

Dated: October 25, 2016.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10622, CMS-339, CMS-460, CMS-R-64, CMS-379, CMS-10311, CMS-1490, CMS-10137, and CMS-10237]

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

AGENCY: Centers for Medicare & Medicaid 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 any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) 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 November 30, 2016.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs,

Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR, Email: OIRA_submission@omb.eop.gov.

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. Email 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: 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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Evaluation of the CMS Quality Improvement Organizations: Reducing Healthcare-Acquired Conditions in Nursing Homes; *Use:* As mandated by Sections 1152-1154 of the Social Security Act, CMS directs the QIO program, one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries. In the 11th SOW, CMS restructured the QIO program to funded Quality Innovation Networks (QIN)-QIOs, Beneficiary and Family-Centered Care (BFCC) organizations, National Coordinating Centers (NCCs), Program Collaboration Centers (PCCs), and the Strategic Innovation Engine (SIE). In the current SOW, 14 QIN-QIOs coordinate the work of 53 QIOs nationwide

including all 50 states and other U.S. territories.

CMS evaluates the quality and effectiveness of the QIO program as authorized in Part B of Title XI of the Social Security Act. CMS created the Independent Evaluation Center (IEC) to provide CMS and its stakeholders with an independent and objective program evaluation of the 11th SOW. Evaluation activities will focus on analyzing how well the QIO program is achieving the three aims of better care, better health, and lower cost as well as the effectiveness of the new QIO program structure. One of the QIN-QIOs' tasks to achieve these three aims is to support participating nursing homes in their efforts to improve quality of care and health outcomes among residents. According to the 2013 CMS Nursing Home Data Compendium, more than 15,000 nursing homes participated in Medicare and Medicaid programs with more than 1.4 million beneficiaries resided in U.S. nursing homes. These residents and their families rely on nursing homes to provide reliable, safe, high quality care. However, cognitive and functional impairments, pain, incontinence, antipsychotic drug use, and healthcare associated conditions (HAC), such as pressure ulcers and falls, remain areas of concern.

This information collection is to provide data to assess QIN-QIOs efforts aimed at addressing these HACs in nursing homes. QIN-QIOs are responsible for recruiting nursing homes to participate in the program. We will conduct an annual survey of administrators of nursing homes participating in the QIN-QIO program (intervention group) and administrators at nursing homes that are not participating in the QIN-QIO program (comparison group). Our proposed survey assesses progress towards the goals of the QIN-QIO SOW, including activities and strategies to increase mobility among residents, reduce infections, reduce use of inappropriate antipsychotic medication among long-term stay residents.

We plan to conduct qualitative interviews with nursing home administrators. This interview will supplement the Nursing Home Survey and provide more in-depth contextual information about the QIN-QIO program implementation within at nursing homes, including: (i) Their experience with, and perceived success of QIN-QIO collaboratives; (ii) their satisfaction with the QIN-QIO Collaborative and QIO support; (iii) perceived value and impact of QIO program; and (iv) drivers and barriers to QIN-QIO involvement and success.

Information from QIO leadership and/or state/territory task leads will be collected by interviews and focus groups. Interviews with Nursing Home Task leaders at the QIN and QIO will be conducted in-person during site visits and/or over the phone. We will conduct focus groups with QIO-level Directors during the annual CMS Quality conference. The purpose of the interviews and focus groups is to examine: (i) QIO processes for recruiting nursing homes, peer coaches, and beneficiaries to participate in the program; (ii) strengths and challenges of QIN-QIO activities related to nursing homes; (iii) partnership and coordination with other QIN-QIO tasks; and (iv) overall lessons learned. We will also conduct qualitative interviews with nursing home peer coaches. Subsequent to the 60-day notice **Federal Register** notice, the survey has been revised by adding questions and rewording questions. *Form Number:* CMS-10622 (OMB control number: 0938-NEW); *Frequency:* Annually; *Affected Public:* Business or other For-profits and Not-for Profits institutions; *Number of Respondents:* 856; *Total Annual Responses:* 856; *Total Annual Hours:* 255. (For policy questions regarding this collection contact Robert Kambic at 410-786-1515.)

2. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Provider Cost Report Reimbursement Questionnaire; *Use:* The information collected in this form (Exhibits 1 and 2) is authorized under Sections 1815(a) and 1833(e) of the Social Security Act, 42 U.S.C. 1395g. Regulations at 42 CFR 413.20 and 413.24 require providers to submit financial and statistical records to verify the cost data disclosed on their annual Medicare cost report. Providers participating in the Medicare program are reimbursed for furnishing covered services to eligible beneficiaries on the basis of an annual cost report (filed with the provider's MAC) in which the proper reimbursement is computed. Consequently, it is necessary to collect this documentation of providers' costs and activities that supports the Medicare cost report data in order to ensure proper Medicare reimbursement to providers. *Form Number:* CMS-339 (OMB control number: 0938-0301); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits); *Number of Respondents:* 2,273; *Total Annual Responses:* 2,273; *Total Annual Hours:* 15,911. (For policy questions regarding this collection

contact Christine Dobrzycki at 410-786-3389.)

3. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Participation Agreement for Physicians and Suppliers; *Use:* Section 1842(h) of the Social Security Act permits physicians and suppliers to voluntarily participate in Medicare Part B by agreeing to take assignment on all claims for services to Medicare beneficiaries. The law also requires that the Secretary provide specific benefits to the physicians, suppliers and other persons who choose to participate. The CMS-460 is the agreement by which the physician or supplier elects to participate in Medicare. *Form Number:* CMS-460 (OMB control number: 0938-0373); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits); *Number of Respondents:* 120,000; *Total Annual Responses:* 120,000; *Total Annual Hours:* 30,000. (For policy questions regarding this collection contact Mark Baldwin at 410-786-8139.)

4. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Indirect Medical Education and Supporting Regulations; *Use:* Section 1886(d)(5)(B) of the Social Security Act requires additional payments to be made under the Medicare Prospective Payment System (PPS) for the indirect medical educational costs a hospital incurs in connection with interns and residents (IRs) in approved teaching programs. In addition, Title 42, Part 413, sections 75 through 83 implement section 1886(d) of the Act by establishing the methodology for Medicare payment of the cost of direct graduate medical educational activities. These payments, which are adjustments (add-ons) to other payments made to a hospital under PPS, are largely determined by the number of full-time equivalent (FTE) IRs that work at a hospital during its cost reporting period. In Federal fiscal year (FY) 2015, the estimated Medicare program payments for indirect medical education (IME) costs amounted to \$8.38 billion. Medicare program payments for direct graduate medical education (GME) are also based upon the number of FTE-IRs that work at a hospital. In FY 2015, the estimated Medicare program payments for GME costs amounted to \$3.1 billion. *Form Number:* CMS-R-64 (OMB control number: 0938-0456); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits); *Number of Respondents:* 1,245; *Total Annual*

Responses: 1,245; *Total Annual Hours:* 2,490. (For policy questions regarding this collection contact Milton Jacobson at 410-786-7553.)

5. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Financial Statement of Debtor; *Use:* Section 1893(f)(1) of the Social Security Act and 42 CFR 401.607 provides the authority for collection of this information. Section 42 CFR 405.607 requires that, CMS recover amounts of claims due from debtors including interest where appropriate by direct collections in lump sums or in installments. In addition, the DOJ Final Rule, the Federal Claims Collection Standards, which was published as 32 CFR parts 900-904, on November 22, 2000, in the **Federal Register**, Section 32 CFR 900.1 stipulates that, standards for Federal agency use in the administrative collection, offset, compromise, and the suspension or termination of collection activity. Section 32 CFR 901.8(a) states that, Agencies should obtain financial statements from debtors who represent that they are unable to pay the debt in one lump sum. *Form Number:* CMS-379 (OMB control number: 0938-0270); *Frequency:* Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 1,000. (For policy questions regarding this collection contact Anita Crosier at 410-786-0217.)

6. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Program/Home Health Prospective Payment System Rate Update for Calendar Year 2010: Physician Narrative Requirement and Supporting Regulation; *Use:* Section (o) of the Act (42 U.S.C. 1395 x) specifies certain requirements that a home health agency must meet to participate in the Medicare program. To qualify for Medicare coverage of home health services a Medicare beneficiary must meet each of the following requirements as stipulated in § 409.42: be confined to the home or an institution that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1) or 1919 of Act; be under the care of a physician as described in § 409.42(b); be under a plan of care that meets the requirements specified in § 409.43; the care must be furnished by or under arrangements made by a participating HHA, and the beneficiary must be in need of skilled services as described in § 409.42(c). Subsection 409.42(c) of our regulations

requires that the beneficiary need at least one of the following services as certified by a physician in accordance with § 424.22: Intermittent skilled nursing services and the need for skilled services which meet the criteria in § 409.32; Physical therapy which meets the requirements of § 409.44(c). Speech-language pathology which meets the requirements of § 409.44(c); or have a continuing need for occupational therapy that meets the requirements of § 409.44(c), subject to the limitations described in § 409.42(c)(4). On March 23, 2010, the Affordable Care Act of 2010 (Pub. L., 111–148) was enacted. Section 6407(a) (amended by section 10605) of the Affordable Care Act amends the requirements for physician certification of home health services contained in Sections 1814(a)(2)(C) and 1835(a)(2)(A) by requiring that, prior to certifying a patient as eligible for Medicare's home health benefit, the physician must document that the physician himself or herself or a permitted non-physician practitioner has had a face-to-face encounter (including through the use of tele-health services, subject to the requirements in section 1834(m) of the Act)", with the patient. The Affordable Care Act provision does not amend the statutory requirement that a physician must certify a patient's eligibility for Medicare's home health benefit, (see Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act. *Form Number:* CMS–10311 (OMB control number: 0938–1083); *Frequency:* Yearly; *Affected Public:* Business or other For-profits; *Number of Respondents:* 345,600; *Total Annual Responses:* 345,600; *Total Annual Hours:* 28,800. (For policy questions regarding this collection contact Hillary Loeffler at 410–786–0456.)

7. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Patient's Request for Medicare Payment; *Use:* The Form CMS–1490S form provides beneficiaries with a relatively easy form to use when filing their claims. Without the collection of this information, claims for reimbursement relating to the provision of Part B medical services/supplies could not be acted upon. This would result in a nationwide paralysis of the operation of the Federal Government's Part B Medicare program, and major problems for the patients/beneficiaries inflicting severe physical and financial hardship on beneficiaries. This form was explicitly developed for easy use by beneficiaries who file their own claims. The CMS–1490S form can be obtained from any Social Security

office or Medicare Administrative Contractors or CMS. When the CMS–1490S is used, the beneficiary must attach to it his/her bills from physicians or suppliers. The form is, therefore, designed specifically to aid beneficiaries who cannot get assistance from their physicians or suppliers for completing claim forms. The form is currently approved under 0938–1197; however, we are submitting for approval as a standalone information collection request. Once a new OMB control number is issued, we will remove the burden for the CMS–1490S that is currently approved under OMB control number 0938–1197. *Form Number:* CMS–1490 (OMB control number: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Individuals and Households; *Number of Respondents:* 167,839; *Total Annual Responses:* 167,839; *Total Annual Hours:* 83,920. (For policy questions regarding this collection contact Sumita Sen at 410–786–5755.)

8. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2018 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug (PD) plans or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion application. *Form Number:* CMS–10137 (OMB control number: 0938–0936); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits and Not-for-profit institutions); *Number of Respondents:* 463; *Total Annual Responses:* 160; *Total Annual Hours:* 1,565. (For policy questions regarding this collection contact Arianne Spaccarelli at 410–786–5715.)

9. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits; *Use:* This information collection includes the process for organizations wishing to

provide healthcare services under MA and/or MA–PD plans must complete an application annually, file a bid, and receive final approval from CMS. The application process has two options for applicants that include: Request for new MA product or request for expanding the service area of an existing product. This collection process is the only mechanism for MA and/or MA–PD organizations to complete the required application process. CMS utilizes the application process as the means to review, assess and determine if applicants are compliant with the current requirements for participation in the Medicare Advantage program and to make a decision related to contract award. *Form Number:* CMS–10237 (OMB control number: 0938–0935); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits and Not-for-profit institutions); *Number of Respondents:* 310; *Total Annual Responses:* 310; *Total Annual Hours:* 10,941. (For policy questions regarding this collection contact Marcella Watts at 410–786–5724.)

Dated: October 26, 2016.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3083]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), the Food and Drug Administration (FDA or Agency) is required to report annually in the **Federal Register** on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct. A supplemental report entitled "Supplementary Report: Performance of Drug and Biologics Firms in Conducting Postmarketing