

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden response (hours)
Mothers	Eligibility Form	750	1	5/60
	Mother Enrollment Survey	550	1	2
	Ages and Stages Questionnaire (2,6,9,12 months)	500	4	15/60
	Mullen Scales of Early Learning	500	1	20/60
	Postpartum Survey (2 months)	500	1	1
	Post-partum Survey (6, 9, 12 months)	500	3	15/60
	Food Frequency Questionnaire/WIC Intake Form	500	1	45/60
	Home Environmental Assessment	550	1	1
Fathers	Father Enrollment Survey	550	1	90/60

Leroy A. Richardson,

Chief, Information Collection Review Office,
Office of Scientific Integrity, Office of the
Associate Director for Science, Office of the
Director, Centers for Disease Control and
Prevention.

[FR Doc. 2015-30595 Filed 12-3-15; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3329-PN]

Medicare and Medicaid Programs: Application From the Institute for Medical Quality for Initial CMS- Approval of Its Ambulatory Surgical Center Accreditation Program

AGENCY: Centers for Medicare and
Medicaid Services, HHS.

ACTION: Notice with request for
comment.

SUMMARY: This proposed notice
acknowledges the receipt of an
application from the Institute for
Medical Quality (IMQ) for recognition
as a national accrediting organization
(NAO) for Ambulatory Surgical Centers
(ASCs) that wish to participate in the
Medicare or Medicaid programs.

DATES: To be assured consideration,
comments must be received at one of
the addresses provided below, no later
than 5 p.m. on January 4, 2016.

ADDRESSES: In commenting, please refer
to file code CMS-3329-PN. Because of
staff and resource limitations, we cannot
accept comments by facsimile (FAX)
transmission.

You may submit comments in one of
four 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-3329-PN, P.O. Box 8010,
Baltimore, MD 21244-8010.

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-3329-PN,
Mail Stop C4-26-05, 7500 Security
Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively,
you may deliver (by hand or courier)
your written ONLY to the following
addresses:

a. For delivery in Washington, DC—
Centers for Medicare & Medicaid
Services, Department of Health and
Human Services, Room 445-G, Hubert
H. Humphrey Building, 200
Independence Avenue SW.,
Washington, DC 20201.

(Because access to the interior of the
Hubert H. Humphrey Building is not
readily available to persons without
Federal government identification,
commenters are encouraged to leave
their comments in the CMS drop slots
located in the main lobby of the
building. A stamp-in clock is available
for persons wishing to retain a proof of
filing by stamping in and retaining an
extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—
Centers for Medicare & Medicaid
Services, Department of Health and
Human Services, 7500 Security
Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your
comments to the Baltimore address, call
telephone number (410) 786-9994 in
advance to schedule your arrival with
one of our staff members.

Comments erroneously mailed to the
addresses indicated as appropriate for

hand or courier delivery may be delayed
and received after the comment period.

For information on viewing public
comments, see the beginning of the
SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT:

Cindy Melanson, (410) 786-0310.
Patricia Chmielewski, (410) 786-6899.
Marie Vashbinder, (410) 786-8665.

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](http://www.regulations.gov). Follow the search
instructions on that Web site to view
public comments.

Comments received timely will also
be available for public inspection as
they are received, generally beginning
approximately 3 weeks after publication
of a document, 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,
phone 1-800-743-3951.

I. Background

Under the Medicare program, eligible
beneficiaries may receive covered
services from 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 an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416 of our Medicare regulations. Thereafter, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (NAO) that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an NAO is voluntary and is not required for Medicare participation.

If an NAO is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A NAO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the NAO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of NAOs are set forth at § 488.5.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a NAO's requirements consider, among other factors, the applying NAO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period.

We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the Institute for Medical Quality (IMQ's) request for initial CMS-approval of its ASC accreditation program. This notice also solicits public comment on whether IMQ's requirements meet or exceed the Medicare conditions for coverage (CfCs) for ASCs.

III. Evaluation of a NAO's Accreditation Program

IMQ submitted all the necessary materials to enable us to make a determination concerning its request for initial CMS-approval of its ASC accreditation program. This application was determined to be complete on October 8, 2015. Under Section 1865(a)(2) of the Act and our regulations at § 488.5, our review and evaluation of IMQ will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of IMQ's standards for ASCs as compared with Medicare's CfCs or ASCs.

- IMQ's survey process to determine the following:

- ++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

- ++ The comparability of IMQ's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- ++ IMQ's processes and procedures for monitoring an ASC found out of compliance with IMQ's program requirements. These monitoring procedures are used only when IMQ identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c)(1).

- ++ IMQ's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

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

- ++ The adequacy of IMQ's staff and other resources, and its financial viability.

- ++ IMQ's capacity to adequately fund required surveys.

- ++ IMQ's policies with respect to whether surveys are announced or

unannounced, to assure that surveys are unannounced.

- ++ 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 CMS may require (including corrective action plans).

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

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. 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.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

Dated: November 18, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015-30316 Filed 12-3-15; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-4399]

Determination That OPHTHAINE (propraracaine hydrochloride) Solution and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means