

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.*).

Dated: October 3, 2016.

**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-1661-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 for Rockwall Regional Hospital, Limited Liability Company Doing Business as (d/b/a) Texas Health Presbyterian Hospital Rockwall

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

**ACTION:** Final notice.

**SUMMARY:** This final notice announces our decision to approve the request of Rockwall Regional Hospital, Limited Liability Company (LLC) doing business as (d/b/a) Texas Health Presbyterian Hospital Rockwall (Texas Health Rockwall) for an exception to the prohibition on expansion of facility capacity.

**DATES:** Effective Date: This notice is effective on October 28, 2016.

**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 February 2, 2016, we published a notice in the **Federal Register** (81 FR 5463) 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:* Rockwall Regional Hospital, LLC, d/b/a Texas Health Presbyterian Hospital Rockwall.

*Address:* 3150 Horizon Road, Rockwall County, Texas 75032-7805.

*County:* Rockwall County, Texas

*Basis for Exception Request:*

Applicable Hospital.

In the notice, we solicited comments from individuals and entities in the community in which Texas Health Rockwall is located. We received 43 comments during the 30-day public comment period. Forty-two comments were in favor of the request and one was in opposition.

The commenter that opposed the expansion request asserted that Texas Health Rockwall did not meet the inpatient Medicaid admissions criterion at § 411.362(c)(2)(ii). The commenter expressed concern that the HCRIS, the data source used by Texas Health Rockwall to demonstrate satisfaction of the inpatient Medicaid admissions criterion, does not accurately reflect all Medicaid admissions and discharges. The commenter expressed its belief that information from a different source, the Texas Health Care Information Collection (THCIC), does not indicate that Texas Health Rockwall's satisfied the inpatient Medicaid admissions criterion.

On April 13, 2016, Texas Health Rockwall submitted a rebuttal statement in response to the comment opposing its request. The statement satisfactorily rebutted the commenters' assertions regarding the inpatient Medicaid admissions criterion and addressed the concerns expressed by the commenter regarding HCRIS and THCIC data.

### IV. Decision

This final notice announces our decision to approve Texas Health Rockwall'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, Texas Health Rockwall submitted the data and certifications necessary to demonstrate that it satisfies the criteria to qualify as an applicable hospital. In accordance with section 1877(i)(3) of the Act, we are granting Texas Health Rockwall's request for an exception to the expansion of facility capacity prohibition based on the following criteria:

- Texas Health Rockwall is located in a county that had a percentage increase in population that is at least 150 percent

of the percentage increase in population of the State in which the hospital is located during the most recent 5-year period for which data are available as of the date that the hospital submitted its request;

- Texas Health Rockwall had an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located during the most recent fiscal year for which data are available as of the date that the hospital submitted its request;

- Texas Health Rockwall 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;

- Texas Health Rockwall is located in a State in which the average bed capacity in the State was less than the national average bed capacity during the most recent fiscal year for which data are available as of the date that the hospital submitted its request; and

- Texas Health Rockwall had an average bed occupancy rate that was greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which data are available as of the date that the hospital submitted its request.

Our decision grants Texas Health Rockwall's request to add a total of 60 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 Texas Health Rockwall is licensed to exceed 200 percent of its baseline number of operating rooms, procedure rooms, and beds. Texas Health Rockwall certified that its baseline number of operating rooms, procedure rooms, and beds is 60. Accordingly, we find that granting an additional 60 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.*).

Dated: October 3, 2016.

**Andrew M. Slavitt,**

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

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2016-N-3330]

#### **Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of Zika Virus; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of four Emergency Use Authorizations (EUAs) (the Authorizations) for four in vitro diagnostic devices for detection and/or diagnosis of Zika virus in response to the Zika virus outbreak in the Americas. FDA issued these Authorizations under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Siemens Healthcare Diagnostics, Inc., Luminex Corporation, InBios International, Inc., and Roche Molecular Systems, Inc. The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostic devices. The Authorizations follow the February 26, 2016, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under the FD&C Act. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

**DATES:** The Authorization for Siemens Healthcare Diagnostics, Inc., is effective as of July 29, 2016; the Authorization for Luminex Corporation is effective as of August 4, 2016; the Authorization for InBios International, Inc., is effective as of August 17, 2016; and the

Authorization for Roche Molecular Systems, Inc., is effective as of August 26, 2016.

**ADDRESSES:** Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

**FOR FURTHER INFORMATION CONTACT:** Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4336, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll-free number).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of

attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA<sup>1</sup> concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing,

<sup>1</sup> The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.