



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS-10198, CMS-10561, CMS-10572, CMS-10286, CMS-10377
and CMS-460]**

Agency Information Collection Activities: Proposed Collection; 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

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 web site 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 N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10198	Creditable Coverage Disclosure to CMS On-Line Form and Instructions
CMS-10561	Essential Community Provider Data Collection to Support QHP Certification
CMS-10572	Transparency in Coverage Reporting by Qualified Health Plan Issuers
CMS-10286	Notice of Research Exception under the Genetic Information Nondiscrimination Act

CMS-10377 Student Health Insurance Coverage

CMS-460 Medicare Participating Physician or Supplier Agreement

Under the 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 requires federal agencies to publish a 60-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.

Information Collections

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Creditable Coverage Disclosure to CMS On-Line Form and Instructions; *Use:* Section 1860D-13 of the Social Security Act, as established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR §423.56(e), require that entities that offer prescription drug benefits under any of the types of coverage described in 42 CFR §423.56(b) provide a disclosure of creditable coverage to CMS. There are other disclosure and notification requirements to Part D eligible individuals in §423.56(c), (d), and (f); this PRA covers the requirement in subsection (e). Entities required to make this disclosure state whether their prescription drug coverage meets the actuarial requirements defined in §423.56(a).

Disclosure of whether prescription drug coverage is creditable provides Medicare with important information relating to whether prescription drug benefits offered by an entity to Medicare Part D eligible individuals is expected to pay at least as much as the standard benefits under Medicare Part D. The form is used as a reporting tool where entities offering prescription

drug coverage indicate whether the coverage being provided is considered creditable or non-creditable. *Form Number:* CMS-10198 (OMB control number 0938-1013); *Frequency:* Yearly; *Affected Public:* Individuals and Households, Private Sector, State, Local, or Tribal Governments, Federal Government, Business, and Not-for Profits; *Number of Respondents:* 141,400; *Number of Responses:* 141,400; *Total Annual Hours:* 11,786. (For questions regarding this collection contact Tammie Wall at 410-786-3317.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Supporting Statement for Essential Community Provider Data Collection to Support QHP Certification; *Use:* Standards for Essential Community Provider (ECP) requirements are codified at 45 CFR 156.235. Issuers must contract with a certain percentage, as determined by Health and Human Services (HHS), of the available ECPs in the plan's service area. HHS will continue to collect more complete data from such providers so that all issuers are held to a more uniform ECP standard. HHS achieves this outcome by soliciting qualified ECPs throughout the year to complete and submit the ECP application in order to be added to the HHS ECP list or update required data fields to remain on the list. In soliciting updates directly from providers, HHS routinely performs research and outreach to providers on the ECP List to verify information about ECPs collected via the ECP application and annual renewal form. These ongoing efforts will result in a more accurate listing of the universe of available ECPs from which issuers select to satisfy the ECP standard. *Form Number:* CMS-10561 (OMB control number: 0938-1295); *Frequency:* Annually; *Affected Public:* Private Sector - Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 19,020; *Number of Responses:* 19,020; *Total Annual Hours:* 4,914. (For questions regarding this collection, contact Samantha Nguyen Kella at 816-426-6339.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Transparency in Coverage Reporting by Qualified Health Plan Issuers; *Use:* Sections 1311(e)(3)(A)-(C) of the ACA, as implemented at 45 CFR

155.1040(a)-(c) and 156.220, establish standards for qualified health plan (QHP) issuers to submit specific information related to transparency in coverage. QHP issuers are required to post and make data related to transparency in coverage available to the public in plain language and submit this data to the Department of Health and Human Services (HHS), the Exchange, and the state insurance commissioner. Section 2715A of the Public Health Service (PHS) Act as added by the ACA largely extends the transparency provisions set forth in section 1311(e)(3) to non-grandfathered group health plans and health insurance issuers offering group and individual health insurance coverage. *Form Number:* CMS-10572 (OMB control number: 0938-1310); *Frequency:* Annually; *Affected Public:* Private Sector, Business, and Not-for Profits; *Number of Respondents:* 400; *Number of Responses:* 400; *Total Annual Hours:* 22,000. (For questions regarding this collection, contact Jack Reeves at 301-492-5152.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Research Exception under the Genetic Information Nondiscrimination Act; *Use:* Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) the research complies with 45 CFR Part 46 or equivalent Federal regulations and applicable State or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes. The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Non-Federal governmental group health plans and issuers solely in the individual health insurance market or Medigap market will be

required to file with the Centers for Medicare & Medicaid Services (CMS). The Notice of Research Exception under the Genetic Information Nondiscrimination Act is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement. *Form Number:* CMS-10286 (OMB control number: 0938-1077); *Frequency:* On Occasion; *Affected Public:* Private Sector; State, Local or Tribal Governments; *Number of Respondents:* 2; *Total Annual Responses:* 2; *Total Annual Hours:* 0.5. (For policy questions regarding this collection contact Erik Gomez at 667-414-0682.)

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Student Health Insurance Coverage; *Use:* Under the Student Health Insurance Coverage Final Rule published March 21, 2012 (77 FR 16453), student health insurance coverage is a type of individual health insurance coverage provided pursuant to a written agreement between an institution of higher education (as defined in the Higher Education Act of 1965) and a health insurance issuer, and provided to students who are enrolled in that institution and their dependents. The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule provided that, for policy years beginning on or after July 1, 2016, student health insurance coverage is exempt from the actuarial value (AV) requirements under section 1302(d) of the Affordable Care Act, but must provide coverage with an AV of at least 60 percent. This provision also requires issuers of student health insurance coverage to specify in any plan materials summarizing the terms of the coverage the AV of the coverage and the metal level (or the next lowest metal level) the coverage would otherwise satisfy under §156.140. This disclosure will provide students with information that allows them to compare the student health coverage with other available coverage options. *Form Number:* CMS-10377 (OMB control number :0938-1157); *Frequency:* Yearly; *Affected Public:* Private Sector; *Number of Respondents:* 46; *Total Annual Responses:* 1,237,980; *Total Annual Hours:* 46. (For policy questions regarding this collection contact

Russell Tipps at (667) 290-9640.)

6. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Participating Physician or Supplier Agreement; *Use:* Form CMS-460 is the agreement a physician, supplier, or their authorized official signs to become a participating provider in Medicare Part B. By signing the agreement to participate in Medicare, the physician, supplier, or their authorized official agrees to accept the Medicare-determined payment for Medicare covered services as payment in full and to charge the Medicare Part B beneficiary no more than the applicable deductible or coinsurance for the covered services. For purposes of this explanation, the term “supplier” means certain other persons or entities, other than physicians, that may bill Medicare for Part B services (*e.g.*, suppliers of diagnostic tests, suppliers of radiology services, durable medical suppliers (DME) suppliers, nurse practitioners, clinical social workers, physician assistants). Institutions that render Part B services in their outpatient department are not considered “suppliers” for purposes of this agreement. *Form Number:* CMS-460 (OMB control number: 0938-0373); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 14,029; *Number of Responses:* 14,029; *Total Annual Hours:* 3,507. (For questions regarding this collection contact Mark G. Baldwin at 410-786-8139.)

William N. Parham, III,

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

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