

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:* Revision of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations; *Use:* The application must be completed by entities performing laboratory's testing specimens for diagnostic or treatment purposes. This information is vital to the certification process. *Form Number:* CMS-116 (OCN: 0938-0581); *Frequency:* Biennially and Occasionally; *Affected Public:* Private sector- Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 242,000; *Total Annual Responses:* 34,200; *Total Annual Hours:* 25,650. (For policy questions regarding this collection contact Sheila Ward at 410-786-3115.)

Dated: February 19, 2014.

**Martique Jones,**

*Deputy 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 Identifier: CMS-10328]

#### 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 *April 25, 2014*.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number (OCN). 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-10328 Medicare Self-Referral Disclosure Protocol

Under the Paperwork Reduction Act (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:* Revision of currently approved collection; *Title of Information Collection:* The Self-Referral Disclosure Protocol (SRDP) is a voluntary self-disclosure instrument that allows providers of services and suppliers to disclose actual or potential violations of section 1877 of the Social Security Act (the Act). CMS analyzes the disclosed conduct to determine compliance with section 1877 of the Act and the application of the exceptions to the physician self-referral prohibition. In addition, the authority granted to the Secretary under section 6409(b) of the ACA, and subsequently delegated to CMS, may be used to reduce the amount due and owing for violations. *Form Number:* CMS-10328 (OCN: 0938-1106); *Frequency:* Once; *Affected Public:* Private sector—Business and other for-profit and Not-for-profit institutions; *Number of Respondents:* 100; *Total Annual Responses:* 100; *Total Annual Hours:* 5,000. (For policy questions regarding this collection contact Matthew Edgar at (410)-786-0698. For all other issues call 410-786-1326.)

Dated: February 19, 2014.

**Martique Jones,**

*Deputy 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**

[CMS-3287-PN2]

**Medicare and Medicaid Programs; Application From The Compliance Team for Initial CMS-Approval of Its Rural Health Clinic Accreditation Program**

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

**ACTION:** Proposed notice.

**SUMMARY:** This proposed notice acknowledges the receipt of an application from The Compliance Team for initial recognition as a national accrediting organization for rural health clinics (RHCs) that wish to participate in the Medicare or Medicaid programs.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 26, 2014.

**ADDRESSES:** In commenting, please refer to file code CMS-3287-PN2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways:

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.regulations.gov>. Follow the "submit a comment" instructions.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3287-PN2, P.O. Box 8016, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3287-PN2, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** James Cowher, (410) 786-1948; Valarie Lazerowich, (410) 786-4750; Cindy Melanson, (410) 786-0310; or Patricia Chmielewski, (410) 786-6899.

**SUPPLEMENTARY INFORMATION:**

*Submitting Comments:* We welcome comments from the public on all issues set forth in this proposed notice to assist us in fully considering issues and developing policies. Referencing the file code CMS-3287-PN2 and the specific "issue identifier" that precedes the section on which you choose to comment will assist us in fully considering issues and developing policies.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search

instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

**I. Background**

Under the Medicare program, eligible beneficiaries may receive covered services from a Rural Health Clinic (RHC) provided certain requirements are met. Section 1861(aa), and 1905(l)(1) of the Social Security Act (the Act), establishes distinct criteria for facilities seeking designation as an RHC. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488, subpart A. The regulations at 42 CFR part 491, subpart A specify the minimum conditions that an RHC must meet to participate in the Medicare program. The conditions for Medicare payment for RHCs are set forth at 42 CFR 405, subpart X.

Generally, to enter into an agreement, a RHC must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 491 of our regulations. Thereafter, the RHC is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by state agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the accrediting organization requires the