

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (October through December 2021)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASBMS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (October through December 2021)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1774-PN]

Medicare Program: Announcement of Request for an Exception to the Prohibition on Expansion of Facility Capacity Under the Hospital Ownership and the Rural Provider Exceptions to the Physician Self-Referral Prohibition

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

ACTION: Notice with request for comment.

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 grants the hospital's request for an exception to that prohibition after considering input on the request from individuals and entities in the community where the hospital is located. The Centers for Medicare & Medicaid Services has received a request from a physician-

owned hospital for an exception to the prohibition on expansion of facility capacity. This notice solicits comments on the request from individuals and entities in the community in which the hospital is located. Community input may inform our determination regarding whether the requesting hospital qualifies for an exception to the prohibition on expansion of facility capacity.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by March 11, 2022.

ADDRESSES: In commenting, refer to file code CMS-1774-PN.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
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-1774-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: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1774-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: *POH-ExceptionRequests@cms.hhs.gov*.

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 website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique

individuals or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique

commenters even if the content is identical or nearly identical to other comments.

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 payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship 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 any improperly referred designated health services. A financial relationship may be an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

Section 1877(d) of the Act sets forth exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers (the “rural provider exception”). In order to qualify for the rural provider exception, the designated health services must be furnished in a rural area (as defined in section 1886(d)(2) of the Act) and substantially all the designated health services furnished by the entity must be furnished to individuals residing in a rural area, and, in the case where the entity is a hospital, the hospital must meet the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. Section 1877(d)(3) of the Act provides an exception for ownership or investment interests in a hospital located outside of Puerto Rico (the “whole hospital exception”). In order to qualify for the whole hospital exception, the referring physician must be authorized to perform services at the hospital, the ownership or investment interest must be in the hospital itself (and not merely in a subdivision of the hospital), and the hospital must meet the requirements of section 1877(i)(1) of the Act no later than September 23, 2011.

II. Prohibition on Facility Expansion

Section 6001(a)(3) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148) amended the rural provider and whole hospital exceptions to provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the effective date of such provider agreement) (the hospital’s “baseline number of operating rooms, procedure rooms, and beds”). Thus, since March 23, 2010, a physician-owned hospital that seeks to avail itself of either exception is prohibited from expanding the number of operating rooms, procedure rooms, and beds (“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.

Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act, which required the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity for hospitals that qualify as an “applicable hospital.” Section 1106 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) amended section 1877(i)(3)(A)(i) of the Act to require the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity for hospitals that qualify as either an “applicable hospital” or a “high Medicaid facility.” These terms are defined at sections 1877(i)(3)(E) and 1877(i)(3)(F) of the Act. The process for requesting an exception to the prohibition on expansion of facility capacity is discussed in section III of this notice.

The requirements for qualifying as an applicable hospital are set forth at § 411.362(c)(2), and the requirements for qualifying as a high Medicaid facility are set forth at § 411.362(c)(3). An applicable hospital means a hospital: (1) That is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity) is at least 150 percent of the percentage increase in the population growth of the State in which the

hospital is located during that period, as estimated by the Bureau of the Census; (2) whose annual percent of total inpatient admissions under Medicaid is equal to or greater than the average percent with respect to such admissions for all hospitals in the county in which the hospital is located during the most recent 12-month period for which data are available (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity); (3) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries; (4) that is located in a State in which the average bed capacity in the State is less than the national average bed capacity; and (5) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located. The regulations at § 411.362(c)(2)(ii), (iv), and (v) specify acceptable data sources for determining whether a hospital qualifies as an applicable hospital. A “high Medicaid facility” means a hospital that: (1) Is not the sole hospital in a county; (2) with respect to each of the three most recent 12-month periods for which data are available, 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; and (3) does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. The regulation at § 411.362(c)(3)(ii) specifies the acceptable data sources for determining whether a hospital qualifies as a high Medicaid facility.

III. Exception Request Process

In the Calendar Year (CY) 2012 Outpatient Prospective Payment System/Ambulatory Surgical Centers (OPPS/ASC) final rule (76 FR 74121), we published regulations establishing the process for a hospital to request an exception from the prohibition on facility expansion (the “exception process”) at § 411.362(c)(4), community input related to a hospital’s request at § 411.362(c)(5), and related definitions at § 411.362(a). In the CY 2021 OPPS/ASC final rule (85 FR 85866), we revised the regulations that set forth the exception process with respect to high Medicaid facilities to remove certain regulatory restrictions that are not included in the Act. As of January 1,

2021, a high Medicaid facility may request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years; may request to expand its facility capacity beyond 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and is not restricted to locating approved expansion capacity on the hospital's main campus.

Section 1877(i)(3)(A)(ii) of the Act and our regulations at § 411.362(c)(5) provide 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 application for the exception. For further information, we refer readers to the CMS website at: http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician-Owned_Hospitals.html. As stated in our regulations, 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 CY 2012 OPPI/ASC final rule, 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 (76 FR 74522). 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)).

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 filed Medicare hospital cost report data (Healthcare Cost Report Information System ("HCRIS") data): (1) The end of the 30-day comment period if 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

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 hospital submitting the request submits a rebuttal statement (§ 411.362(c)(5)(ii)).

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).

IV. 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: Doctors Hospital at Renaissance, Ltd.

Location: 5501 South McColl Road, Edinburg, Texas 78539

Basis for this 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 website at: 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.

Individuals and entities wishing to submit comments on the hospital's request should state whether or not they are in the community in which the hospital is located. We suggest that parties review the **DATES** and **ADDRESSES** sections above to ensure timely submission of their comments.

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.*).

VI. Response to Comments

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

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: February 4, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3404]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by March 11, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0727. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD