

Dated: March 18, 2011.

Martique Jones,

Director, Regulations Development Group,
Division B, Office of Strategic Operations and
Regulatory Affairs.

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Centers for Medicare and Medicaid
Services**

[Document Identifier CMS-10320]

**Emergency Clearance: Public
Information Collection Requirements
Submitted to the Office of Management
and Budget (OMB)**

AGENCY: Center for Medicare and
Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320(a)(2)(ii). This is necessary to ensure compliance with an initiative of the Administration.

1. *Type of Information Collection Request:* Reinstatement of Previously Approved Collection; *Title of Information Collection:* Health Care Reform Insurance Web Portal

Requirements 45 CFR part 159; *Use:* In accordance with sections 1103 and 10102 of the Affordable Care Act, the U.S. Department of Health and Human Services created a Web site called healthcare.gov to meet these and other provisions of the law, and data collection was conducted for six months based upon an emergency information collection request. The interim final rule published on May 5, 2010 served as the emergency Federal Register Notice for the prior Information Collection Request (ICR). The Office of Management and Budget (OMB) reviewed this ICR under emergency processing and approved the ICR on April 30, 2010. CMS will be submitting a revised ICR to OMB for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies.

As previously stated, this information collection is mandated by sections 1103 and 10102 of the Affordable Care Act. Once all of the information is collected from insurance issuers of major medical health insurance hereon referred to as issuers, it will be processed for display at <http://www.healthcare.gov>. The information that is provided will help the general public make educated decisions about private health care insurance options.

CMS is mandating the issuers verify and update their information for a June refresh of the Web site. In the event that an issuer has enhanced or modified its existing plans, created new plans, or deactivated plans, the organization would be required to update the information in the Web portal. States and High Risk Pool administrators are unaffected under this emergency PRA request. *Form Number:* CMS-10320 (OMB#: 0938-1086); *Frequency:* Reporting—Annually/Monthly; *Affected Public:* For Profit Firms, States; *Number of Respondents:* 700; *Total Annual Responses:* 13,050; *Total Annual Hours:* 101,960. (For policy questions regarding this collection contact Beth Liu at 301-492-4268. For all other issues call 410-786-1326.)

CMS is requesting OMB review and approval of this collection by *May 1, 2011*, with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by *April 25, 2011*.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/regulations/pr> or E-mail your request,

including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by April 25, 2011.

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

3. *By Facsimile or E-mail to OMB.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, E-mail:

OIRA_submission@omb.eop.gov.

Dated: March 18, 2011.

Martique Jones,

Director, Regulations Development Group,
Division B, Office of Strategic Operations and
Regulatory Affairs.

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Centers for Medicare and Medicaid
Services**

[CMS-4154-FN]

**Medicare and Medicaid Programs;
Renewal of Deeming Authority of the
National Committee for Quality
Assurance for Medicare Advantage
Health Maintenance Organizations and
Local Preferred Provider Organizations**

AGENCY: Centers for Medicare and
Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces the decision to renew the Medicare Advantage Deeming Authority of the National Committee for Quality Assurance (NCQA) for Health

Maintenance Organizations and Preferred Provider Organizations for a term of 4 years. The new term of approval began October 19, 2010, and ends October 18, 2014.

DATES: *Effective Date:* This notice is effective on April 25, 2011.

FOR FURTHER INFORMATION CONTACT: Caroline L. Baker, (410) 786-0116.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services through a Medicare Advantage (MA) organization that contracts with the Centers for Medicare & Medicaid Services (CMS) provided certain requirements are met under 42 CFR part 422. Part C of Title XVIII of the Social Security Act (the Act), specifies the services that an MA organization must provide and the requirements that the organization must meet to be an MA contractor. Other relevant sections of the Act are Parts A and B of Title XVIII and Part A of Title XI of the Act pertaining to the provision of services by Medicare certified providers and suppliers.

To assure compliance with certain Medicare requirements, an MA organization may choose to become accredited by a CMS approved accrediting organization (AO). By doing so, the MA organization may be "deemed" compliant in one or more of 6 requirements set forth in section 1852(e)(4)(B) of the Act. In order for an AO to be able to "deem" an MA plan as compliant with these MA requirements, the AO must prove to CMS that its standards are at least as stringent as the Medicare requirements. MA organizations that are licensed as health maintenance organizations (HMOs) or preferred provider organizations (PPOs) and are accredited by an approved accrediting organization may receive, at their request, deemed status for CMS requirements in the following 6 MA survey areas: (1) Quality Improvement; (2) Antidiscrimination; (3) Access to Services; (4) Confidentiality and Accuracy of Enrollee Records; (5) Information on Advanced Directives; and (6) Provider Participation Rules. (See 42 CFR 422.156(b).) We note that at this time, deeming does not include the Part D areas of review listed in § 422.156(b).

