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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10146, CMS-10377, CMS-10465 and CMS-10409]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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 (the 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 any of the following subjects: 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, you may make your request using one of following:

1. Access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

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-10146 Notice of Denial of Medicare Prescription Drug Coverage

CMS-10377 Student Health Insurance Coverage

CMS-10465 Minimum Essential Coverage

CMS-10409 Long Term Care Hospital (LCTH) Continuity Assessment Record and Evaluation (CARE) Data Set

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.

1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Notice of Denial of Medicare Prescription Drug Coverage; Use: The notice provides information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process. Form Number: CMS-10146 (OMB control number: 0938-0976); Frequency: Occasionally; Affected Public: Private sector (Business or other for-profits); Number of Respondents: 580; Total Annual Responses: 1,902,055; Total Annual Hours: 475,514. (For policy questions regarding this collection contact Amber

Casserly at 410-786-0976.)

2. Type of Information Collection Request: Revision 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), an issuer that provides student health insurance coverage that does not meet the annual dollar limits requirements under Public Health Service Act (PHS Act) section 2711 must provide notice in the insurance policy or certificate and in any other written materials informing students that the policy being issued does not meet the annual limits requirements under the Affordable Care Act. The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule removed outdated provisions in §147.145(b)(2) and (d) allowing student health insurance issuers to impose restricted annual dollar limits on policies started before January 1, 2014, with an accompanying requirement that student health issuers must provide notice to students. Those provisions, by their own terms, no longer apply and student health insurance issuers are subject to the prohibition on annual dollar limits under PHS Act section 2711 and §147.126 for policy years beginning on or after January 1, 2014. Therefore, the annual limit notification requirement is being discontinued. The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule further provides 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: Annually; Affected Public: Private Sector; Number of Respondents: 49; Total Annual Responses: 1,255,000; Total Annual Hours: 49. (For policy questions regarding this collection contact Russell Tipps at 301-492-4371.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Minimum Essential Coverage; Use: The final rule titled “Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions,” published July 1, 2013 (78 FR 39494) designates certain types of health coverage as minimum essential coverage. Other types of coverage, not statutorily designated and not designated as minimum essential coverage in regulation, may be recognized by the Secretary of Health and Human Services (HHS) as minimum essential coverage if certain substantive and procedural requirements are met. To be recognized as minimum essential coverage, the coverage must offer substantially the same consumer protections as those enumerated in the Title I of Affordable Care Act relating to non-grandfathered, individual health insurance coverage to ensure consumers are receiving adequate coverage. The final rule requires sponsors of other coverage that seek to have such coverage recognized as minimum essential coverage to adhere to certain procedures. Sponsoring organizations must submit to HHS certain information about their coverage and an attestation that the plan substantially complies with the provisions of Title I of the Affordable Care Act applicable to non-grandfathered individual health insurance coverage. Sponsors must also provide notice to enrollees informing them that the plan has been recognized as minimum essential coverage for the purposes of the individual coverage requirement. Form Number: CMS-10465 (OMB control number 0938-1189); Frequency: Occasionally; Affected Public: Private Sector (Business or other for-profits); Number of Respondents: 10; Total Annual

Responses: 10; Total Annual Hours: 53. (For policy questions regarding this collection contact Russell Tipps at 301-492-4371.)

4. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Long Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set; Use: Section 3004 of the Affordable Care Act authorized the establishment of quality reporting program for long term care hospitals (LTCHs). Beginning in FY 2014, LTCHs that fail to submit quality measure data may be subject to a 2 percentage point reduction in their annual update to the standard Federal rate for discharges occurring during a rate year. The LTCH CARE Data Set was developed specifically for use in LTCHs for data collection of NQF #0678 Pressure Ulcer measures beginning October 1, 2012, with the understanding that the data set would expand in future rulemaking years with the adoption of additional quality measures. Relevant data elements contained in other well-known and clinically established data sets, including but not limited to the Minimum Data Set 3.0 (MDS 3.0) and CARE, were incorporated into the LTCH CARE Data Set V1.01, V2.00 and V2.01. LTCH CARE Data Set V3.00 will be implemented April 1, 2016. Form Number: CMS-10409 (OMB control number: 0938-1163); Frequency: Occasionally; Affected Public: Private Sector: Business or other for-profit and not-for-profit institutions; Number of Respondents: 424; Total Annual Responses: 405,344; Total Annual Hours: 328,346. (For policy questions regarding this collection contact Staci Payne at 410-786-2838.)

Dated: March 7, 2016

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

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