

ADDENDUM B.—FY 2002 WAGE INDEX FOR URBAN AREAS—PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (Constituent Counties)	Wage index
8560	TULSA, OK	0.8902
8600	TUSCALOOSA, AL	0.8171
8640	TYLER, TX	0.9641
8680	UTICA-ROME, NY	0.8329
8720	VALLEJO-FARIFIELD-NAPA, CA	1.3562
8735	VENTURA, CA	1.0994
8750	VICTORIA, TX	0.8328
8760	VINELAND-MILLVILLE-BRIDGETON, NJ	1.0441
8780	VISALIA-TULARE-PORTERVILLE, CA	0.9628
8800	WACO, TX	0.8129
8840	WASHINGTON, DC—MD—VA—WV	1.0962
8920	WATERLOO-CEDAR FALLS, IA	0.8041
8940	WAUSAU, WI	0.9696
8960	WEST PALM BEACH-BOCA RATON, FL	0.9777
9000	WHEELING, WV—OH	0.7985
9040	WICHITA, KS	0.9606
9080	WICHITA FALLS, TX	0.7867
9140	WILLIAMSPORT, PA	0.8628
9160	WILMINGTON-NEWARK, DE—MD	1.0877
9200	WILMINGTON, NC	0.9409
9260	YAKIMA, WA	1.0567
9270	YOLO, CA	0.9701
9280	YORK, PA	0.9441
9320	YOUNGSTOWN-WARREN, OH	0.9563
9340	YUBA CITY, CA	1.0359
9360	YUMA, AZ	0.8989

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

Dated: March 12, 2002.

Thomas A. Scully,
Administrator, Health Care Financing Administration.

Dated: May 10, 2002.

Tommy G. Thompson,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4023–FN]

RIN 0938–ZA16

Medicare Program; Medicare+Choice Organizations—Approval of the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) for Medicare+Choice (M+C) Deeming Authority of M+C Organizations That Are Licensed as Health Maintenance Organizations (HMOs) or Preferred Provider Organizations (PPOs)

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

ACTION: Final notice.

SUMMARY: This final notice announces the approval of the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) for deeming authority of Medicare+Choice (M+C) organizations that are licensed as health maintenance organizations (HMOs) or preferred provider organizations (PPOs). We have found that the AAAHC's standards for managed care plans submitted to us and amended during the application process, meet or exceed those established by the Medicare program. Therefore, M+C organizations that are licensed as HMOs or PPOs and are accredited by AAAHC 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)(B) of the Social Security Act (the Act).

Regulations set forth in § 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.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services through a managed care organization that has a Medicare+Choice (M+C) contract with us. 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. Those regulations implement Part C of Title XVIII of the Social Security Act (the Act), that specifies the services that a managed care organization 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, we engage in routine monitoring of the M+C organization to ensure continuing compliance. The monitoring process is comprehensive and uses a written protocol that specifies the Medicare requirements the M+C organization must meet.

A M+C organization may be exempt from our monitoring of the requirements that are in the areas listed in section 1852(e)(4)(B) of the Act if the organization is 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 we may approve an accrediting organization may not exceed 6 years as stated in § 422.157(b)(2). For continuing approval, the accrediting organization will have to re-apply to us.

II. Provisions of the Proposed Notice

On August 1, 2001, we published a proposed notice in the **Federal Register** (66 FR 39773) announcing the receipt of an application from AAAHC for approval of deeming authority for M+C organizations that are licensed as health maintenance organizations (HMOs) or preferred provider organizations (PPOs). In the proposed notice, we provided the factors on which we would base our evaluation. In accordance with § 422.157(b)(1)(iii) of the M+C regulations, we provided a 30-day public comment period. We received one public comment in support of AAAHC's application for M+C deeming authority.

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 AAAHC's accreditation program (including their standards and monitoring protocol) were compared to the requirements set forth in part 422 for the M+C program.

A. Components of the Review Process

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

1. Site Visit

We conducted a site visit to AAAHC's headquarters to assess—

- The corporate policies and procedures that relate to the managed care accreditation program;
- The survey, decision-making, and report-writing processes used in AAAHC's managed care accreditation program;
- The resources available for accreditation reviews and AAAHC's ability to financially sustain an M+C deeming program;
- The staff and surveyor training and evaluation programs;
- The communication, customer support, and public accessibility of accreditation information; and
- AAAHC's ability to investigate and respond appropriately to complaints

against accredited managed care organizations.

