OMB control numbers	Approved CFR Sections in Title 42, Title 45, and Title 20 (Note: Sections in Title 45 are preceded by ''45 CFR,'' and sections in Title 20 are preceded by ''20 CFR'')
0938–0802	419.43
0938–0818	410.141, 410.142, 410.143, 410.144, 410.145, 410.146, 414.63
0938–0829	422.568
0938–0832	489 and 491
0938–0833	483.350–483.376
0938–0841	431.636, 457.50, 457.60, 457.70, 457.340, 457.350, 457.431, 457.440, 457.525, 457.560, 457.570, 457.740, 457.750, 457.810, 457.940, 457.945, 457.965, 457.985, 457.1005, 457.1015, 457.1180
0938–0842	412.23, 412.604, 412.606, 412.608, 412.610, 412.614, 412.618, 412.626, 413.64
0938–0846	411.352–411.361
0938–0857	419
0938–0860	419
0938–0866	*45 CFR* Part 162
0938–0872	413.337, 483.20
0938–0873	422.152
0938–0874	*45 CFR* Parts 160 and 162
0938–0878	422 Subpart F & G
0938–0883	*45 CFR* Parts 160 and 164
0938–0884	405.940
0938–0887	*45 CFR* 148.316, 148.318, 148.320
0938–0897	412.22, 412.533
0938–0907	412.230, 412.304, 413.65
0938–0910	422.624, 422.626, 422.620
0938–0911	426.400, 426.500
0938–0916	483.16
0938–0920	438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102, 438.114, 438.202, 438.206, 438.207, 438.240, 438.242, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.710, 438.722, 438.724, 438.810
0938–0921	414.804

[FR Doc. 04–28156 Filed 12–29–04; 8:45 am]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9026–N]

RIN 0938–AN112

Medicare Program; Timeline for Publication of Medicare Final Regulations After Proposed or Interim Final Regulations

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

ACTION: Notice.

SUMMARY: This notice implements section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which establishes a general 3-year timeline for publishing a Medicare final regulation after a proposed regulation or an interim final regulation has been published. In accordance with the statute, this notice permits an extension of a published timeline under exceptional circumstances. The notice also establishes a transition period for publishing Medicare final regulations for previously published interim final regulations.

EFFECTIVE DATE: This notice is effective on December 30, 2004.

FOR FURTHER INFORMATION CONTACT: Renee Swann, (410) 786–4492.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

The general statutory authority for the Department to issue Medicare regulations is found in section 1871 of the Social Security Act (the Act). Specifically, section 1871(a)(1) of the Act authorizes us to publish regulations to administer the Medicare program. Section 1871(a)(2) of the Act states that, with the exception of national coverage determinations, we must publish a regulation ''that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits* * *''

Before issuing a final regulation, section 1871(b)(1) of the Act generally requires us to publish a proposed regulation that solicits comments (for at least 60 days) from the public. There are, however, several exceptions that permit the Secretary to issue final regulations or interim final regulations without first obtaining advance public comments.

Executive Order 12866 (issued on September 20, 1993) requires that all Federal agencies prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of the Office of Information and Regulatory Affairs, of the Office of Management and Budget.

We announce in the Semi-Annual Unified Regulations Agenda the regulations we plan to publish during the 12-month period following publication of the Agenda in the **Federal Register**. The Agenda is generally published in April and October each year.

In October 2001, to better serve all of our constituencies, including our health care providers, we began publishing regulations on the fourth Friday of every month (except when a statutory deadline demands otherwise), and we began issuing a quarterly publication called the *Quarterly Provider Update* (QPU). The QPU is publicly available on the Internet and lists all of the regulations that we plan to publish in the coming quarter, as well as the publication date and page reference to all regulations published in the previous quarter. The QPU is published on the CMS web site at *http://qa.cms.hhs.gov/providerupdate/main.asp.*

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. 108–173) was enacted. Section 902 of the MMA added a new paragraph (a)(3) to section 1871 of the Act. New section 1871(a)(3)(A) of the Act requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish a standardized timeline for the publication of a Medicare final regulation after the

publication of a proposed or an interim final regulation. Section 1871(a)(3)(B) of the Act allows the timeline for publishing Medicare final regulations to vary based on the complexity of the regulation, the number and scope of comments received, and other related factors. The timeline for publishing the final regulation, however, cannot exceed 3 years from the date of publishing the proposed regulation or interim final regulation, unless there are exceptional circumstances. The Secretary may extend the initial targeted publication date of the final regulation, if the Secretary provides public notice including a brief explanation of the justification for the variation no later than the regulation's previously established proposed publication date.

