

factor that has increased the costs of the evaluation is that OCSE is using the grants management information system developed for the grantees to monitor their enrollment and service delivery, which requires additional programming and customized reports. Finally, OCSE has asked for an internal memo describing preliminary impact findings which was not included in the FOA.

As a consequence of these unanticipated costs, the \$700,000 supplemental grant will be used for the following activities: (1) Conduct the day-to-day operation of the evaluation, including all costs involved in ensuring continued compliance with human subject research requirements; (2) conduct research and analyze information from the multiple implementation sites; (3) conduct the baseline and follow-up surveys; (4) maintain and provide evaluation-related technical assistance to OCSE and the grantees for the grants management information system; and (5) complete an internal memo describing interim impact findings.

Statutory Authority: Section 1115 of the Social Security Act authorizes funds for experimental, pilot, or demonstration projects that are likely to assist in promoting the objectives of Part D of Title IV.

Christopher Beach,

Senior Grants Policy Specialist, Office of Administration.

[FR Doc. 2015-32702 Filed 12-28-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Developmental Disabilities Protection and Advocacy Statement of Goals and Priorities

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration on Intellectual and Developmental Disabilities (AIDD), Administration for Community Living (ACL) is announcing an opportunity to comment on the proposed collection of information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow for public comment in response to the notice. This notice collects comments on the information collection requirements relating to an existing collection: Developmental Disabilities Protection and Advocacy Statement of Goals and Priorities (0985-0034).

DATES: Submit written comments on the collection of information by January 28, 2016.

ADDRESSES: Submit written comments on the collection of information by email to *OIRA_submission@omb.eop.gov* Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Clare Barnett, Administration for Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, One Massachusetts Avenue NW., Room 4204, Washington, DC 20201, 202-357-3426.

SUPPLEMENTARY INFORMATION: Federal statute and regulation require each State Protection and Advocacy (P&A) System annually prepare for public comment a Statement of Goals and Priorities (SGP) for the P&A for Developmental Disabilities (PADD) program for each coming fiscal year. Following the required public input for the coming fiscal year, the P&A is required by Federal statute and regulation to submit the final version of the SGP to the Administration on Intellectual and Developmental Disabilities (AIDD). AIDD reviews the SGP for compliance and will aggregate the information in the SGPs into a national profile of programmatic emphasis for P&A Systems in the coming year to provide an overview of program direction, and permit AIDD to track accomplishments against goals and formulate areas of technical assistance and compliance with Federal requirements.

ACL estimates the burden of this collection of information as follows:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
PADD SGP	57	1	16	912

Estimated Total Annual Burden Hours: 2,508

Dated: December 22, 2015.

Kathy Greenlee,

Administrator & Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1318]

Electroconvulsive Therapy Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians, and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Electroconvulsive Therapy

(ECT) Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians, and FDA Staff." The purpose of this guidance is to make recommendations for 510(k) submissions and complying with special controls being proposed to support reclassification of ECT Devices into Class II (special controls) for severe major depressive episode (MDE) associated with Major Depressive Disorder (MDD) or Bipolar Disorder (BPD) in patients 18 years of age and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition. This draft guidance is not final nor is it in effect at this time.