2. Desk-Top Review

We conducted a desk-top review of AAAHC's managed care accreditation program, including—

- A description of AAAHC's survey process for managed care plans, 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 network 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 governing AAAHC staff and surveyors;
- A description of the data management and analysis system, the types (full, partial, or denial) and categories (provisional, conditional, temporary) of accreditation offered by AAAHC, the duration of each category of accreditation, and a statement identifying the types and categories that would serve as a basis for accreditation, if we grant AAAHC 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 AAAHC provides accreditation information to the general public;
- The policies and procedures for (1) withholding, denying and removing accreditation status, and the other actions AAAHC may take in response to noncompliance with their standards and requirements, and (2) how AAAHC treats 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) AAAHC-accredited M+C organizations, (2) managed care plans surveyed by AAAHC in the past 3 years, and (3) managed care plans that were scheduled to be surveyed by AAAHC within 3 months of submitting their application;

- A written presentation of AAAHC's 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, AAAHC agreed to comply with the ongoing responsibility requirements stated in § 422.157(c).

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

As part of the application, AAAHC submitted a crosswalk that compared its standards and methods of evaluations with corresponding M+C requirements. A multicomponent team of our regional and central office staff then reviewed and evaluated AAAHC'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 a AAAHC Accreditation Survey

An observation of an AAAHC accreditation survey of a managed care organization allowed our staff to (1) validate that the accreditation review methods described in AAAHC's application were equal to (or exceeded) the corresponding Medicare requirements, and (2) resolve outstanding issues that were identified during the review of AAAHC's application materials.

B. Results of the Review Process

We determined that AAAHC's current accreditation program for managed care plans either did not address or did not "meet or exceed" several of the M+C requirements contained in the six categories set forth in section 1852(e)(4)(C) of the Act. To address this issue, AAAHC agreed to complement their current managed care accreditation program. Thus, when assessing M+C organizations that seek deemed status for the Medicare requirements contained in the six categories established in the Act (including delegation requirements, which are contained in five of the six deeming categories), AAAHC will add the requirements described below.

1. Quality Assurance (§ 422.152)

AAAHC will add to its accreditation standards requirements for M+C organizations to—

- Conduct quality improvement projects that meet or exceed the requirements specified in § 422.152;
- Achieve and report minimum performance levels when we establish them;
- Designate a policymaking body and senior official that are accountable for the quality assurance program and that encourage providers and consumers to participate actively;
- Collect data related to (1) acute and chronic conditions as related to preventive services and care outcomes, (2) the use of clinical resources for high volume services, and (3) the availability, accessibility, and cultural competency of services;
- Select quality indicators that are objective, clearly defined, based upon current research, and generally used in the public health community. Indicators must be measured over time, monitored for at least 1 year after the desired level of performance is achieved (sustained improvement), and benchmarked to targets if we specify targets;
- Correct significant systemic problems that come to their attention through internal surveillance, complaints, enrollee satisfaction surveys, or other mechanisms, such as the use of appeals and grievances; and
- Evaluate the effectiveness of the quality assurance program strategy on an annual basis and modify as necessary.

2. Provider Participation Rules (42 CFR Part 422 Subpart E)

AAAHC will add to its accreditation standards requirements for M+C organizations to—

- Provide written notice of rules of participation regarding terms of payment, credentialing, participation decisions that are adverse to physicians and material changes in participation rules before changes are put into effect;
- Provide at least 60 days written notice (applies to provider as well) before terminating a contract without cause;
- Establish a formal mechanism to consult with physicians regarding medical policy, quality assurance programs, and medical management procedures;
- Communicate practice guidelines and any admission, continued stay, and discharge criteria to all providers and enrollees when appropriate;
- Apply participation procedures equally to physicians within all contracted subgroups;
- Address notice requirements when suspending or terminating physician agreements;

- Communicate a physician's right to appeal a suspended or terminated agreement and ensure that the hearing panel is composed of members who are peers of the affected physician;
- Address procedures for initial credentialing (including verification for Medicare payment and attestation by the applicant of the completeness of the application) and for recredentialing (time frame) that are consistent with the Medicare requirements;
- Determine and redetermine that the institutional provider or supplier is licensed to operate in the State and is approved for participation in Medicare (if applicable) and that the M+C organization does not employ or contract with providers who have been excluded from the Medicare program;
- Enable providers to communicate treatment options to all Medicare beneficiaries;
- Make available information on the plan's policies about objecting to cover, furnish, or pay for a particular service on the basis of moral or religious reasons; and
- Provide for limitations on provider indemnification that is stated in § 422.212.

AAAHC agreed to a Physician Incentive Plan (PIP) review strategy that we proposed. M+C organizations will continue to provide PIP information directly to us. We will notify AAAHC when a M+C organization that they have deemed is "noncompliant" for any of the PIP requirements; AAAHC will then contact the M+C organization to inform it that it 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 refer the case to us.

