DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1642–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 Harsha Behavioral Center, Incorporation (HBC) 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.
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 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 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 to the expansion exception process. Because the Centers for Medicare & Medicaid Services (CMS) formally accepted this request prior to the effective date of that rule, CMS is reviewing and processing the request in accordance with the regulations that were published on November 30, 2011 and which were in effect at the time of submission.

In the November 30, 2011 final rule, we specified that prior to our review of the request, we will solicit community input on the request by publishing a notice of the request in the **Federal Register** (§ 411.362(c)(5)). We also stated that individuals and entities in the hospital's community have 30 days to submit comments on the request. If we receive timely comments from the community, we will notify the hospital, 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 specfies that a request for an exception to the facility expansion prohibition is considered complete if no comments from the community are received by the close of the 30-day comment period. If we receive timely comments from the community, we consider the request to be complete 30 days after the hospital is notified of the comments.

If we grant the request for an exception to the prohibition against 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)).

III. Public Response to Notice With Comment Period

On June 19, 2015, we published a notice in the **Federal Register** (80 FR 35363) 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 June 19, 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: Harsha Behavioral Center, Inc. (HBC).

Address: 1420 East Crossing Boulevard, Terre Haute, Indiana 47802.

County: Vigo County, Indiana.

Basis for Exception Request: High Medicaid Facility.

In the June 19, 2015 notice, we also solicited comments from individuals and entities in the community in which HBC is located. We received no comments during the 30-day public comment period. Accordingly, CMS deemed the request complete on July 20, 2015, the end date of the public comment period.

IV. Decision

This final notice announces our decision to approve HBC's request for

an exception to the prohibition against expansion of facility capacity. As required by the November 30, 2011final rule and our public guidance documents, HBC submitted the data and certifications necessary to demonstrate that it satisfies the criteria to qualify as a high Medicaid facility. In accordance with section 1877(i)(3) of the Act, we have granted HBC's request for an exception to the expansion of facility capacity prohibition based on the following criteria:

• HBC is not the sole hospital in Vigo, Indiana, the county in which it is located;

• HBC 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; and

• With respect to each of the 3 most recent fiscal years for which data were available as of the date HBC submitted its request, it has an annual percentage of total inpatient admissions under Medicaid that is estimated to be greater than such percentage with respect to such admissions for any other hospital located in Vigo County, Indiana, the county in which it is located.

Our approval grants HBC's request to add a total of 44 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 HBC is licensed to exceed 200 percent of its baseline number of operating rooms, procedure rooms, and beds. HBC certified that its baseline number of operating rooms, procedure rooms, and beds is 44. Accordingly, we find that granting an additional 44 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.*).

Dated: August 18, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–22856 Filed 9–9–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1156]

International Conference on Harmonisation; Guidance on Q3D Elemental Impurities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q3D Elemental Impurities.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance establishes permitted daily exposures for 24 elements in drug products based on evaluation of toxicity data. Permitted daily exposures are provided for each element by three routes of administration—oral, parenteral and inhalation. The guidance also provides for a risk-based approach to assessing the likelihood that elemental impurities with established permitted daily exposures will be present in a pharmaceutical product. The guidance is intended to provide a harmonized approach to control of elemental impurities in pharmaceutical products in order to avoid the uncertainty and duplication of work that results from different requirements in different ICH regions.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* John Kauffman, Center for Drug Evaluation and Research, Food and Drug Administration, 645 S. Newstead Ave., St. Louis, MO 63110, 314–539–2168;

Regarding the ICH: Michelle Limoli, CBER International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7212, Silver Spring, MD 20993–0002, 301–796–8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.