13132, Federalism. Because this proposed notice would simply provide notice of funding ceilings, as determined under the statute, and is not proposing any new requirements, we have determined that this proposed notice would not significantly affect the rights, roles, and responsibilities of States.

Authority: Sections 1902(a)(10)(E) and 1933 of the Social Security Act (42 U.S.C. 1396a(a)(10)(E) and 1396x).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: January 14, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid, Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4025–FN]

RIN 0938–ZA15

Medicare Program; Medicare+Choice Organizations—Approval of the Deeming Authority of the National Committee for Quality Assurance (NCQA) for Medicare+Choice (M+C) Managed Care Organizations That Are Licensed as Health Maintenance Organizations (HMOs)

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

ACTION: Final notice.

SUMMARY: This final notice announces the approval of the National Committee for Quality Assurance (NCQA) for deeming authority of Medicare+Choice (M+C) organizations that are licensed as health maintenance organizations (HMOs). We have found that NCQA's standards for managed care organizations (MCOs) submitted to us in the application process meet or exceed those established by the Medicare program. Therefore, M+C organizations that are licensed as HMOs and are accredited by NCQA may receive, at their request, deemed status for the M+C requirements in the six areas—Quality Assurance, Information on Advance Directives, Antidiscrimination, Access to Services, Provider Participation Rules, and Confidentiality and Accuracy of Enrollee Records—that are specified in Section 1852(e)(4)(C) of the Social Security Act (the Act). Regulations set forth in 42 CFR 422.157(b)(2) specify that the Secretary will publish a **Federal Register** notice that indicates whether an accreditation organization's request for approval has been granted and the effective date and term of the approval, which may not exceed 6 years.

FOR FURTHER INFORMATION CONTACT: Trisha Kurtz, (410) 786–4670.

SUPPLEMENTARY INFORMATION:

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I. Background

Under the Medicare program, eligible beneficiaries may receive covered services through a managed care organization (MCO) that has a Medicare+Choice (M+C) contract with the Centers for Medicare & Medicaid Services (CMS). To enter into an M+C contract, the organization must be licensed by the State as a risk bearing entity and must meet the requirements that are set forth in 42 CFR part 422. These regulations implement Part C of Title XVIII of the Social Security Act (the Act), which specifies the services that an MCO must provide and the requirements that the organization must meet to be an M+C contractor. Other relevant sections of the Act are Parts A and B of Title XVIII and Part A of Title XI pertaining to the provision of services by Medicare certified providers and suppliers.

Following approval of the M+C contract, CMS engages in routine monitoring of the M+C organization to ensure continuing compliance. The monitoring process is comprehensive and uses a written protocol that itemizes the Medicare requirements the M+C organization must meet.

An M+C organization may be exempt from CMS monitoring of the requirements that are in the areas listed in section 1852(e)(4)(C) of the Act as a result of the organization being accredited by a CMS-approved accrediting organization. In essence, the Secretary ''deems'' that the Medicare requirements are met based on a determination that the accrediting organization's standards are at least as stringent as Medicare requirements. Regulations for the M+C deeming program are set forth in §§ 422.156, 422.157, and 422.158. The term for which an accrediting organization may be approved by CMS may not exceed 6 years as stated in § 422.157(b)(2). For continuing approval, the accrediting organization will have to re-apply to CMS.

II. Provisions of the Proposed Notice

On August 1, 2001, we published a proposed notice in the **Federal Register** (66 FR 39775) announcing the receipt of an application from NCQA for approval of deeming authority for M+C organizations that are licensed as health maintenance organizations (HMOs). In the proposed notice, we provided the factors on which we would base our evaluation. In accordance with § 422.157(b)(iii) of the proposed notice, we provided a 30-day public comment period. We did not receive public comments in response to the proposed notice for NCQA.

III. Deeming Approval Review and Evaluation

As set forth in section 1852(e)(4) of the Act and our regulations at § 422.158, the review and evaluation of the NCQA's accreditation program was compared to the requirements set forth in part 422 for the M+C program.

A. Components of the Review Process

The review of NCQA's application for approval of M+C deeming authority included the following components.