3. Information on Advance Directives (§ 422.128)

AAAHC will add to its accreditation standards requirements for M+C organizations to—

- Maintain written policies and procedures on advance directives;
- Give information to patients (directly or by contracting with other entities) regarding advance directives that (1) are written, (2) address the right to accept or refuse treatment and formulate advance directives, and (3) reflect changes in State law within 90 days of the effective date;
- Comply with State laws that allow the provider to decline care that conflicts with an advance directive and to conscientiously object to implementing certain advance directives; and

- Inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State survey and certification agency.

4. Antidiscrimination (§ 422.110, § 422.502(h))

AAAHC will add to its accreditation standards requirements for M+C organizations to—

- Prohibit the denial, limitation, or conditioning of coverage or benefits to eligible enrollees on the basis of any factor that relates to health status, except in the case of an individual with end-stage renal disease;
- Implement procedures to ensure that enrollees are not discriminated against in the delivery of services or that health care professionals are not discriminated against on the basis of license or certification;
- Furnish written notice (with a reason for the decision) to any provider whose application for participation in a network has been declined; and
- Comply with all applicable laws and regulations related to discrimination and payment sources.

5. Access to Services (§ 422.112)

AAAHC will add to its accreditation standards requirements for M+C organizations to—

- Instruct enrollees regarding their right to access emergency health care services without prior authorization when the enrollee determines need based upon a prudent layperson standard;
- Offer a panel of primary care providers and arrange for necessary specialty care, including women's health services;
- Ensure that services are provided in a culturally competent manner to all enrollees and that the organization establishes standards for timeliness of access to care and member services that meet or exceed any related standards that we may establish;
- Ensure that each enrollee has an ongoing source of primary care or that each enrollee has been offered a primary care source and that, for each enrollee who accepts the offer, a primary care source exists;
- Provide coordination-of-care programs that include (1) an initial health care needs assessment and a follow-up process, (2) policies regarding ongoing coordination of care by primary care providers or other means, (3) procedures for the identification of, and treatment plans for, individuals with complex or serious needs, and (4) coordination of plan services with community and social services; and

• Transmit information about services used by the enrollee to their primary care provider when a point of service or nonnetwork benefit is offered.

6. Delegation Requirements (Contained in Five of the Six Deeming Categories)

AAAHC will ensure that M+C organizations oversee and are accountable for any functions or responsibilities that are described in the standards for which AAAHC receives deeming authority, if the area (or standard) is delegated to another entity.

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 June 15, 2002, we notified AAAHC of our approval of their application as a national accreditation organization for managed care plans that request participation in the M+C program. We are granting this deeming authority for 4 years—from June 15, 2002 through June 14, 2006.

IV. Paperwork Reduction Act

The requirements associated with granting and withdrawal of deeming authority to national accreditation organization, codified in part 422, Medicare+Choice Program, are currently approved by OMB under OMB approval number 0938–0690, with an expiration date of September 30, 2002. Consequently, this notice 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 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) September 19, 1980 (Pub. L. 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, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million to \$25 million or less in any 1 year (for details, see the Small Business Administration's publication that set

forth size standards for health care industries at 65 FR 69432). 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 AAAHC as a national accreditation organization that has approval for deeming authority for HMOs or PPOs 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 6 of those M+C organizations were accredited by AAAHC. 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.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by OMB.

Authority: Secs. 1851 and 1855 of the Social Security Act (42 U.S.C. 1395w–21 and 42 U.S.C. 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: May 12, 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

Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), (**Federal Register**, Vol. 67, No. 81, pp. 20804–20805 dated April 26, 2002) is amended to reflect a change to the organizational structure of CMS by establishing the Office of Operations Management.

The specific amendments to part F are described below:

- Section F.10. (Organization) is amended to read as follows:
 1. Public Affairs Office (FAC)
 2. Center for Beneficiary Choices (FAE)
 3. Office of Legislation (FAF)
 4. Center for Medicare Management (FAH)
 5. Office of Equal Opportunity and Civil Rights (FAJ)
 6. Office of Research, Demonstration, and Information (FAK)
 7. Office of Communications and Operations Support (FAL)
 8. Office of Clinical Standards and Quality (FAM)
 9. Office of the Actuary (FAN)
 10. Center for Medicaid and State Operations (FAS)
 11. Northeastern Consortium (FAU)
 12. Southern Consortium (FAV)
 13. Midwestern Consortium (FAW)
 14. Western Consortium (FAX)
 15. Office of Operations Management (FAY)
 16. Office of Internal Customer Support (FBA)
 17. Office of Information Services (FBB)
 18. Office of Financial Management (FBC)

- Section F.20. (Functions) is amended by adding the functional statement for the Office of Operations Management. The new functional statement reads as follows: