained to accurately reflect how the recipient is investing their funding under this program.
4. Assurance that the award recipient will provide within 180 days of award an updated operational plan that covers activities through 2028.
5. Assurance that funds will be spent in ways consistent with the Elder Justice Act Section 2042(b) and guidance

provided by ACL, including the examples of activities consistent with the purposes of the authorizing legislation contained in this notice:

- Personnel costs;
- Providing goods and services to APS clients;
- Community outreach;
- Training;
- Acquiring personal protection equipment and supplies;
- Improving and enhancing technology systems;
- Improving data collection and reporting at the case worker, local-, and State-levels in a manner that is consistent with the National Adult Maltreatment Reporting System;
- Improving or enhancing existing APS processes;
- Working with tribal adult protective services efforts;
- Establishing or enhancing the availability for elder shelters and other emergency, short-term housing and accompanying “wrap-around” services;
- Establishing, expanding, or enhancing state-wide and local-level elder justice networks;
- Improving and supporting remote work;
- Establishing new, or improving existing processes for responding to alleged scams and frauds;
- Transportation costs;
- Assisting APS clients secure the least restrictive option for emergency or alternative housing, and with obtaining, providing, or coordinating with care transitions as appropriate; and
- Establishing grants and contracts as needed.

6. Assurance to provide Federal financial reports and annual program reports related to the activities performed for each fiscal year of funding received.

B. Spend Plans

An *Initial Spend Plan* is required with the submission of the Letter of Assurance, and prior to awards for each new budget period through the end of the project period. The Initial Spend Plan should outline how the State/Territory intends to spend their fiscal year allotment in response to the needs and challenges to their APS program. The plan should be consistent with the purpose of the authorizing legislation and the description and examples outlined above. The Initial Spend Plan should have the following format: 3–5 pages in length, double-spaced, with 12pt font and 1” margins, with a layout of 8.5” x 11” paper. The Initial Spend Plan submitted is considered a preliminary framework for how the State/Territory will plan to spend the

funds for the specified fiscal year, and they should be maintained on a regular basis to reflect accurately how the APS program is investing their funding.

C. Unique Entity ID Number

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.

D. Intergovernmental Review

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

IV. Submission Information

A. Submission Process

To receive funding, eligible entities must provide a *Letter of Assurance* and an *Initial Spend Plan* (if applicable) containing all the information outlined in section III A. and B. above.

Materials should be addressed to: Alison Barkoff, Administration for Community Living, 330 C Street SW, Washington, DC 20201.

Letters of Assurance and the Initial Spend Plan should be submitted electronically via email to aps@acl.hhs.gov.

B. Submission Dates and Times

To receive consideration, Letters of Assurance and the Initial Spend Plan must be submitted by 11:59 p.m. (EST) March 15, 2024. Letters of Assurance and the Initial Spend Plan should be submitted electronically via email to aps@acl.hhs.gov and have an electronic time stamp indicating the date/time submitted.

V. Agency Contacts

A. Programmatic Issues/Questions

Direct programmatic inquiries to: Erin Kee, erin.kee@acl.hhs.gov and/or 202-795-7312.

B. Submission Issues/Questions

Direct inquiries regarding submission of applications to aps@acl.hhs.gov. ACL will provide a response within 2 business days.

Dated: February 8, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024-03010 Filed 2-13-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2022-E-2222 and FDA-2022-E-2223]

Determination of Regulatory Review Period for Purposes of Patent Extension; SIMPLIFY CERVICAL ARTIFICIAL DISC

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SIMPLIFY CERVICAL ARTIFICIAL DISC and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claim that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by April 15, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 12, 2024. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 15, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 Nos. FDA-2022-E-2222 and FDA-2022-E-2223 for "Determination of Regulatory Review Period for Purposes of Patent Extension; SIMPLIFY CERVICAL ARTIFICIAL DISC." Received comments, those filed in a timely manner (see **ADDRESSES**), 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