

economic value of screening to diagnose current HCV infection among adults and pregnant women in the United States.

**DATES:** Written comments must be received on or before December 27, 2019.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2019-0094 by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Division of Viral Hepatitis, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop U12-3, Atlanta, GA 30329, Attn: Docket No. CDC-2019-0094.

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** CDR Sarah Schillie, MD, MPH, MBA, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop U12-3, Atlanta, GA 30329. Email: [DVHpolicy@cdc.gov](mailto:DVHpolicy@cdc.gov). Telephone: (404) 639-8000.

**SUPPLEMENTARY INFORMATION:**

**Public Participation**

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on the following questions:

- Based on the evidence presented in the full recommendations document (see the Supporting and Related Materials tab in the docket), do you agree with CDC's proposed recommendations for HCV infection screening? If not, please state the reason why and, if available, provide additional evidence for consideration.
- Are CDC's recommendations (see Supporting and Related Materials) clear as written? If not, what changes do you propose to make them clearer?
- If implemented as proposed, do you believe these recommendations would result in a reduction in HCV infections and associated health and financial consequences in the United States? If not, please provide an explanation.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or

inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted in preparation of the final recommendation and may revise as appropriate.

**Background and Brief Description**

Hepatitis C Virus (HCV) infection is the most commonly reported blood-borne infection in the United States (CDC Viral Hepatitis Surveillance, 2019; Rosenberg et al, 2018), and during 2013-2016 there were an estimated 2.4 million people in the nation (or 1.0% of the U.S. population) living with hepatitis C (Hofmeister et al, 2019). Percutaneous exposure (e.g., injection drug use, blood transfusion) is the most efficient mode of HCV transmission, and injection drug use is the primary risk factor for infection (CDC Viral Hepatitis Surveillance, 2017). National surveillance data reveal an increase in reported cases of acute HCV infection every year from 2009 through 2017, the most recent year for which there is data. The highest rates of acute cases are among persons aged 20-39 years (CDC Viral Hepatitis Surveillance, 2017). As new HCV infections have risen among reproductive aged adults, rates of HCV infection nearly doubled from 2009-2014 among women with live births (Patrick et al, 2017). In 2015, 0.38% of live births were delivered by HCV-infected women (Schillie et al, 2018). Given the current rate and trends of HCV infections, CDC has decided to augment the current guidelines to address the rise in HCV infections among adults in the U.S.

As described in the recommendation document found in the Supporting and Related Materials tab of the docket, these recommendations augment previously published CDC recommendations for the identification of hepatitis C in the United States (Smith et al, 2012; CDC HCV Recommendations, 1998).

Dated: October 23, 2019.

**Sandra Cashman,**

*Executive Secretary, Centers for Disease Control and Prevention.*

[FR Doc. 2019-23521 Filed 10-25-19; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier CMS-3427 and CMS-484, 846, 854, 847, 848, 849, 10125, and 10126]

**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 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 December 27, 2019.

**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' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.
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:** 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-3427 End Stage Renal Disease Application and Survey and Certification Report  
CMS-484, 846, 854, 847, 848, 849, 10125, and 10126 Durable Medical Equipment Medicare Administrative

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:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease Application and Survey and Certification Report; *Use:* Part I of this form is a facility identification and screening measurement used to initiate the certification and recertification of

ESRD facilities. Part II is completed by the Medicare/Medicaid State survey agency to determine facility compliance with ESRD conditions for coverage.

*Form Number:* CMS-3427 (OMB control number: 0938-0360); *Frequency:* Every three years; *Affected Public:* Private sector (Business or other for-profit and Not-for profit institutions); *Number of Respondents:* 7,493; *Total Annual Responses:* 2,473; *Total Annual Hours:* 824. (For policy questions regarding this collection contact Jennifer Milby at 410-786-8828).

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Durable Medical Equipment Medicare Administrative Contractor Certificate of Medical Necessity and Supporting Documentation Requirements; *Use:* The certificates of medical necessity (CMNs) collect information required to help determine the medical necessity of certain items. CMS requires CMNs where there may be a vulnerability to the Medicare program. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those who bill for the items) complete the administrative information (e.g., patient's name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinicians (e.g., physician assistant, LPN, etc.) who completes questions pertaining to the beneficiary's medical condition and signs the CMN. The physician or other clinician returns the CMN to the supplier who has the option to maintain a copy and then submits the CMN electronically to CMS, along with a claim for reimbursement. *Form Numbers:* CMS-484, 846, 847, 848, 849, 10125, 10126 (OMB control number: 0938-0679); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 1,335,658; *Total Annual Responses:* 1,335,658; *Total Annual Hours:* 267,132. (For policy questions regarding this collection contact Melissa Singer at 410-786-0365.)

Dated: October 23, 2019.

**William N. Parham, III,**

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

[FR Doc. 2019-23504 Filed 10-25-19; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier CMS-10400]

### 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 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 on the collection(s) of information must be received by the OMB desk officer by *November 27, 2019*.

**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](mailto: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' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/>