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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1667-FN]

Medicare Program; Approval of 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: Final notice.

SUMMARY: This final notice announces our decision to approve the request of Deaconess Women's Hospital of Southern Indiana doing business as (d/b/a) The Women's Hospital (The Women's Hospital) for an exception to the prohibition on expansion of facility capacity.

EFFECTIVE DATE: This notice is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

POH-ExceptionRequests@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

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, known as the rural provider exception, for physician ownership or investment interests in rural providers. 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)(D) 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. 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 facility expansion 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. Section 1877(i)(3)(H) of the Act states that the Secretary shall publish in the **Federal Register** the final decision with respect to the request for an exception to the prohibition against facility expansion not later than 60 days after receiving a complete application.

II. Exception Approval 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. These revisions include, among other things, permitting the use of data from an external data source or data from the Hospital Cost Report Information System (HCRIS) for specific eligibility criteria.

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)(ii)).

A request for an exception to the facility expansion prohibition is considered complete as follows:

- If the request, any written comments, and any rebuttal statement include only HCRIS data: (1) the end of the 30-day comment period if the Centers for Medicare & Medicaid Services (CMS) receives no written comments from the community; or (2) the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement (§411.362(c)(5)(i)).

- If the request, any written comments, or any rebuttal statement include data from an external data source, no later than: (1) 180 days after the end of the 30-day comment period if CMS receives no written comments from the community; and (2) 180 days after the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement (§411.362(c)(5)(ii)).

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 to exceed 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds (§411.362(c)(6)). The CMS decision to grant or deny a hospital's request for an exception to the prohibition on expansion of facility capacity must be published in the **Federal**

Register in accordance with our regulations at §411.362(c)(7).

III. Public Response to Notice with Comment Period

On July 28, 2016, we published a notice in the **Federal Register** (81 FR 49662) entitled “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”. In the notice, we stated that, as permitted by section 1877(i)(3) of the Act and our regulations at §411.362(c), the following physician-owned hospital requested an exception to the prohibition on expansion of facility capacity:

Name of Facility: Deaconess Women’s Hospital of Southern Indiana d/b/a The Women’s Hospital.

Address: 4199 Gateway Blvd., Newburgh, IN 47630.

County: Warrick County, Indiana.

Basis for Exception Request: High Medicaid Facility.

In the notice, we solicited comments from individuals and entities in the community in which The Women’s Hospital is located. During the 30-day public comment period, we received no public comments.

IV. Decision

This final notice announces our decision to approve The Women’s Hospital’s request for an exception to the prohibition against expansion of facility capacity. As required by the November 30, 2011 final rule (76 FR 74122) and our public guidance documents, The Women’s Hospital submitted the data and certifications necessary to demonstrate that it satisfies the criteria to qualify as a high Medicaid facility. Therefore in accordance with section 1877(i)(3) of

the Act, we are granting The Women's Hospital's request for an exception to the expansion of facility capacity prohibition based on the following criteria:

- The Women's Hospital is not the sole hospital in the county in which the hospital is located;
- With respect to each of the 3 most recent 12-month periods for which data are available as of the date the hospital submitted its request, The Women's Hospital had 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; and
- The Women's Hospital certified that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

Our decision grants The Women's Hospital's request to add a total of 75 operating rooms, procedure rooms, and beds. Pursuant to §411.362(c)(6), 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 Women's Hospital is licensed to exceed 200 percent of its baseline number of operating rooms, procedure rooms, and beds. The Women's Hospital certified that its baseline number of operating rooms, procedure rooms, and beds is 81. Accordingly, we find that granting an additional 75 operating rooms, procedure rooms, and beds will not exceed the limitation on a permitted expansion.

V. 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.).

CMS-1667-FN

Dated: October 3, 2016

Andrew M. Slavitt

Acting Administrator,

Centers for Medicare & Medicaid Services.

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