

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)

PICOTS	KQ1	KQ2
Population	Adults 18+ years of age with Down syndrome. <i>Subgroups:</i> demographics (age, race, ethnicity, gender), geography (rural and urban), socioeconomic status.	Adults 18+ years of age with Down syndrome <i>Subgroups:</i> demographics (age, race, ethnicity, gender), geography (rural and urban), socioeconomic status.
Intervention	Screening/diagnostic tests for co-occurring medical conditions in adults with Down syndrome.	Treatment interventions for co-occurring medical conditions in adults with Down syndrome.
Comparator	Alternative test for screening/diagnosis or no screening.	For all conditions, compared with usual care or alternative intervention for treatment.
Outcome	<i>Benefits:</i> accurate diagnosis, time to diagnosis or intervention/treatment. Health and quality of life outcomes. <i>Harms:</i> adverse events related to screening/diagnosis (mortality, medical trauma, unnecessary testing, etc.).	<i>Intermediate outcomes:</i> Treatment adherence. Lab values. Healthcare utilization. <i>Final outcomes:</i> Change in standardized symptom measures. Morbidity/mortality. Quality of life. Functional outcomes (e.g., activities of daily living, assisted living/nursing home status). Caregiver or family outcomes (including caregiver health and quality of life). <i>Harm outcomes:</i> Adverse treatment effects.
Timing	All duration and follow up.	All duration and follow up.
Setting	US and non-US settings. All healthcare settings (e.g., primary care, specialty care, specialized clinics, etc.)	US and non-US settings. All healthcare settings (e.g., primary care, specialty care, specialized clinics, etc.).

Abbreviations: KQ = key question.

Dated: December 3, 2024.

Marquita Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-319, CMS-2088-17, CMS-224-14 and CMS-R-297/CMS-L564]

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 January 8, 2025.

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. 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, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/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. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Use:* Title XIX and title XXI State agencies are required to submit the MEQC pilot planning document in accordance with § 431.814(b), and the MEQC case level and CAP reports based on pilot findings in accordance with §§ 431.816 and 431.820, respectively.

The primary users of this information are State Medicaid (and where applicable CHIP) agencies and CMS. State agencies are expected to use the information collected for continuous quality improvement purposes. They will identify patterns of error in their eligibility processing operations and systems and take corrective actions to address issues and improve the eligibility determination process. CMS will use the data collected to identify and help those States that are most in need of technical assistance. CMS will also use the data set to identify potential weaknesses in Federal regulations. It will propose regulatory modifications designed to ensure that there are more effective quality controls in the eligibility determination process.; *Form Number:* CMS-319 (OMB control number: 0938-0147); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 35; *Number of Responses:* 647; *Total Annual Hours:* 9,840. (For policy questions regarding this collection contact Camiel Rowe at 410-786-0069.)

2. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Community Mental Health Center Cost Report *Use:* CMS requires the Form CMS-2088-17 to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. In addition, CMHCs may receive reimbursement through the cost report for Medicare reimbursable bad debts. CMS uses the Form CMS-2088-17 for rate setting; payment refinement activities, including market basket analysis; Medicare Trust Fund projections; and to support program operations. The primary function of the cost report is to determine provider reimbursement for services rendered to Medicare beneficiaries. Each CMHC submits the cost report to its contractor for reimbursement determination. Section 1874A of the Act describes the functions of the contractor. CMHCs must follow the principles of cost reimbursement, which require they maintain sufficient financial records and statistical data for proper determination of costs. The S series of worksheets collects the provider's location, CBSA, date of certification, operations, and unduplicated census days. The A series of worksheets collects the provider's trial balance of expenses for overhead costs, direct patient care services, and non-revenue generating cost centers. The B series of

worksheets allocates the overhead costs to the direct patient care and non-revenue generating cost centers using functional statistical bases. The Worksheet C computes the apportionment of costs between Medicare beneficiaries and other patients. The D series of worksheets are Medicare specific and calculate the reimbursement settlement for services rendered to Medicare beneficiaries. The Worksheet F collects the provider's revenues and expenses data from the provider's income statement. *Form Number:* CMS-2088-17 (OMB control number: 0938-0378); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 191; *Total Annual Responses:* 191; *Total Annual Hours:* 17,190. (For policy questions regarding this collection contact Jill Keplinger at 410-786-4550.)

3. Type of Information Collection Request: Extension of a previously approved collection; *Title of Information Collection:* Federally Qualified Health Center Cost Report Form; *Use:* The Form CMS-224-14 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and to calculate the FQHC settlement amount. These providers, paid under the FQHC prospective payment system (PPS), may receive reimbursement outside of the PPS for Medicare reimbursable bad debts, pneumococcal, influenza, and COVID-19 vaccines, and monoclonal antibody products. CMS uses the Form CMS-224-14 for rate setting; payment refinement activities, including developing a FQHC market basket; Medicare Trust Fund projections; and to support program operations. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the FQHC Medicare cost report data to calculate Medicare margins; to formulate recommendations to Congress regarding the FQHC PPS; and to conduct additional analysis of the FQHC PPS. *Form Number:* CMS-224-14 (OMB control number: 0938-1298); *Frequency:* Yearly; *Affected Public:* Private Sector, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-Profit Institutions; *Number of Respondents:* 2,967; *Total Annual Responses:* 2,967; *Total Annual Hours:* 172,086. (For policy questions regarding this collection contact LuAnn Piccione at 410-786-5423.)

4. Type of Information Collection Request: Extension of a currently approved information collection; *Title*

of Information Collection: Medicare Request for Employment Information; *Use:* Section 1837(i) of the Social Security Act (the Act) provides for a SEP for individuals who delay enrolling in Medicare Part B because they are covered by a group health plan based on their own or a spouse's current employment status. Disabled individuals with Medicare may also delay enrollment because they have large group health plan coverage based on their own or a family member's current employment status. When these individuals apply for Medicare Part B, they must provide proof that the group health plan coverage is (or was) based on current employment status. Form CMS L564 provides this proof so that SSA can determine eligibility for the SEP. Individuals eligible for the SEP can enroll in Part B without incurring a late enrollment penalty (LEP). Individuals may also use this form to prove that their group health plan coverage is based on current employment status and to have the assessed Medicare LEP reduced. *Form Number:* CMS-R-297/CMS-L564 (OMB control number: 0938-0787); *Frequency:* Annually; *Affected Public:* Individuals or households, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 594,998; *Total Annual Responses:* 594,998; *Total Annual Hours:* 243,949. (For policy questions regarding this collection contact Candace Carter at 410-786-8466 or Candace.Carter@cms.hhs.gov).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget for Review and Approval; "State SNAP Agency NDNH Matching Program Performance Report" (Office of Management Budget #: 0970-0464)

AGENCY: Office of Child Support Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: OCSS is requesting the Office of Management and Budget (OMB) to approve the "State SNAP Agency NDNH Matching Program Performance Report,"