

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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## 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

prohibition to impose additional restrictions on physician ownership and investment in hospitals and rural providers. Since March 23, 2010, a physician-owned hospital that seeks to avail itself of either exception is prohibited from expanding facility capacity unless it qualifies as an "applicable hospital" or "high Medicaid facility" (as defined in sections 1877(i)(3)(E), (F) of the Act and 42 CFR 411.362(c)(2), (3) of our regulations) and has been granted an exception to the prohibition by the Secretary of the Department of Health and Human Services (the Secretary). Section 1877(i)(3)(A)(ii) of the Act provides that individuals and entities in the community in which the provider requesting the exception is located must have an opportunity to provide input with respect to the provider's request for the exception. For further information, we refer readers to the CMS Web site at: [http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician\\_Owned\\_Hospitals.html](http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html).

## II. Exception Request Process

On November 30, 2011, we published a final rule in the **Federal Register** (76 FR 74122, 74517 through 74525) that, among other things, finalized § 411.362(c), which specified the process for submitting, commenting on, and reviewing a request for an exception to the prohibition on expansion of facility capacity. We published a subsequent final rule in the **Federal Register** on November 10, 2014 (79 FR 66770) that made certain revisions to the expansion exception process; however, because this particular request was received prior to the effective date of that rule, it is being processed in accordance with the regulations that were in place at the time of submission.

As stated in regulations at § 411.362(c)(5), we will solicit community input on the request for an exception by publishing a notice of the request in the **Federal Register**. Individuals and entities in the hospital's community will have 30 days to submit comments on the request. Community input must take the form of written comments and may include documentation demonstrating that the physician-owned hospital requesting the exception does or does not qualify as an applicable hospital or high Medicaid facility, as such terms are defined in § 411.362(c)(2) and (3). In the November 30, 2011 final rule (76 FR 74522), we gave examples of community input, such as documentation demonstrating that the hospital does not satisfy one or more of the data criteria or that the hospital discriminates

against beneficiaries of Federal health programs; however, we noted that these were examples only and that we will not restrict the type of community input that may be submitted. If we receive timely comments from the community, we will notify the hospital, and the hospital will have 30 days after such notice to submit a rebuttal statement (§ 411.362(c)(5)).

In the November 30, 2011 final rule (76 FR 74522 through 74523), this request for an exception to the facility expansion prohibition will be considered complete and ready for CMS review if no comments from the community are received by the close of the 30-day comment period. If we receive timely comments from the community, we will consider this request to be complete 30 days after the hospital is notified of the comments.

If we grant the request for an exception to the prohibition on expansion of facility capacity, the expansion may occur only in facilities on the hospital's main campus and may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds (§ 411.362(c)(6)). Our decision to grant or deny a hospital's request for an exception to the prohibition on expansion of facility capacity will be published in the **Federal Register** in accordance with our regulations at § 411.362(c)(7).

## III. Hospital Exception Request

As permitted by section 1877(i)(3) of the Act and our regulations at § 411.362(c), the following physician-owned hospital has requested an exception to the prohibition on expansion of facility capacity:

Name of Facility: Harsha Behavioral Center, Incorporation.

Address: 1420 East Crossing Boulevard, Terre Haute, Indiana 47802.

County: Vigo County, Indiana.

Basis for Exception Request: High Medicaid Facility.

We seek comments on this request from individuals and entities in the community in which the hospital is located. We encourage interested parties to review the hospital's request, which is posted on the CMS Web site at: [http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician\\_Owned\\_Hospitals.html](http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html). We especially welcome comments regarding whether the hospital qualifies as a high Medicaid facility. In November 30, 2011 final rule (76 FR 74521 through 74522), a high Medicaid facility is a hospital that satisfies the following criteria:

- The hospital is not the sole hospital in the county in which it is located;
- The hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries; and

- With respect to each of the 3 most recent fiscal years for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located.

Individuals and entities wishing to submit comments on the hospital's request should review the **DATES** and **ADDRESSES** sections above and state whether or not they are in the community in which the hospital is located.

## IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

## V. Response to Public Comments

We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble.

Dated: June 5, 2015.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-5514-N2]

### Medicare Program; Oncology Care Model: Request for Applications; Extension of the Submission Deadline for Applications

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

**ACTION:** Notice.

**SUMMARY:** This notice extends the application submission deadline for organizations to participate in the