

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Community Living****Administration on Intellectual and Developmental Disabilities, President's Committee for People With Intellectual Disabilities**

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

DATES: Wednesday, November 30, 2016 from 9:00 a.m. to 5:00 p.m.; and Thursday, December 1, 2016 from 9:00 a.m. to 3:00 p.m.

These meetings will be open to the general public.

ADDRESSES: These meetings will be held in U.S. Department of Health and Human Services/Hubert H. Humphrey Building located at 200 Independence Avenue SW., Conference Room 505A, Washington, DC 20201. Individuals who would like to participate via conference call may do so by dialing toll-free #: 888-677-5620, when prompted enter pass code: 1697798. Individuals whose full participation in the meeting will require special accommodations (e.g., sign language interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should notify Ms. Allison Cruz, Director, Office of Innovation, via email at Allison.Cruz@acl.hhs.gov, or via telephone at 202-795-7334, *no later than Monday, November 18, 2016*. The PCPID will attempt to accommodate requests made after this date, *but cannot guarantee the ability to grant requests received after the deadline*. All meeting sites are barrier free, consistent with the Americans with Disabilities Act (ADA) and the Federal Advisory Committee Act (FACA).

AGENDA: The Committee Members will discuss preparation of the PCPID 2017 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report. They will also receive presentations from selected experts in the field of Intellectual and Developmental Disabilities.

ADDITIONAL INFORMATION: For further information, please contact Ms. Allison Cruz, Director, Office of Innovation, 330 C Street SW., Switzer Building, Room 1114, Washington, DC 20201. Telephone: 202-795-7334. Fax: 202-795-7334. Email: Allison.Cruz@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: The PCPID acts in an advisory capacity to

the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and support for individuals with intellectual disabilities. The PCPID executive order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: October 27, 2016.

Aaron Bishop,

Commissioner, Administration on Disabilities (AoD)

[FR Doc. 2016-26880 Filed 11-7-16; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Community Living****Agency Information Collection Activities; Proposed Collection; Public Comment Request; Evaluation of the State Health Insurance Assistance Program (SHIP)**

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Comments must be received by December 8, 2016.

ADDRESSES: Submit written comments on the collection of information by fax 202.395.5806 or by email to OIRA_submission@omb.eop.gov, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT:

Katherine Glendening by phone: 202-795-7350 or email:

Katherine.Glendening@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with section 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance.

Proposed Collection: Evaluation of the State Health Insurance Assistance Program (SHIP), U.S. Department of Health and Human Services (HHS), U.S. Administration for Community Living (ACL).

Need and Use of Information

Collection: The SHIP Customer Satisfaction Survey is a survey of individuals who meet with State Health Insurance Assistance Program (SHIP) Counselors to better understand their Medicare options. SHIP provides free, one-on-one counseling to the public, and the SHIP Customer Satisfaction Survey will be used to measure individuals' satisfaction with their counseling experience.

The State Health Insurance Assistance Program (SHIP) was created under Section 4360 of the Omnibus Budget Reconciliation Act (OBRA) of 1990 (P.L. 101-508). SHIP was created to provide grant funding to states/territories, who in turn provide "... information, counseling, and assistance . . . to individuals who are eligible to receive benefits under title XVIII of the Social Security Act" (Medicare). SHIP grants help Medicare beneficiaries and their families to obtain information about topics, such as Medicare enrollment (Parts A and B), Medicare Advantage plans (Part C), prescription drug coverage (Part D), Medicare Savings Programs (MSPs), supplemental insurance policies (Medigap), Medicaid issues, and other health insurance issues. The survey will gauge individuals' satisfaction with the services provided by SHIP counselors. While the SHIP program currently tracks the number of contacts the program makes with individual citizens, as well as descriptive information about counseling sessions such as topic, location, and beneficiary demographics, the program does not track outcome measurements, including customer satisfaction.

