

future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. *Form Number:* CMS-10302 (OMB control number: 0938-1078); *Frequency:* Annually; *Affected Public:* Business and other for-profits and Not-for-profit institutions; *Number of Respondents:* 845; *Total Annual Responses:* 900; *Total Annual Hours:* 5,135. (For policy questions regarding this collection contact Cheryl Gilbreath at 410-786-5919.)

3. *Type of Information Collection Request:* Extension of a previously approved collection; *Title of Information Collection:* Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; *Exchanges:* Eligibility and Enrollment; *Use:* The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, expands access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP). The Exchanges, which became operational on January 1, 2014, enhanced competition in the health insurance market, expanded access to affordable health insurance for millions of Americans, and provided consumers with a place to easily compare and shop for health insurance coverage. The reporting requirements and data collection in Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; *Exchanges:* Eligibility and Enrollment (CMS-2334-F) address: (1) Standards related to notices, (2) procedures for the verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan; and (3) other eligibility and enrollment provisions to provide detail necessary for state implementation. *Form Number:* CMS-10468 (OMB control number: 0938-1207); *Frequency:* Annually; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 13,200; *Total Annual Responses:*

13,200; *Total Annual Hours:* 8,899. (For policy questions regarding this collection contact Sarah Boehm at 301-492-4429.)

Dated: July 26, 2016.

**Martique Jones,**

*Director, Regulations Development Group,  
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-10311, CMS-10242]**

#### Agency Information Collection Activities: Proposed Collection; 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 (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: (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 must be received by September 27, 2016.

**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. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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-10311** Medicare Program/Home Health Prospective Payment System Rate Update for Calendar Year 2010: Physician Narrative Requirement and Supporting Regulation

**CMS-10242** Documentation Requirements Concerning Emergency and Nonemergency Ambulance Transports Described in the Beneficiary Signature Regulations in 42 CFR 424.36(b)

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 Collection

#### 1. 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:** Private sector (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.)

#### 2. 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 (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:** Private sector (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: July 26, 2016.

**Martique Jones,**

*Director, Regulations Development Group,  
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–1773]

### Change of Address for the Food and Drug Administration Center for Food Safety and Applied Nutrition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is providing notice that the street address for the Center for Food Safety and Applied Nutrition's (CFSAN's) Harvey W. Wiley Federal Building in College Park, MD has changed. The new street address is 5001 Campus Drive.

**FOR FURTHER INFORMATION CONTACT:** John Reilly, Center for Food Safety and Applied Nutrition (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.

**SUPPLEMENTARY INFORMATION:** The purpose of this notice is to inform the public that the street address for CFSAN's Harvey W. Wiley Federal Building in College Park, MD has changed. The street, formerly known as Paint Branch Parkway, has been renamed "Campus Drive" and the street number has been changed to "5001." Thus, the building's street address has changed from 5100 Paint Branch Parkway to 5001 Campus Drive, and our full address is: Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740.

Consequently, any mailed correspondence addressed to CFSAN's Harvey W. Wiley Federal Building should use the new street address beginning immediately.