

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services**

[Document Identifiers CMS–10680, CMS–10692 and CMS–10788]

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by July 28, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/>

*Paperwork Reduction Act of 1995/PRA-Listing.*

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Title of Information Collection:* Electronic Visit Verification Compliance Survey; *Type of Information Collection Request:* Extension without change of a currently approved collection; *Use:* The web-based survey will allow states to self-report their progress in implementing electronic visit verification (EVV) for personal care services (PCS) and home health care services (HHCS), as required by section 1903(l) of the Social Security Act. CMS will use the survey data to assess states' compliance with section 1903(l) of the Act and levy Federal Medical Assistance Percentage (FMAP) reductions where necessary as required by 1903(l) of the Act.

The survey will be disseminated to all 51 state Medicaid agencies (including the District of Columbia) and the Medicaid agencies of five U.S. territories. States will be required to complete the survey in order to demonstrate that they are compliant with Section 1903(l) of the Act by reporting on their EVV implementation status for PCS provided under sections 1905(a)(24), 1915(c), 1915(i), 1915(j), 1915(k), and Section 1115 of the Act; and HHCS provided under 1905(a)(7) of the Act or under a demonstration project or waiver (e.g., 1915(c) or 1115 of the Act).

The survey will be a live form, meaning states will have the ability to update their 1903(l) compliance status

on a continuous basis. As FMAP reductions are assigned quarterly per 1903(l) of the Act, states who are not in compliance will be asked to review their survey information on a quarterly basis to ensure it is up-to-date and to update their survey responses as needed until they come into compliance. *Form Number:* CMS–10680 (OMB control number: 0938–1360); *Frequency:* On occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Number of Responses:* 336; *Total Annual Hours:* 504. (For questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Home and Community Based Services (HCBS) Incident Management Survey; *Use:* The Survey will be disseminated to all 51 state Medicaid agencies (including the District of Columbia) to assess incident management systems in 1915(c) waivers. States will be surveyed to identify methods and promising practices for identifying, reporting, tracking, and resolving incidents of abuse, neglect, and exploitation. The survey results will also be used to review the strengths and weaknesses of each state's incident management system and will inform guidance to help ensure compliance with sections 1902(a)(30(A) and 1915(c)(2)(A) of the Social Security Act. *Form Number:* CMS–10692 (OMB control number: 0938–1362); *Frequency:* Once and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 102; *Total Annual Hours:* 153. (For policy questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Prescription Drug and Health Care Spending; *Use:* On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA) was signed into law. Section 204 of Title II of Division BB of the CAA added parallel provisions at section 9825 of the Internal Revenue Code (the Code), section 725 of the Employee Retirement Income Security Act (ERISA), and section 2799A–10 of the Public Health Service Act (PHS Act) that require group health plans and

health insurance issuers offering group or individual health insurance coverage to annually report to the Department of the Treasury, the Department of Labor (DOL), and the Department of Health and Human Services (HHS) (collectively, “the Departments”) certain information about prescription drug and health care spending, premiums, and enrollment under the plan or coverage. This information will support the development of public reports that will be published by the Departments on prescription drug reimbursements for plans and coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under the plans or coverage. The 2021 interim final rules, “Prescription Drug and Health Care Spending” issued by the Departments and the Office of Personnel Management (OPM) implement the provisions of section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act, as enacted by section 204 of Title II of Division BB of the CAA. OPM joined the Departments in issuing the 2021 interim final rules, requiring Federal Employees Health Benefits (FEHB) carriers to report information about prescription drug and health care spending, premiums, and plan enrollment in the same manner as a group health plan or health insurance issuer offering group or individual health insurance coverage. *Form Number:* CMS–10788 (OMB control number: 0938–1405); *Frequency:* Annual; *Affected Public:* Private Sector; *Number of Respondents:* 356; *Total Annual Responses:* 356; *Total Annual Hours:* 1,684,080. (For policy questions regarding this collection, contact Christina Whitefield at 301–492–4172.)

