DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1758-FN]

Medicare Program: Approval 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 Solutions Medical Consulting, LLC d/b/a Serenity Springs Hospital for an exception to the prohibition on expansion of facility capacity.

DATES: This decision is applicable beginning [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

POH-ExceptionRequests@cms.hhs.gov.

Joi Hosley, (410) 786-2194.

Patricia Taft, (410) 786-4561.

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 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 meets 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 meets the requirements of section 1877(i)(1) of the Act no later than September 23, 2011.

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. 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.

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 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)).

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, under the regulations in place at the time the request was filed, 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)).\(^{1}\) The CMS decision to grant or deny a hospital’s request for an exception to

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\(^{1}\) When approving an expansion exception request, we are required to follow the regulations in effect as of the date the request is filed. The regulations at 42 CFR 411.362(c)(6) were modified effective January 1, 2021 (85 FR 85866; https://www.federalregister.gov/documents/2020/12/29/2020-26819/medicare-program-hospital-outpatient-
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 December 11, 2020, we published a notice in the Federal Register (85 FR 80111) 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 December 2020 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: Solutions Medical Consulting, LLC d/b/a Serenity Springs Hospital
Location: 1495 Frazier Road, Ruston, Louisiana 71270–1632
Basis for Exception Request: High Medicaid Facility

In the December 2020 notice, we solicited comments from individuals and entities in the community in which Solutions Medical Consulting, LLC d/b/a Serenity Springs 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 Solutions Medical Consulting, LLC d/b/a Serenity Springs Hospital’s request for an exception to the prohibition against expansion of facility capacity. Solutions Medical Consulting, LLC d/b/a Serenity Springs Hospital 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 Solutions Medical Consulting, LLC d/b/a Serenity Springs Hospital’s request for an exception to the expansion of facility capacity prohibition based on the following criteria:

- Solutions Medical Consulting, LLC d/b/a Serenity Springs Hospital is not the sole prospective-payment-and-ambulatory-surgical-center-payment.
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, Solutions Medical Consulting, LLC d/b/a Serenity Springs 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

- Solutions Medical Consulting, LLC d/b/a Serenity Springs 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 Solutions Medical Consulting, LLC d/b/a Serenity Springs Hospital’s request to add a total of 18 operating rooms, procedure rooms, and beds. Under the regulations in place at the time the request was filed, 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 Solutions Medical Consulting, LLC d/b/a Serenity Springs Hospital is licensed to exceed 200 percent of its baseline number of operating rooms, procedure rooms, and beds. Solutions Medical Consulting, LLC d/b/a Serenity Springs Hospital certified that its baseline number of operating rooms, procedure rooms, and beds is 18. Accordingly, we find that granting an additional 18 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.).

The Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), Elizabeth Richter, 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: March 8, 2021.

Lynette Wilson,

Federal Register Liaison,

Department of Health and Human Services.

[FR Doc. 2021-05095 Filed: 3/10/2021 8:45 am; Publication Date: 3/11/2021]