Section 1871(a)(3)(C) of the Act states that a Medicare interim final regulation will not continue in effect if the final regulation is not published before the expiration of the regular timeline, unless a notice of continuation (for a 1-year period) is published in the **Federal Register** before the proposed publication date for the final regulation. The notice of continuation must establish a new timeline and provide an explanation for missing the previous timeline. If the notice is published before the end of the previous timeline, the timeline for publishing the final regulation will be extended for 1 additional year. The statute allows for additional extensions if this process is followed for additional continuation notices.

Section 1871(a)(3)(D) of the Act requires the Secretary to report annually to the Congress on all instances when the Secretary failed to publish a Medicare final regulation within the applicable timeline and to provide an explanation for failing to meet the timeline.

The provisions of section 902 of the MMA were effective on the date of enactment of the MMA (that is, December 8, 2003). Section 902 of the MMA instructs the Secretary to provide an appropriate transition for previously published Medicare interim final regulations.

II. Timeline of Regulatory Documents

A. Medicare Final Regulations for Proposed Regulations and Interim Final Regulations

We are continuing to improve our efforts to be more responsive to Medicare beneficiaries. Thus, we are establishing a timeline for publishing Medicare final regulations. We believe these changes will enhance our ability to better serve Medicare beneficiaries and to be better business partners with the health care community.

In accordance with section 902(a) of the MMA, we will publish all future Medicare final regulations within 3 years from the publication date of the proposed regulation or interim final regulation, unless there is good cause or there are exceptional circumstances. We will consult with the Office of Management and Budget and set regulation-specific timelines for publishing Medicare final regulations on a case-by-case basis within the 3-year standardized timeline. We will continue to use the QPU to announce all CMS regulations that we will publish during the quarter.

We will continue to announce the timelines for all CMS regulations in the Semi-Annual Unified Regulations Agenda for the period covered by the Agenda. Except for certain Medicare payment regulations and certain other statutorily-mandated regulations, we scheduled all Medicare final regulations for publication within the 3-year standardized time limit in the current Unified Agenda. We do not intend to delay publishing a Medicare final regulation for 3 years if we are able to publish it sooner.

If it appears likely that we will miss the applicable timeline for finalizing a Medicare interim final regulation, we will publish a notice of continuation announcing the extended timeline and furnish a brief explanation for the delay.

Although we do not believe that section 902 of the MMA prohibits the Secretary from finalizing every proposed regulation that was published more than 3 years before December 8, 2003, we recognize that section 902 of the MMA may be susceptible to more than one interpretation. Accordingly, out of an abundance of caution, we are interpreting section 902 of the MMA as rendering ineffective most Medicare proposed regulations that have not been finalized within 3 years of the proposed regulation publication dates. This also includes proposed regulations published before December 8, 2003, unless there is good cause. In those limited cases when we believe there is good cause, that is, when the agency finds that the notice and comment procedure is impracticable, unnecessary, or contrary to the public interest, we will publish the proposed regulation as an interim final regulation. The interim final regulation will be subject to the 3-year standard timeline set by section 902 of the MMA. Otherwise, if we believe that the substance of a proposed regulation rendered ineffective by the statute should move forward, we will publish the proposed regulation with an appropriate timeline, not to exceed 3 years.

B. Appropriate Transition for Previously Published Medicare Interim Final Regulations

The enactment of the MMA brought about the most extensive revisions to the Medicare program since its inception in 1965. As a result, we must develop and publish numerous regulations by specific statutory effective dates. In addition to this new priority workload, we must annually publish numerous proposed and final regulations that are required by the statute to update the various Medicare payment systems. Section 902 of the MMA recognizes the need for a transition period to allow for the publication of Medicare final regulations for those interim final regulations that were published before the enactment of the MMA (that is, December 8, 2003). It is our intention to publish these Medicare final regulations as time allows while publishing other regulations required by the statute, but no later than December 8, 2006.

In accordance with the Congress' instruction to devise an appropriate transition for existing interim final regulations, we will be extending all Medicare interim final regulations that have not been finalized for 3 years from the date of passage of the MMA until December 8, 2006. Over the course of the 3 years, we will be reviewing the Medicare interim final regulations to determine the basis for finalizing the regulation and the possible impact of not implementing a final regulation. If we determine that a regulation needs to be repealed, we will issue a separate rulemaking document. For those Medicare interim final regulations that we do not finalize within 3 years, the regulation will expire in accordance with the statute, and we will take the appropriate actions to amend the Code of Federal Regulations.

