year 2019, the SNP–MOC program area has been more accurately renamed Special Needs Program Care Coordination Quality Improvement Performance Evaluation (SNP–CCQIPE). In addition, the Medication Therapy Management (MTM) pilot protocol has been suspended until further notice. For that reason, it is no longer posted to the CMS website.

Beginning in audit year 2019, the data collected via program-specific record layouts, and collected via impact analyses on an as-needed basis, will be consolidated into each program area data request document. The pre-audit issue summary was updated for technical terminology changes. Three of the questionnaires and the power point template that previously have been distributed as part of our CPE audits will remain. However, the CPE self-assessment questionnaire and the CDAG and ODAG questionnaires have been removed. We have added new questionnaires for FA and SNP–CCQIPE. A revised template for collecting root cause analyses from organizations on an as-needed basis during the program audit has been included in this package.

We have also included a new independent validation audit work plan template that will be collected from sponsors that are required to undergo an independent validation audit. The validation audit is part of our robust audit process where CMS requires sponsoring organizations that have been audited and found to have deficiencies to undergo a validation audit to ensure correction. The validation audit utilizes the same audit protocols, but only tests the elements where deficiencies were found, as opposed to re-administering the entire audit. This validation audit work plan template will be populated by the sponsoring organization's independent auditing firm to describe how it plans to test for correction of the deficiencies identified during the program audit.

To assist in improving the audit process, we have also included an audit feedback questionnaire that is representative of the survey link we send to sponsoring organizations at the end of each program audit. Completion of this questionnaire is optional for sponsoring organizations to provide feedback on the audit process.

The proposed changes to each data collection instrument, along with the new FA and SNP–CCQIPE questionnaires, root cause template, validation audit work plan template and audit feedback questionnaire are included in the posted PRA package.

Finally, separate from the audit process and in order to address sponsoring organizations' concerns regarding undue harm in Star Ratings during audit years. The number of sponsoring organizations that are required to submit universes annually for their coverage/organization determinations and appeals increased. In 2016, CMS expanded this annual collection to all MA and Part D sponsoring organizations. The universes are submitted in the same format as required for audits under the Part D CDAG protocol and the Part C ODAG protocol. The universes are then analyzed for timeliness on an annual basis, across all sponsoring organizations, to allow a more comprehensive review of the accuracy of Part C and D appeals data to calculate Star Ratings. *Form Number:* CMS–10191 (OMB control number: 0938–1000); *Frequency:* Yearly; *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions); *Number of Respondents:* 166; *Total Annual Responses:* 211; *Total Annual Hours:* 51,548. (For policy questions regarding this collection contact Brenda Hudson at 443–743–9299.)

Dated: March 28, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–06645 Filed 3–30–18; 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; Public Comment Request; Older American Act Title III and Title VII (Chapters 3 and 4) Annual State Program Reporting (Annual Performance Data Collection); This is a Revision to the Existing State Program Report (OMB Approval 0985–0008)

AGENCY: Administration for Community Living (ACL), HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living 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 as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to annual performance data from State grantees under the Older Americans Act related to Title III and Title VII (Chapters 3 and 4) of that act. Title III includes, for example, home delivered and congregate meal services, transportation and caregiver service; and Title VII includes Elder Abuse Prevention and Legal Assistance Development (ICR Rev).

DATES: Submit written comments on the collection of information by May 2, 2018.

ADDRESSES: Submit written comments on the collection of information by:

(a) *Email to: OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL;

(b) Fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or

(c) By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: ACL's Office of Performance and Evaluation at *SPRredesign.comments@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. This collection is a revision of the 2016 approved version of the State Program Report and incorporates significant reduction in data collected. This data collection is essential to provide performance measures as required by Congress and the GPRA Modernization Act of 2010 (GPRAMA). Significant revisions to the SPR were last implemented in 2005. This proposed collection is a revision of the currently approved version (effective 2016–2019). The factors that influenced the proposed revision of the SPR, include: (1) The need to modernize the data structure to allow for more efficient reporting and the ability to use current technology for reporting and analysis; (2) the interest in aligning data elements within and across data collections; (3) the need to consider alternative data elements that reflect the current Aging Network and long-term care services and supports; and (4) the need to reduce reporting burden while enhancing data quality. The proposed SPR revision reduces the number of data elements reported by 70% and the amount of time for completion by 30% as compared to the current 2016–2019 SPR. This is a reduction of 874 hours from the previous version.

