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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1721-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 St. James Behavioral Health Hospital Inc for an exception to the prohibition on expansion of facility capacity.

APPLICABLE DATES: This notice is effective on February 11, 2019.

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 our regulations at 42 CFR 411.362(c)(2) and (3)) 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, 74517-74525) 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.

Our regulations at § 411.362(c)(5) require us to 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 74122), 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 CMS grants 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 October 24, 2018, we published a notice in the **Federal Register** (83 FR 53634) 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: St. James Behavioral Health Hospital Inc.

Address: 3136 S Saint Landry Ave., Gonzales, Louisiana 70737–5801.

County: Ascension Parish.

Basis for Exception Request: High Medicaid Facility.

In the notice, we solicited comments from individuals and entities in the community in which St. James Behavioral Health Hospital Inc is located. During the 30-day public comment period, we received one comment. However, the comment was out of scope because it expressed only general views regarding the expansion exception process and was not community input on St. James Behavioral Health Hospital Inc’s exception request.

IV. Decision

This final notice announces our decision to approve St. James Behavioral Health Hospital Inc’s request for an exception to the prohibition against expansion of facility capacity. St. James Behavioral Health Hospital Inc submitted the data and certifications necessary to demonstrate that it satisfies the criteria to qualify as a high Medicaid facility as specified in the November 30, 2011 final rule. In accordance with section 1877(i)(3) of the Act, we are granting St. James Behavioral Health Hospital Inc’s request for an exception to the expansion of facility capacity prohibition based on the following criteria:

- St. James Behavioral Health Hospital Inc 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, St. James Behavioral Health Hospital Inc 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

- St. James Behavioral Health Hospital Inc 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 St. James Behavioral Health Hospital Inc’s request to add a total of 28 operating rooms, procedure rooms, and beds. Under § 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 St. James Behavioral Health Hospital Inc is licensed to exceed 200 percent of its baseline number of operating rooms, procedure rooms, and beds. St. James Behavioral Health Hospital Inc certified that its baseline number of operating rooms, procedure rooms, and beds is 28. Accordingly, we find that granting an additional 28 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: January 31, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–E–5052 and FDA–2017–E–5054]

Determination of Regulatory Review Period for Purposes of Patent Extension; EXONDYS 51

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for EXONDYS 51 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by April 12, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 12, 2019. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 12, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 12, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.