In accordance with the provisions of Executive Order 12866, this notice has been reviewed by the Office of Management and Budget.

Authority: Section 1871 of the Social Security Act (42 U.S.C. 1395hh).

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

Dated: March 31, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 6, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 04–28158 Filed 12–29–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4077–FN]

RIN 0928–ZA59

Medicare Program; Approval of the National Committee for Quality Assurance Deeming Authority for Medicare Advantage Local Preferred Provider Organizations

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 for deeming authority as a national accreditation program for local preferred provider organizations that wish to participate in the Medicare Advantage program.

FOR FURTHER INFORMATION CONTACT: Gwyneveyre Pasquale, (410) 786–7701.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services through a managed care organization (MCO) that has a Medicare Advantage (MA) (formerly, Medicare+Choice) contract with the Centers for Medicare & Medicaid Services (CMS). The regulations specifying the Medicare requirements that must be met in order for an MCO to enter into an MA contract with CMS are located at 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 MA 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.

Generally, for an organization to enter into an MA contract, the organization must be licensed by the State as a risk bearing organization as set forth in part 422 of our regulations. Additionally, the organization must file an application demonstrating that it meets other Medicare requirements in part 422 of our regulations. Following approval of the contract, we engage in routine monitoring and oversight audits of the MA organization to ensure continuing compliance. The monitoring and oversight audit process is comprehensive and incorporates ongoing analysis of various performance data in addition to biennial audits by CMS staff who use a written protocol that itemizes the Medicare requirements the MA organization must meet.

As an alternative for some Medicare requirements, an MA organization may be exempt from CMS monitoring of certain requirements in subsets listed in section 1852(e)(4)(B) of the Act as a result of an MA organization's accreditation by a CMS–approved accrediting organization (AO); that is, the Secretary deems that the Medicare requirements are met based on a determination that the AO's standards are at least as stringent as Medicare requirements. As we specify at § 422.157(b)(2) of our regulations, the term for which an AO may be approved by CMS may not exceed 6 years. For continuing approval, the AO must re-apply to CMS.

The applicant organization is generally recognized as an entity that accredits MCOs that are licensed as a health maintenance organization (HMO) or a preferred provider organization (PPO).

II. Deeming Application Approval Process

Section 1852(e)(4)(C) of the Act requires that within 210 days of receipt of an application, the Secretary shall determine whether the applicant meets criteria specified in section 1865(b)(2) of the Act. Under these criteria, the Secretary will consider for a national accreditation body, its requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation.

Section 1865(b)(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 accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We must publish a finding of approval or denial of the application within 210 days from the receipt of the completed application.

III. Provisions of the Proposed Notice

On September 24, 2004, we published a proposed notice in the **Federal Register** (69 FR 57310) announcing the National Committee for Quality Assurance's (NCQA's) request for recognition as a national accreditation program for PPOs that wish to participate in the MA program. This notice informed the public of our consideration of NCQA's application for approval as a deeming authority for MA organizations that are licensed as a PPO for the following six categories:

- Quality improvement.
- Access to services.
- Antidiscrimination.
- Information on advance directives.
- Provider participation rules.
- Confidentiality and accuracy of enrollees' records.

In the notice, we described our evaluation criteria. Under § 422.158(a), we conducted a review of NCQA's application in accordance with the criteria specified by our regulations, which include, but are not limited to, the following:

- The equivalency of NCQA's requirements for PPOs to CMS' comparable MA organization requirements.
- NCQA's survey process, to determine the following:
  + The frequency of surveys.
  + The types of forms, guidelines, and instructions used by surveyors.
  + Descriptions of the accreditation decision making process, deficiency notification and monitoring process, and compliance enforcement process.
- Detailed information about individuals who perform accreditation surveys including—
  + Size and composition of the survey team;
  + Education and experience requirements for the surveyors;
  + In-service training required for surveyor personnel;
  + Surveyor performance evaluation systems; and
  + Conflict of interest policies relating to individuals in the survey and accreditation decision process.
- Descriptions of the organization's—
  + Data management and analysis system;
  + Policies and procedures for investigating and responding to complaints against accredited organizations; and
  + Types and categories of accreditation offered and MA organizations currently accredited within those types and categories.