Organizations that apply for MA deeming authority are generally recognized by the health care industry as entities that accredit HMOs and PPOs. As we specified in § 422.157(b)(2), the term for which an AO may be approved by CMS may not

exceed 6 years. For continuing approval, the AO must renew their application with CMS.

II. Approval of Deeming Organizations

Section 1852(e)(4)(C) of the Act provides a statutory timetable to ensure that our review of deeming applications in conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. At the end of the 210 day period, we must publish an approval or denial of the application in the **Federal Register**.

III. Provisions of the Proposed Notice and Response to Comments

On November 29, 2010, we published a proposed notice (75 FR 73087) in the **Federal Register** announcing re-approval of Medicare Advantage Deeming Authority of the National Committee for Quality Assurance (NCQA). In the proposed notice, we detailed our evaluation criteria. As set forth in section 1852(e)(4) of the Act and our regulations at § 422.158, the review and evaluation of NCQA's accreditation program (including its standards and monitoring protocol) were compared to the requirements set forth in part 422 for the MA program.

The review of NCQA's application for approval of MA deeming authority included the following components:

- The types of MA plans that it would review as part of its accreditation process.
- A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).
- Detailed information about the organization's survey process, including—
 - ++ Frequency of surveys and whether surveys are announced or unannounced.
 - ++ Copies of survey forms, and guidelines and instructions to surveyors.
 - ++ Description of the survey review process and the accreditation status decision making process.
 - ++ The procedures used to notify accredited MA organizations of deficiencies and to monitor the correction of those deficiencies.
 - ++ The procedures used to enforce compliance with accreditation requirements.
 - Detailed information about the individuals who perform surveys for the accreditation organization, including—
 - ++ The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process.

- ++ The education and experience requirements surveyors must meet.
- ++ The content and frequency of the in-service training provided to survey personnel.

- ++ The evaluation systems used to monitor the performance of individual surveyors and survey teams.

- The organization's policies and practice with respect to the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

- A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

- A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

- A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

- A description of all types (for example, full and partial) and categories (for example, provisional, conditional, and temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.

- A list of all currently accredited MA organizations and the type, category, and expiration date of the accreditation held by each of them.

- A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

- The name and address of each person with an ownership or control interest in the accreditation organization.

- The NCQA's past performance in the deeming program and results of recent deeming validation reviews, or look-behind audits conducted as part of continuing Federal oversight of the deeming program under § 422.157(d).

No comments were received in response to the proposed notice published November 29, 2010.

Therefore, based on the review and observations described in section III of this final notice, we have determined that NCQA's requirements for HMOs and local PPOs continue to meet or exceed our requirements. We renew the MA deeming authority of the NCQA for HMOS and PPOs for a term of 4 years. The new term of approval began October 19, 2010, and ends October 18, 2014.

IV. Results of the Review Process

Using the information listed in section III of this final notice, we determined that NCQA's current accreditation program for HMO and PPO MA plans continues to be at least as stringent as the MA requirements contained in the 6 categories specified in section 1852(e)(4)(C) of the Act and our methods of evaluation for those areas.

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. Chapter 35).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 9, 2011.
Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.
 [FR Doc. 2011-6222 Filed 3-24-11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Voluntary Establishment of Paternity—NPRM.
OMB No.: 0970-0175.
Description: Section 466(a)(5)(C) of the Social Security Act requires States to pass laws ensuring a simple civil process for voluntarily acknowledging paternity under which the State must provide that the mother and putative father must be given notice, orally and in writing, of the benefits and legal responsibilities and consequences of acknowledging paternity. The information is to be used by hospitals, birth record agencies, and other entities participating in the voluntary paternity establishment program that collect information from the parents of children that are born out of wedlock.
Respondents:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Disclosure	1,167,097	1	0.17	198,406.49

Estimated Total Annual Burden Hours: 198,406.49.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202-395-7285, *E-mail:* OIRA_SUBMISSION@OMB.EOP.GOV, *Attn:* Desk Officer for the

Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.
 [FR Doc. 2011-7077 Filed 3-24-11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0620]

The National Antimicrobial Resistance Monitoring System Strategic Plan 2011-2015; Request for Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice that appeared in the **Federal Register** of January 24, 2011 (76 FR 4120). In the notice, FDA requested comments on a

document for the National Antimicrobial Resistance Monitoring System (NARMS) entitled "NARMS Strategic Plan 2011-2015." The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments. Based on requests received, additional information is being placed in the docket related to the development of the Strategic Plan. This information can also be viewed at the Web sites listed in section III of this document.

DATES: Submit either electronic or written comments by May 24, 2011.
ADDRESSES: Submit electronic comments 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: Patrick McDermott, Center for Veterinary Medicine (HFV-530), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301-210-4213, *e-mail:* patrick.mcdermott@fda.hhs.gov.