Comments in Response to the 60-Day Federal Register Notice

A notice was published in the **Federal Register** in Vol. 81, No. 124/Tuesday, June 28, 2016, Pages 41974-41975, announcing that ACL was requesting approval of a data collection (ICR New). No comments were received.

Estimated Data Burden

The SHIP survey will be conducted over a three-year period beginning in Fiscal Year 2017 (FY 2017), with sites in each of the 50 states, the District of Columbia and the territories of Guam, Puerto Rico and the U.S. Virgin Islands being surveyed once during the three-year period. Results from the surveys

will be used to understand satisfaction among individuals who receive SHIP Medicare assistance/counseling, as well, as how the program can be improved to provide better service to its target population. Eighteen (18) unique states/territories will be surveyed in FY 2017, with each state/territory expected to generate 75 unique responses, for a total of 1,350 individual responses in Year 1. This process will then be replicated in Year 2 (FY 2018) and Year 3 (FY 2019), with a different unique group of 18 states and territories being surveyed each year. By the end of FY19, SHIP will obtain 4,050 completed surveys to measure satisfaction at the state and national levels (18 states/territories \times 75 responses per state \times 3 years). SHIP will use the following factors to draw a representative sample of beneficiaries who received assistance/counseling:

- Review counseling sessions at two points each year:
 - One week in the spring (outside of the annual Medicare Open Enrollment Period)

- One week in the fall (during the annual Medicare Open Enrollment Period)
 - Focus only on non-redundant individuals (*i.e.*, a random sample without replacement of individuals who receive SHIP counseling).

- Randomly select 18 states and territories to be surveyed each year, with the states/territories stratified by data collection method* and the size of the Medicare-eligible population.

* Data collection method refers to how each state/territory collects and enters its records of counseling sessions. The majority of states/territories (29 of 54) directly enter counseling records into SHIP's National Performance Reporting (NPR) system, but the remaining states/territories upload data in batches at the end of each month. To ensure that the batch upload states/territories will be able to pull weekly samples twice per year, we will limit these states/territories to Years 2 and 3 of the survey administration period, thereby allowing for technical assistance to these states/territories if necessary.

To generate a sample with a 95% confidence level at the national level

384 responses will be required ($n = 3,000,000$ counseling sessions in 2015). SHIP anticipates collecting 75 completed surveys per state/territory, for a total collection of 4,050 completed surveys over the 3-year period. This larger collection will enable ACL to make state-to-state comparisons, which is an important feature of this survey. Specifically, state-to-state comparisons will allow ACL to identify which states/territories are providing the best services to their beneficiaries, and what best practices can be shared across states/territories. The larger collection will also provide each state/territory with sufficient information to take local action to improve service within budgetary constraints.

The proposed survey instrument may be viewed on the Web site: <http://www.acl.gov/Programs/CIP/OHIC/index.aspx>.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The average annual burden associated with these activities is summarized below:

Respondent type	Number of respondents	Responses per respondent	Average burden hours per response (hours)	Total average annual burden (hours)
Stratified Random Sample	1,350	1	8/60	180

Dated: October 27, 2016.

Edwin L. Walker,

Acting Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-3362]

Intent To Review a Study Data Standardization Plan Template; Notice of Availability; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research, is establishing a public docket to collect comments related to a proposed Study Data Standardization Plan (SDSP) template. As part of FDA's ongoing collaboration

with the Pharmaceutical Users Software Exchange (PhUSE), an independent, non-profit consortium addressing computational science issues, a PhUSE working group developed the PhUSE SDSP template. The purpose of this review is to evaluate the template and determine whether FDA will recommend its use either as is, or in a modified form, for regulatory submissions of study data. FDA is seeking public comment on the use of the PhUSE SDSP template for regulatory submissions.

DATES: Although you can comment on the PhUSE SDSP template at any time, to ensure that the Agency considers your comments in this review, please submit either electronic or written comments by January 9, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to <http://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 <http://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):** Division of Dockets Management (HFA-305), Food