Dated: June 23, 2022.

**William N. Parham, III,**

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

[FR Doc. 2022–13769 Filed 6–27–22; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Administration on Disabilities, The President’s Committee for People with Intellectual Disabilities

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The President’s Committee for People with Intellectual Disabilities

(PCPID) will host a virtual meeting for its members to identify emerging topics to examine in the Committee’s Report to the President. All the PCPID meetings, in any format, are open to the public. This virtual meeting will be conducted in a presentation and discussion format.

**DATES:** Thursday, July 28, 2022 from 12:00 p.m. to 4:00 p.m. (EST).

**AGENDA:** The Committee will discuss survey responses, collectively discuss emerging issues facing people with intellectual disabilities, and the preparation of the PCPID Report to the President, including its proposed content and format, and related data collection and analysis required to complete the writing of the Report.

**ADDITIONAL INFORMATION:** For further information, please contact Mr. David Jones, Director, Office of Intellectual Developmental Disabilities, 330 C Street SW, Switzer Building, Room 1126, Washington, DC 20201. Telephone: 202–795–7367. Fax: 202–795–7334. Email: [David.Jones@acl.hhs.gov](mailto:David.Jones@acl.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

Stakeholder input is very important to the PCPID. Comments and suggestions especially from people with intellectual and developmental disabilities, are welcomed. If there are comments or feedback you would like to share with the PCPID as it begins to prioritize its work, please share them through the following *ACL.gov* link: [https://acl.gov/form/pcpid?j=1555178&sfmc\\_sub=191090082&l=6707\\_HTML&u=34777761&mid=515008575&jb=0](https://acl.gov/form/pcpid?j=1555178&sfmc_sub=191090082&l=6707_HTML&u=34777761&mid=515008575&jb=0).

Comments received by June 30, 2022 will be shared with the PCPID at the July 28th meeting. Comments received after June 30, 2022 will be compiled and shared with the PCPID quarterly.

**Webinar/Conference Call:** The virtual meeting is scheduled for Thursday, July 28, 2022 from 12:00 p.m. to 4:00 p.m. (EST) and may end early if discussions are finished. The meeting will be held through a zoom meeting platform. In order to participate, you must register in advanced of the meeting at the following link: <https://www.zoomgov.com/meeting/register/vJIsdeCpqzgsEiNHISQhI6VBwprCzllu8BU>.

**BACKGROUND INFORMATION ON THE COMMITTEE:**

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 Charter 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 and the Secretary of Health and Human Services to promote full participation of people with intellectual disabilities in their communities, such as: (A) expanding educational opportunities; (B) promoting housing opportunities; (C) expanding opportunities for competitive integrated employment; (D) improving accessible transportation options; (E) protecting rights and preventing abuse; and (F) increasing access to assistive and universally designed technologies; and (3) provide advice to the President and the Secretary of Health and Human Services to help advance racial equity and support for people with intellectual disabilities within underserved communities.

Dated: June 22, 2022.

**Jill Jacobs,**

*Commissioner, Administration on Disabilities.*

[FR Doc. 2022–13699 Filed 6–27–22; 8:45 am]

**BILLING CODE 4154–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2020–D–1496]

#### Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment; 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 final guidance for industry entitled “Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment.” This guidance is intended to facilitate the development of drugs and biologics for the adjuvant treatment of renal cell carcinoma and provides recommendations for the sponsor on this topic. The guidance includes recommendations regarding eligibility criteria, choice of comparator, followup imaging assessments, determination of disease recurrence, analyses of disease-free survival, and interpretation of trial results. This guidance finalizes the draft guidance of the same title issued on October 2, 2020.

**DATES:** The announcement of the guidance is published in the **Federal Register** on June 28, 2022.

**ADDRESSES:** You may submit either electronic or written comments on