Reductions in data elements are found throughout the data collection but are concentrated in the consumer demographic components. Due to the aggregate level nature of the SPR, information on combinations of demographic characteristics (*e.g.,* number of women served who are 65 years or older and have 2 activity of daily living limitations) require exponentially larger numbers of data elements compared to single demographic characteristics (*e.g.* number of women served). To reduce the reporting burden associated with the number of data elements ACL is proposing to limit data element combinations. For example, the revised SPR asks for demographic characteristic such as age, race, and gender for three or more ADL and IADLs rather than for zero, one, two and three or more ADLs and IADLs. The remaining proposed demographic data elements include indicators of priority populations (*i.e.,* social and economic vulnerability and frailty) found in the OAA and will allow ACL to continue to measure efforts to target services.

Limited expansions in data elements are found in the Title III–E National Family Caregiver Support Program service component. The proposal separates out three service areas that were reported as a whole (*i.e.,* counseling, training and support group services). Separation allows for support group services to be categorized as a non-registered service for which consumer demographic details are no longer reported. Additional information regarding the types of respite services provided under the OAA is sought. The proposal separates assistance services into two types: (1) Case management, and (2) information and assistance. Case management assistance services are categorized as registered, meaning caregiver demographic data are reported while information and assistance services do not include reporting of demographic data. Supplemental services are reported in the same manner as ''other service'' under Title III–B, Home and Community-based Services (HCBS) program. Across the OAA services, greater detail regarding expenditure data is proposed. Under Title III–B, HCBS program, the proposed data collection expands data regarding Title VII legal assistance services. The ACL seeks data on the OAA identified priority legal issues for closed cases.

Comments in Response to the 60-Day *Federal Register* Notice

A 60-day **Federal Register** Notice was published in the **Federal Register** on June 1, 2017, Vol. 82, No. 104, pp. 25293–25294.

ACL received comments from fourteen (14) organizations and one (1) individual about the State Performance Report (SPR) redesign. ACL reviewed all of the comments, but some of the comments were deemed not relevant because they were: (a) About the data submission process itself (b) did not request a change (c) only commented on the format (d) indicated topics for technical assistance and training for the final data collection or (e) provided commentary without referencing the SPR. Regarding concerns about the:

- Timeline-ACL proposes moving the effective date back by 12 months,
- Cost, burden, and changes to data elements-ACL recognizes that there is always a cost to changing data systems, but believes that the anticipated improvement in the data justifies the proposed changes,
- New items related to Legal Services-ACL worked closely with program staff and stakeholders to develop a reasonable data collection to measure the contribution of this important program about which performance data were not previously collected,
- Need for additional elements including sub-state and individual level data-ACL is not adding more elements or more granular data collection at this time but will consider those suggestions for future data collections,
- Need for improved definitions and language-ACL made several changes to specific elements and is using these comments to inform the training and technical assistance it provides, and
- Caregiver program-ACL made revisions to several items and is using these comments to inform the training and technical assistance it provides.

A detailed analysis of the comments and responses can be found at (*https://www.reginfo.gov/public/do/PRAMain.*

The proposed data collection template may be found on the ACL website at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden of this collection of information as follows: 56 State Agencies on Aging respond annually and it will take an average of 33.5 hours for a total of 1,876 hours. This is a reduction of 874 hours from the previous version. The burden estimate of 33.5 hours was derived from feedback from grantees.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Older American Act Title III and Title VII (Chapters 3 and 4) Annual State Program Reporting	56	1	33.5	1,876
Total	56	1	33.5	1,876

Dated: March 26, 2018.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2018–06662 Filed 3–30–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1010]

Food and Drug Administration Prescription Drug User Fee Act VI Benefit-Risk Implementation Plan; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft 5-year plan describing the Agency's approach to further the implementation of structured benefit-risk assessment, including the incorporation of the patient's voice in drug development and decision-making, in the human drug review program and the opportunity for public comment on the draft plan. This new draft plan is an update to the 5-year plan published in February 2013 on FDA's website. This new draft plan is