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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1640-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 from Doctors Hospital at Renaissance for an exception to the prohibition against expansion of facility capacity.

DATES: EFFECTIVE DATE: This notice is effective on September 11, 2015.

FOR FURTHER INFORMATION CONTACT:

Patricia Taft, (410) 786-4561 or Teresa Walden, (410) 786-3755.

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 hospital ownership and rural provider 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 an 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 a 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 specifies 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, 66987 through 66997) that made certain revisions. These revisions include, among other things, permitting the use of data from an external data source, as defined in our regulations, or from the Hospital Cost Report Information System (HCRIS) for specific eligibility criteria.

As stated in our regulations at §411.362(c)(5), we solicit community input on a request for an exception by publishing a notice of the request in the **Federal Register**. Individuals and entities have 30 days to submit written comments on the request, which 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 defined in §411.362(c)(2) and (c)(3), respectively. We notify the hospital of comments received, and the hospital has 30 days after such notice to submit a rebuttal statement (§411.362(c)(5)(ii)). Section 411.362(c)(5) also specifies the timing for when CMS deems a request for an exception to the facility expansion prohibition complete.

If we grant the request for an exception, 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)).

III. Public Response to Notice with Comment Period

On May 8, 2015, we published a notice in the **Federal Register** (80 FR 26566) 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 May 8, 2015 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:	Doctors Hospital at Renaissance (DHR)
Location:	5501 South McColl Road Edinburg, Texas 78539
Basis for Exception Request:	Applicable Hospital

In the May 8, 2015 notice, we also solicited comments from individuals and entities in the community in which DHR is located.

We received 21 comments, 14 of which were variations of a form letter, and commenters generally opposed DHR's request to expand.

One or more of the commenters raised questions or concerns regarding:

- Whether DHR's request conforms to the procedural requirements set forth at §411.362(c);

- Whether DHR demonstrated that it satisfied the population growth criterion using the data required under §411.362(c)(2)(i);
 - Whether the data source used by DHR to demonstrate satisfaction of the inpatient Medicaid admissions criterion at §411.362(c)(2)(ii) was permissible;
 - Whether DHR satisfied the non-discrimination criterion at §411.362(c)(2)(iii);
 - How a facility expansion by DHR would affect the community in which it is located;
- and
- The amount of increased facility capacity requested by DHR.

On June 16, 2015, as required by §411.362(c)(5)(ii), we notified DHR that we received comments in response to the May 8, 2015 notice and that these comments were available for public viewing at <http://www.regulations.gov>. DHR submitted a rebuttal statement on July 15, 2015. The statement rebutted each of the commenters' assertions regarding the applicable hospital eligibility criteria and addressed the concerns expressed by the commenters regarding an expansion by the hospital.

IV. Decision

This final notice announces our decision to approve DHR's request for an exception to the prohibition against expansion of facility capacity. As required by our current regulations and public guidance documents, DHR submitted the data and certifications necessary to demonstrate that it satisfies the criteria to qualify as an applicable hospital. Further, CMS considered the assertions of the commenters about DHR's compliance with the procedural requirements set forth at §411.362(c), the population growth criterion under §411.362(c)(2)(i), the data source used by DHR to demonstrate satisfaction of the inpatient Medicaid admissions criterion at §411.362(c)(2)(ii), and the non-discrimination criterion at §411.362(c)(2)(iii). Following our

review of the information provided by the commenters, we are not persuaded that DHR failed to satisfy one or more of the applicable hospital eligibility criteria or that its request failed to conform to our procedural requirements. Also, CMS cannot consider any concerns unrelated to the statutory and regulatory eligibility criteria when determining whether to grant an exception to a requesting hospital. In addition, if a hospital qualifies as either an applicable hospital or high Medicaid facility, CMS does not have the discretion to grant less than the requested increase in facility capacity.

In accordance with section 1877(i)(3) of the Act, we are granting DHR's request for an exception to the prohibition against expansion of facility capacity based on the following criteria:

- DHR is located in Hidalgo County, which has a percentage increase in population that is at least 150 percent of the percentage increase in Texas' population during the most recent 5-year period for which data was available as of the date that DHR submitted its request;
- DHR has an annual percentage of total inpatient admissions under Medicaid that is equal to or greater than the average percentage with respect to such admissions for all hospitals located in Hidalgo County during the most recent 12-month period for which data are available as of the date that DHR submitted its request;
- DHR certified and provided satisfactory documentation 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;
- DHR is located in Texas, which has an average bed capacity that is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submitted its request, contained data from a sufficient number of hospitals to determine Texas' average bed capacity and the national average bed capacity; and

- DHR has an average bed occupancy rate that is greater than the average bed occupancy rate in Texas during the most recent fiscal year for which HCRIS, as of the date that DHR submitted its request, contained data from a sufficient number of hospitals to determine its average bed occupancy rate and Texas' average bed occupancy rate.

In determining that DHR satisfied the Medicaid inpatient admissions, bed capacity and bed occupancy criteria, we deemed the HCRIS and Texas State Medicaid Agency data used by DHR to satisfy the standards set forth in the regulations published on November 10, 2014, for those criteria.

Our approval grants DHR's request to add a total of 551 operating rooms, procedure rooms, and beds for which DHR is licensed. 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 hospital is licensed to exceed 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds. DHR certified that its baseline number of operating rooms, procedure rooms, and beds for which it was licensed as of March 23, 2010, was 551. Accordingly, we find that granting the additional 551 operating rooms, procedure rooms, and beds will not exceed the limitation on a permitted expansion.

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.).

CMS-1642-FN

Dated: September 4, 2015.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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