1. Site Visit

A site visit to NCQA's headquarters to assess—

- Corporate policies and procedures that relate to the MCO accreditation program;
- The survey, decision-making, and report-writing processes used in NCQA's MCO accreditation program;
- The resources available for accreditation reviews and the ability to financially sustain an M+C deeming program;
- The staff and surveyor training and evaluation programs;

• The ability to investigate and respond appropriately to complaints against accredited MCOs; and

• Communication, customer support and release of accreditation information to the public.

2. Desk-Top Review

A desk-top review of NCQA's MCO accreditation program, including—

• A description of NCQA's survey process for MCOs, including the frequency of surveys performed, whether the surveys are announced or unannounced, surveyor instructions, the review and accreditation status decision-making process, procedures used to notify accredited M+C organizations of deficiencies and monitoring of the correction of deficiencies, and the procedures used to enforce compliance with accreditation requirements;

• Information about the individuals who perform MCO accreditation reviews, including the size and composition of the survey team, the methods of compensation, the education and experience requirements, the content and frequency of the in-service training, the evaluation system used to monitor performance, and conflict of interest requirements;

• A description of the data management and analysis system, the types (full, partial, or denial) and categories (provisional, conditional, temporary) of accreditation offered by NCQA, the duration of each category of accreditation, and a statement identifying the types and categories that would serve as a basis for accreditation if CMS grants NCQA M+C organization deeming authority;

• The procedures used to respond to and investigate complaints or identify other problems with accredited organizations, including coordination of these activities with licensing bodies and ombudsmen programs;

• A description of how NCQA provides accreditation information to the general public;

• The policies and procedures for (1) withholding, denying and removal of accreditation status, and the other actions NCQA may take in response to noncompliance with their standards and requirements, and (2) how NCQA deals with accreditation of organizations that are acquired by another organization, have merged with another organization, or that undergo a change of ownership or management;

• Lists of all (1) NCQA accredited M+C organizations, (2) MCOs surveyed by NCQA in the past 3 years, and (3) MCOs that were scheduled to be surveyed by NCQA within 3 months of submitting their application;

• A written presentation of NCQA ability to furnish data electronically, via telecommunications;

• A resource analysis that included financial statements for the past 3 years (audited, if possible) and the projected number of deemed status surveys for the upcoming year; and

• A statement acknowledging that, as a condition of approval, NCQA agreed to comply with the ongoing responsibility requirements stated in § 422.157(c).

3. Assessment of NCQA's Standards and Methods of Evaluation

As part of the application, NCQA submitted a crosswalk that compared their standards and methods of evaluations with corresponding M+C requirements. A multicomponent team of CMS regional and central office staffs then reviewed and evaluated NCQA's standards and processes and compared them to the M+C requirements in six areas: Quality Assurance, Access to Services, Antidiscrimination, Information on Advance Directives, Provider Participation Rules, and Confidentiality and Accuracy of Enrollee Records.

4. Observation of an NCQA Accreditation

An observation of an NCQA accreditation of an MCO allowed CMS staff to (1) validate that the accreditation review methods described in NCQA's application were equal to (or exceeded) the corresponding Medicare requirements, and (2) resolve outstanding issues that were identified during the review of NCQA's application materials.

B. Results of the Review Process

We determined that NCQA's current accreditation program for MCOs did not either address or ''meet or exceed'' several of the M+C requirements that are contained in 5 of the 6 categories set forth in section 1852(e)(4)(C) of the Act. To address this issue, NCQA agreed to complement their current MCO accreditation program by applying a ''Medicare+Choice Module'' (M+C Module). Thus, when assessing M+C organizations that seek deemed status for the Medicare requirements contained in the six categories established in the Act, NCQA will complement their current accreditation program with the M+C Module. The M+C Module will include the following:

1. Quality Assurance (42 CFR 422.152)

• A statement that ''if/when'' CMS establishes minimum performance levels, the M+C organization must meet the performance level(s) and report them to CMS.

• A requirement that M+C organizations must meet the full range of CMS Quality Assessment and Performance Improvement project topic requirements.

2. Provider Participation Rules (42 CFR Subpart E)

• A requirement for a written notice of (1) material changes in participating rules before the changes are put into effect, (2) initial participation decisions that are adverse to physicians, and (3) the appeals process and reasons for the action when a participating provider is suspended or terminated.

• A requirement that the majority of the appeals hearing panel members are peers of the affected physician.

• A requirement that both the M+C organization and contracting provider provide at least 60 days written notice to each other before terminating the contract without cause.

