implements a corrective action plan to bring its procedures to process eligibility determinations under its Medicaid program into compliance with the federal requirements.

The state has 30 days from the date of this letter to request a hearing. As specified in the accompanying **Federal Register** notice, the Arkansas DHS has an opportunity for an administrative hearing prior to this determination becoming final. However, the Arkansas DHS must request a hearing. If a request for a hearing is submitted timely, the hearing will be convened by the Hearing Officer designated below no later than 60 days after the date of the **Federal Register** notice, or a later date by agreement of the parties and the Hearing Officer, at the CMS Regional Office in Dallas, Texas, in accordance with the procedures set forth in federal regulations at 42 CFR part 430, subpart D. The issue in any such hearing will be whether benefits are being provided during a reasonable opportunity period to individuals who have declared under penalty of perjury that they are in a to a satisfactory immigration status pending verification of such status, if they meet all other eligibility requirements, in accordance with the state plan and 42 CFR 435.911(c). Any request for such a hearing should be sent to the designated Hearing Officer. The Hearing Officer also should be notified if the Arkansas DHS requests a hearing but cannot meet the timeframe expressed in this notice. The Hearing Officer designated for this matter is: Benjamin R. Cohen, Hearing Officer, Centers for Medicare & Medicaid Services, 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244.

If the Arkansas DHS plans to come into compliance with the approved state plan, the Arkansas DHS should submit, within 30 days of the date of this letter, an explanation of how the Arkansas DHS plans to come into compliance with federal requirements and the timeframe for doing so. If that explanation is satisfactory, CMS may consider postponing any requested hearing, which could also delay the imposition of the withholding of funds as described above. Our goal is to have the Arkansas DHS come into compliance, and CMS continues to be available to provide technical assistance to the Arkansas DHS in achieving this outcome.

Should you not request a hearing within 30 days, a notice of withholding will be sent to you and the withholding of federal funds will begin as described above.

If you have any questions or wish to discuss this determination further, please contact: Bill Brooks, Associate Regional Administrator, Division of Medicaid and Children's Health Operations, CMS Dallas Regional Office, 1301 Young Street, Suite 714, Dallas, TX 75202, 214–767–4461.

Sincerely,
Andrew M. Slavitt
Acting Administrator

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program.)

Dated: July 22, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–17923 Filed 7–27–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1667–PN]

Medicare Program; 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: Proposed notice.

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 (the Secretary) grants the hospital's request for an exception to that prohibition after considering input on the hospital's request from individuals and entities in the community where the hospital is located. The Centers for Medicare & Medicaid Services (CMS) has received a request from a physician-owned hospital for an exception to the prohibition against expansion of facility capacity. This notice solicits comments on the request from individuals and entities in the community in which the physician-owned hospital is located. Community input may inform our determination regarding whether the requesting hospital qualifies for an exception to the prohibition against expansion of facility capacity.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 29, 2016.

ADDRESSES: In commenting, please refer to file code CMS–1667–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this exception request to *http://www.regulations.gov*. Follow the instructions under the ''More Search Options'' tab.

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–1667–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: Department of Health and Human Services, Attention: CMS–1667–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 Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

We will allow stakeholders 30 days from the date of this notice to submit written comments. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of this notice, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please phone 1–800–743–3951.

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 for physician ownership or investment interests in rural providers (the ''rural provider exception''). 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) 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 and rural providers. 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 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 application for the exception. For further information, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html*.

II. Exception Request 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 included, 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)).

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 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. 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: Deaconess Women's Hospital of Southern Indiana d/b/a The Women's Hospital.

Location: 4199 Gateway Blvd., Newburgh, IN 47630.

Basis for 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 Web site 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. Under § 411.362(c)(3), a high Medicaid facility is a hospital that satisfies all of the following criteria:

- 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 submits its request, 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.

• Does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

Individuals and entities wishing to submit comments on the hospital's request should review the **DATES** and **ADDRESSES** sections and state whether or not they are in the community in which the hospital is located.

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.*).

V. Response to Public Comments

We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: July 14, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–17928 Filed 7–27–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2017 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Drug User Fee Amendments of 2013 (ADUFA III), authorizes FDA to collect user fees for certain animal drug applications and supplements, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2017.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6888. For general questions, you may also email the Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12) establishes four different types of user fees: (1) Fees for certain types of animal drug applications and supplements; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j–12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts established for years after FY 2014 are subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)). Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: Revenue from application fees shall be 20 percent of total fee revenue; revenue from product fees shall be 27 percent of total fee revenue; revenue from establishment fees shall be 26 percent of total fee revenue; and revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j–12(b)(2)).

For FY 2017, the animal drug user fee rates are: $350,700 for an animal drug application; $175,350 for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $8,195 for an annual product fee; $111,900 for an annual establishment fee; and $103,100 for an annual sponsor fee. FDA will issue invoices for FY 2017 product, establishment, and sponsor fees by December 31, 2016, and payment will be due by January 31, 2017. The application fee rates are effective for applications submitted on or after October 1, 2016, and will remain in effect through September 30, 2017. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the Animal Drug User Fee program (ADUFA program).

II. Revenue Amount for FY 2017

A. Statutory Fee Revenue Amounts

ADUFA III, Title I of Public Law 113–14, specifies that the aggregate fee revenue amount for FY 2017 for all animal drug user fee categories is $21,600,000 (21 U.S.C. 379j–12(b)(1)(B).).

B. Inflation Adjustment to Fee Revenue Amount

The fee revenue amount established in ADUFA III for FY 2015 and subsequent fiscal years are subject to an inflation adjustment (21 U.S.C. 379j–12(c)(2)).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first three of the four preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs for the first three of the four preceding fiscal years (see 21 U.S.C. 379j–12(c)(2)(A) and (B)). The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes that actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first three of the four fiscal years preceding FY 2017. The 3-year average is 1.8759 percent.