managed care or fee-for-service. Data produced as part of the MCBS are enhanced with our administrative data (*e.g.* fee-for-service claims, prescription drug event data, enrollment, etc.) to provide users with more accurate and complete estimates of total health care costs and utilization. The MCBS has been continuously fielded for more than 20 years (encompassing over 1 million interviews), and consists of three annual interviews per survey participant.

The MCBS continues to provide unique insight into the Medicare program and helps CMS and our external stakeholders better understand and evaluate the impact of existing programs and significant new policy initiatives. In the past, MCBS data have been used to assess potential changes to the Medicare program. For example, the MCBS was instrumental in supporting the development and implementation of the Medicare prescription drug benefit by providing a means to evaluate prescription drug costs and out-of-pocket burden for these drugs to Medicare beneficiaries. The revision will streamline some questionnaire sections, add a few new measures, and update the wording of questions and response categories. Most of the revised questions reflect an effort to bring the MCBS questionnaire in line with other national surveys that have more current wording of questions and response categories with well-established measures. As a whole, these revisions do not change the respondent burden; there is a small increase in overall burden reflecting a program change to oversample small population groups. *Form Number:* CMS–P–0015A (OMB control number: 0938–0568); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 16,071; *Total Annual Responses:* 43,199; *Total Annual Hours:* 60,103. (For policy questions regarding this collection contact William Long at 410–786–7927.)

Dated: April 26, 2016.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2016–10084 Filed 4–28–16; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–3329–FN]**

### Medicare and Medicaid Programs; Approval of the Institute for Medical Quality's Ambulatory Surgical Center Accreditation Program

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Final notice.

**SUMMARY:** This final notice announces our decision to approve the Institute for Medical Quality (IMQ) for recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that wish to participate in the Medicare or Medicaid programs. An ASC that participates in Medicaid must also meet the Medicare conditions for coverage (CfCs) as required under our regulations.

**DATES:** This final notice is effective April 29, 2016 through April 29 2020.

**FOR FURTHER INFORMATION CONTACT:** Lillian Williams, (410) 786–8636. Monda Shaver, (410) 786–3410. Patricia Chmielewski, (410) 786–6899.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an Ambulatory Surgical Center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as an ASC. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 416 specify the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for ASCs.

Generally, to enter into a Medicare provider agreement, an ASC must first be certified as complying with the conditions set forth in part 416 and be recommended to the Centers for Medicare & Medicaid Services (CMS) for participation by a state survey agency. Thereafter, the ASC is subject to periodic surveys by a state survey agency to determine whether it continues to meet these conditions. However, there is an alternative to certification surveys by state agencies. Accreditation by a nationally recognized Medicare accreditation program approved by CMS may substitute for both initial and ongoing state review.

Section 1865(a)(1) of the Act provides that if the Secretary of the Department of Health and Human Services finds that accreditation of a provider entity by an approved national accrediting organization meets or exceeds all applicable Medicare conditions, we may treat the provider entity as having met those conditions, that is, we may ''deem'' the provider entity to be in compliance. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

Part 488 subpart A, implements the provisions of section 1865 of the Act and requires that a national accrediting organization applying for approval of its Medicare accreditation program must provide CMS with reasonable assurance that the accrediting organization requires its accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.5.

## II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

## III. Provisions of the Proposed Notice

In the December 04, 2015 **Federal Register** (80 FR 75866), we published a proposed notice announcing the Institute for Medical Quality's (IMQ's) request for initial approval of its Medicare ASC accreditation program. In the December 04, 2015 proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of IMQ's Medicare ASC accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

• An onsite administrative review of IMQ's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its ASC surveyors; (4) ability to investigate and respond appropriately to complaints against accredited ASCs; and (5) survey review and decision-making process for accreditation.

• The comparison of IMQ's Medicare ASC accreditation program standards to CMS' current Medicare ASC conditions for coverage (CfCs).

• A documentation review of ASC's survey process to:

++ Determine the composition of the survey team, surveyor qualifications, and IMQ's ability to provide continuing surveyor training.

++ Compare IMQ's processes to those we require of state survey agencies, including survey frequency and the ability to investigate and respond appropriately to complaints against accredited ASCs.

++ Evaluate IMQ's processes and procedures for monitoring ASCs it has found to be out of compliance with IMQ's program requirements. (This pertains only to monitoring procedures when IMQ identifies non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.9(c).)

++ Assess IMQ's ability to report deficiencies to the surveyed ASC and respond to the ASCs plan of correction in a timely manner.

++ Establish IMQ's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of IMQ's staff and other resources, and its financial viability.

++ Confirm IMQ's ability to provide adequate funding for performing required surveys.

++ Confirm IMQ's policies with respect to surveys being unannounced, to assure that surveys are unannounced.

++ Obtain IMQ's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the December 04, 2015 proposed notice also solicited public comments regarding whether IMQ's requirements met or exceeded the Medicare CfCs for ASCs. We received 10 comments in response to our proposed notice. All of the comments received expressed unanimous support for IMQ's ASC accreditation program.

## IV. Provisions of the Final Notice

### *A. Differences Between IMQ's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements*

We compared IMQ's ASC accreditation requirements and survey process with the Medicare CfCs of part 416, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of IMQ's ASC application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, IMQ has revised its standards and certification processes to meet the requirements at:

• § 416.2, to ensure its Medicare ASC accreditation program applies to a single distinct entity and that each entity independently meets all of the requirements at part 416.

• § 416.41, to ensure the governing body assumes full legal responsibility of the ASC.

• § 416.41(a), to ensure all contracted services are provided in a safe and effective manner.

• § 416.41(b)(1) through (2), to ensure the ASC has an effective procedure for immediate transfer, to a local hospital, of patients requiring emergency medical care.

• § 416.41(b)(3)(ii), to remove chiropractors from its list of professionals that perform surgical procedures.

• § 416.41(c)(1) through (2), to address the ASCs responsibility to coordinate its emergency preparedness plan with state and local authorities.

• § 416.42, to ensure the ASC is responsible for performing its own complete process for granting privileges through the governing body.

• § 416.42(a)(1), to ensure all procedures performed in the ASC are documented in the patients' medical record and that a physician examine the patient before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

• § 416.42(a)(2), to ensure that before discharge from the ASC, a physician or anesthetist as defined at § 410.69(b) evaluates the patient for proper anesthesia recovery.

• § 416.44, to ensure ASCs have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

• § 416.44(a)(2), to ensure ASCs have a separate recovery room and waiting area.

• § 416.44(b)(1), to ensure ASCs meets the provisions applicable to the Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association.

• § 416.44(b)(2), to address the regulatory requirement where CMS may waive, for periods deemed appropriate, specific provisions of the LSC which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

• § 416.44(b)(4), to ensure the ASC is in compliance with the Emergency Lighting Chapter 21.2.9.1 of the LSC.

• § 416.44(c), to address the requirement for emergency equipment to be immediately available for use during emergency situations and for emergency equipment to be maintained by appropriate personnel.

• § 416.44(d), to ensure personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation are available whenever there is a patient in the ASC.

• § 416.45(a), to ensure all members of the medical staff are legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted.

• § 416.46(a), to ensure patient care responsibilities are delineated for all nursing service personnel, that nursing services are provided in accordance with recognized standards of practice, and that there is a registered nurse available for emergency treatment whenever there is a patient in the ASC.

• § 416.47, to ensure the ASC maintains complete, comprehensive and accurate medical records to ensure adequate patient care.

• § 416.47(b)(1) through (8), to ensure patient medical records meet CMS standards.

• § 416.48, to address the ASCs responsibility to provide drugs and biologicals in accordance with accepted professional practice.

• § 416.48(a)(2), to ensure blood and blood products are administered by only physicians or registered nurses.

• § 416.48(a)(3), to require all verbal orders for drugs and biologicals are followed by a written order and signed by the prescribing physician.

• § 416.50, to address the ASC's responsibility to inform the patient or the patient's representative or surrogate of the patient's rights and to provide notice of the patients' rights prior to the start of the surgical procedure.

• § 416.50(c)(1), to address providing the patient or the patient's representative with written information

concerning its policies on advance directives.

- § 416.50(c)(2), to ensure the patient or the patient's representative is informed of the right to make informed decisions regarding the patient's care.
- § 416.50(f)(3), to ensure the patient has the right to be free from all forms of abuse or harassment.
- § 416.51(b)(3), to provide a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.
- § 416.52(a)(1), to ensure each patient receives a comprehensive medical history and physical not more than 30 calendar days before the date of the scheduled surgery.
- § 416.52(c)(1), to address the ASCs responsibility to provide overnight supplies when discharged from the ASC.
- § 416.52(c)(2), to ensure each patient has a discharge order, signed by a physician who performed the surgery or procedure in accordance with applicable state health and safety laws, standards of practice, and ASC policy.
- § 416.52(c)(3), to ensure all patients are discharged in the company of a responsible adult unless exempted by the attending physician.
- § 488.5(a)(4)(ii), to ensure IMQ's surveyors observe at least one surgical procedure during an onsite ASC survey.
- § 488.5(a)(4)(iv), to ensure each statement of deficiency contains a clear, detailed description of the deficient practice and relevant findings that includes the use of numerators and denominators, when applicable, as well as a regulatory reference based on the relevant Medicare requirement.
- § 488.5(a)(9), to ensure IMQ's evaluation system used to monitor the performance of its surveyors meets the Medicare requirements.
- § 488.5(a)(12), to ensure IMQ's policies for responding to and investigating complaints against accredited facilities meets the Medicare requirements.
- § 489.13(b), to ensure IMQ does not provide an effective date of accreditation until the facility meets all applicable federal requirements, this includes both the Medicare requirements and IMQ standards.
- § 488.20(b) and § 488.28(a), to ensure that IMQ has a policy regarding our requirements for submission of a plan of correction by the ASC and the completion of an onsite follow-up survey to determine compliance with the Medicare CfCs after citing condition level noncompliance during a recertification survey.
- Section 2005A of the State Operations Manual (SOM), to ensure that IMQ has a policy regarding condition level noncompliance identified during an initial accreditation survey for participation in Medicare.
- Section 2700 of the SOM, to ensure all Medicare surveys are conducted on an unannounced basis.
- Section 2728 of the SOM, to ensure policies regarding timeframes for sending and receiving a plan of correction meets the Medicare requirements.

*B. Term of Approval*

Based on our review and observations described in section III of this final notice, we approve IMQ as a national accreditation organization for ASCs that request participation in the Medicare program, effective April 29, 2016 through April 29, 2020.

## V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: April 13, 2016.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2016–10165 Filed 4–28–16; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–1050]**

### Recommendations on the Regulation of Combination Drug Medicated Feeds; Availability; Reopening of Comment Period; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; reopening of comment period; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or we) is reopening the comment period and requesting public input on possible modifications to the current review processes for new animal drug applications (NADAs) for the use of multiple new animal drugs in combination drug medicated feeds. We are also announcing the availability of a Center for Veterinary Medicine (CVM) recommendations document for the animal drug user fee negotiating committee.

**DATES:** Submit either electronic or written comments by July 29, 2016.

**ADDRESSES:** You may submit comments as follows:

**Electronic Submissions**

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

**Written/Paper Submissions**

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2014–N–1050 for ''Regulation of Combination Drug Medicated Feeds.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.