• A requirement that participating providers and suppliers who provide services to Medicare enrollees are approved for participation in Medicare and that the M+C organization does not employ or contract with providers who have opted-out of Medicare participation.

• A requirement that M+C organizations do not discriminate against health care professionals who serve high-risk populations or who specialize in the treatment of costly conditions in the formal selection and retention criteria.

• A requirement that the M+C organization provide sufficient notice to CMS and enrollees, if they object to covering, furnishing or paying for counseling or referral service on the basis of moral or religious grounds and that the M+C organization provides conscience protection policies to enrollees.

• NCQA agreed to a Physician Incentive Plan (PIP) review strategy proposed by CMS. M+C organizations will continue to provide PIP information to CMS. CMS will notify accrediting organizations of M+C organizations that they have deemed are ''noncompliant'' for any of the PIP requirements; then the accrediting organization will contact the M+C organization to inform them that they must comply with the PIP provisions. If, at the end of the accrediting organization's corrective action process,

the M+C organization continues to be noncompliant, the accrediting organization will turn the case over to CMS. However, PIP disclosure for 2002 is delayed until further notice. CMS is working to modify the regulations for disclosure as part of the effort to reduce administrative burdens on managed care organizations.

- A requirement that addresses the limitation on provider indemnification that is stated in § 422.212.

3. Information on Advance Directives (42 CFR 422.128)

- NCQA agreed to add all the CMS requirements regarding information on advance directives to their M+C Module.

4. Antidiscrimination (42 CFR 422.110, 422.502(h))

- A requirement that an M+C organization may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an M+C plan offered by the organization on the basis of any factor that is related to health status.

- A requirement that an M+C organization may not enroll an individual who has been medically determined to have end-stage renal disease and a requirement that an enrollee who develops end-stage renal disease while enrolled in an M+C organization may not be disenrolled for that reason.

5. Access to Services (42 CFR 422.112)

- A requirement that M+C organizations have policies and procedures that allow an enrollee's representative to facilitate care or treatment decisions when the enrollee is unable to do so.

- A requirement that M+C organizations support a network of providers with written arrangements that address the provision of services covered under the M+C program.

- A requirement that M+C organizations provide direct access to women's health services for routine and preventive health care services.

- A statement that ensures that M+C organizations have procedures to identify individuals with complex needs and/or serious medical conditions.

- A requirement that M+C organizations should make a ''best effort'' attempt to conduct an initial assessment of enrollee health care needs within 90 days of the effective date of enrollment.

C. Term of Approval

Regulations at § 422.157(b)(2) permit us to grant a term of approval for deeming authority for accreditation organizations of up to 6 years. On January 18, 2002, we notified NCQA of our approval of their application as a national accreditation organization for MCOs that request participation in the M+C program. We are granting this deeming authority through January 17, 2008.

IV. Paperwork Reduction Act

The requirements associated with granting and withdrawal of deeming authority to national accreditation, codified in part 422, Medicare+Choice Program, are currently approved by OMB under OMB approval number 0938–0690, with an expiration date of June 30, 2002. Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA.

V. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This notice merely recognizes NCQA as a national accreditation organization that has approval for deeming authority for HMOs that are participating in the M+C program. Since M+C organizations are monitored every 2 years by CMS's regional office staff to determine compliance with M+C requirements, we believe that the M+C deeming program has the potential to reduce both the regulatory and administrative burdens associated with the Medicare+Choice program. In FY 2001, there were 179 M+C contracts and 5,578,605 enrollees. Approximately, 75 of those M+C organizations were accredited by NCQA.

This notice, however, is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

Therefore, we have determined, and the Secretary certifies, that this notice will not result in a significant impact on small entities and will not have an effect on the operations of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice has no consequential effect on State, local, or tribal governments. We believe the private sector costs of this notice fall below this threshold as well.

In accordance with Executive Order 13132, this notice will not significantly affect the rights of States and does not significantly affect State authority. This regulation describes only processes that must be undertaken to fulfill our obligation to conduct enforcement as required by the April 8, 1997 regulation.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by OMB.

Authority: Secs. 1851 and 1855 of the Social Security Act (42 USC 1395w–21 and 42 USC 1395w–25)

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

Dated: December 10, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–1874 Filed 1–24–02; 8:45 am]

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