

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Nurses .....	FGS1	5,000	1	15/60
	FGS2	2,500	1	15/60
	FGS3	5,000	1	15/60
Medical Doctors .....	FGS1	3,500	1	15/60
	FGS2	1,750	1	15/60
	FGS3	3,500	1	15/60

**Leroy A. Richardson,**

*Chief, Information Collection Review Office,  
Office of Scientific Integrity, Office of the  
Associate Director for Science, Office of the  
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Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10141 and CMS-10540]

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

**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 July 20, 2015.

**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 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](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:** 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:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Prescription Drug Benefit Program; *Use:* Part D plans and, to the extent applicable, MA organizations use the information to comply with the eligibility and associated Part D participating requirements. We use this information to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and to ensure that correct information is disclosed to potential and current enrollees. *Form Number:* CMS-10141 (OMB control number 0938-0964); *Frequency:* Once; *Affected Public:* Private sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 4,101,066; *Total Annual Responses:* 46,099,944; *Total Annual Hours:* 7,572,223. (For policy questions regarding this collection contact Deborah Larwood at 410-786-9500).

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Quality Improvement Strategy Implementation Plan and Progress Report; *Use:* Section 1311(c)(1)(E) of the Affordable Care Act requires qualified health plans (QHPs) offered through an Exchange must implement a quality improvement strategy (QIS) as described in section 1311(g)(1). Section 1311(g)(3) of the Affordable Care Act specifies the guidelines under Section 1311(g)(2) shall require the periodic reporting to the applicable Exchange the activities that a qualified health plan has conducted to implement a strategy as described in section 1311(g)(1). We intend to have QHP issuers complete the QIS Plan and Reporting Template annually for initial certification and subsequent annual updates of progress in implementation of their strategy. The

template will include topics to assess an issuer's compliance in creation on a payment structure that provides increased reimbursement or other incentives to improve the health outcomes of plan enrollees, prevent hospital readmissions, improve patient safety and reduce medical errors, promote wellness and health, and reduce health and health care disparities, as described in Section 1311(g)(1) of the Affordable Care Act.

The Quality Improvement Strategy Plan and Reporting Template will allow (1) HHS to evaluate the compliance and adequacy of QHP issuers' quality improvement efforts, as required by Section 1311(c) of the Affordable Care Act, and (2) HHS will use the issuers' validated information to evaluate the issuers' quality improvement strategies for compliance with the requirements of Section 1311(g) of the Affordable Care Act. *Form Number:* CMS-10540 (OMB control number: 0938-NEW); *Frequency:* Annually; *Affected Public:* Individuals and Households; Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 251,681; *Total Annual Responses:* 251,681; *Total Annual Hours:* 82,800. (For policy questions regarding this collection contact Kimberly Kufel at 410-786-1750).

Dated: June 16, 2015.

**William N. Parham, III,**

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

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1642-PN]

#### Medicare Program; Request for an Exception to the Prohibition on Expansion of Facility Capacity Under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed notice.

**SUMMARY:** The Social Security Act prohibits a physician-owned hospital from expanding its facility capacity, unless the Secretary of the Department of Health and Human Services (the Secretary) grants the hospital's request for an exception to that prohibition after considering input on the hospital's

request from individuals and entities in the community in which the hospital is located. The Centers for Medicare & Medicaid Services (CMS) has received a request from a physician-owned hospital for an exception to the prohibition against expansion of facility capacity. This notice solicits comments on the request from individuals and entities in the community in which the physician-owned hospital is located. Community input may inform our determination regarding whether the requesting hospital qualifies for an exception to the prohibition against expansion of facility capacity.

**DATES:** *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 20, 2015.

**ADDRESSES:** In commenting, please refer to file code CMS-1642-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this exception request to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1642-PN, P.O. Box 8010, Baltimore, MD 21244-1850.

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: Department of Health and Human Services, Attention: CMS-1642-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

**FOR FURTHER INFORMATION CONTACT:** Patricia Taft, (410) 786-4561 or Teresa Walden, (410) 786-3755.

#### **SUPPLEMENTARY INFORMATION:**

##### **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.

We will allow stakeholders 30 days from the date of this notice to submit written comments. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of this notice, 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, please phone 1-800-743-3951.

#### **I. Background**

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law—(1) prohibits a physician from making referrals for certain "designated health services" (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral.

Section 1877(d)(2) of the Act provides an exception for physician ownership or investment interests in rural providers (the "rural provider exception"). In order for an entity to qualify for the rural provider exception, the DHS must be furnished in a rural area (as defined in section 1886(d)(2) of the Act) and substantially all the DHS furnished by the entity must be furnished to individuals residing in a rural area.

Section 1877(d)(3) of the Act provides an exception, known as the hospital ownership exception, for physician ownership or investment interests held in a hospital located outside of Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

Section 6001(a)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111-148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (hereafter referred to together as "the Affordable Care Act") amended the rural provider and hospital ownership exceptions to the physician self-referral