includes questions at the beginning of the interview that will capture the age, sex, active duty military status, race, and ethnicity of everyone who usually lives or stays in the household. Some content from the family questionnaire (*e.g.*, family income, financial burden of medical care, housing tenure) will be moved into the two remaining questionnaires.

Public comment on the first draft of these questionnaires will be critical as we continue to revise and improve the content and question text during the redesign process. The first draft of the questionnaires may be found in the docket under Supporting and Related Materials.

Dated: October 4, 2016.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2016–24348 Filed 10–6–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10605, CMS–R–5, CMS–10311, and CMS–10242]

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 7, 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 the 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:* The Health Insurance Enforcement and Consumer Protections Grant Program; *Use:* Section 1003 of the Affordable Care Act (ACA) adds a new section 2794 to the PHS Act entitled, ''Ensuring That Consumers Get Value for Their Dollars.'' Specifically, section 2794(a) requires the Secretary of the Department of Health and Human Services (the Secretary) (HHS), in conjunction with the States, to establish a process for the annual review of health insurance premiums to protect consumers from unreasonable rate increases. Section 2794(c) directs the Secretary to carry out a program to award grants to States. Section 2794(c)(2)(B) specifies that any appropriated Rate Review Grant funds that are not fully obligated by the end of FY 2014 shall remain available to the Secretary for grants to States for planning and implementing the insurance market reforms and consumer protections under Part A of title XXVII of the Public Health Service Act (PHS Act). States that apply for funds are required to complete the grant application. States that are awarded funds under this funding opportunity are required to provide the CMS with four quarterly reports, and one annual report per year (except for the last year of the grant) until the end of the grant period detailing the state's progression towards planning and/or implementing the market reforms under Part A of Title XXVII of the PHS Act. A final report is due at the end of the grant period. *Form Number:* CMS–10605 (OMB control number: 0938—NEW); *Frequency:* Annually and Quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 23; *Total Annual Responses:* 115; *Total Annual Hours:* 2,898. (For policy questions regarding this collection contact Jim Taing at 301–492–4182.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Physician Certification/Recertification in Skilled Nursing Facilities (SNFs) Manual Instructions; *Use:* Section 1814(a) of the Social Security Act (the Act) requires specific certifications in order for Medicare payments to be made for certain services. Before the enactment of the Omnibus Budget Reconciliation Act of 1989 (OBRA1989, Public Law 101–239), section 1814(a)(2) of the Act required that, in the case of post hospital extended care services, a physician certify that the services are or were required to be given because the individual needs or needed, on a daily basis, skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in a SNF on an inpatient basis. The

physician certification requirements were included in the law to ensure that patients require a level of care that is covered by the Medicare program and because the physician is a key figure in determining the utilization of health services. *Form Number:* CMS–R–5 (OMB control number: 0938–0454); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 2,711,136; *Total Annual Responses:* 2,711,136; *Total Annual Hours:* 624,515. (For policy questions regarding this collection contact Kia Sidbury at 410–786–7816.)

3. *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. 1395x) 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.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Documentation Requirements Concerning Emergency and Nonemergency Ambulance Transports Described in the Beneficiary Signature Regulations in 42 CFR 424.36(b); *Use:* The statutory authority requiring a beneficiary's signature on a claim submitted by a provider is located in section 1835(a) and in 1814(a) of the Social Security Act (the Act), for Part B and Part A services, respectively. The authority requiring a beneficiary's signature for supplier claims is implicit in sections 1842(b)(3)(B)(ii) and in 1848(g)(4) of the Act. Federal regulations at 42 CFR 424.32(a)(3) state that all claims must be signed by the beneficiary or on behalf of the beneficiary (in accordance with 424.36). Section 424.36(a) states that the beneficiary's signature is required on a claim unless the beneficiary has died or the provisions of 424.36(b), (c), or (d) apply. We believe that for emergency and nonemergency ambulance transport services, where the beneficiary is physically or mentally incapable of signing the claim (and the beneficiary's authorized representative is unavailable or unwilling to sign the claim), that it is impractical and infeasible to require an ambulance provider or supplier to later locate the beneficiary or the person authorized to sign on behalf of the beneficiary, before submitting the claim to Medicare for payment. Therefore, we created an exception to the beneficiary signature requirement with respect to emergency and nonemergency ambulance transport services, where the beneficiary is physically or mentally incapable of signing the claim, and if certain documentation requirements are met. Thus, we added subsection (6) to paragraph (b) of 42 CFR 424.36. The information required in this ICR is needed to help ensure that services were in fact rendered and were rendered as billed. *Form Number:* CMS–10242 (OMB control number: 0938–1049); *Frequency:* Yearly; *Affected Public:* Business or other for-profits, Not-for-profit institutions); *Number of Respondents:* 10,402; *Total Annual Responses:* 14,155,617; *Total Annual Hours:* 1,180,578. (For policy questions regarding this collection contact Martha Kuespert at 410–786–4605.)

Dated: October 4, 2016.

William N. Parham, III,

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

[FR Doc. 2016–24341 Filed 10–6–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2872]

Medical Device User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Medical Device User Fee Amendments.'' The purpose of the meeting is to discuss proposed recommendations for the reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years (FYs) 2018 through 2022. MDUFA authorizes FDA to collect fees and use them for the process for the review of medical device applications. The current legislative authority for MDUFA expires October 1, 2017. At that time, new legislation will be required for FDA to continue collecting medical device user fees in future fiscal years. Following discussions with the device industry and periodic consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) directs FDA to publish the recommendations for the reauthorized program in the **Federal Register,** hold a meeting at which the public may present its views on such recommendations, and provide for a period of 30 days for the public to provide written comments on such recommendations. FDA will then