• 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.

[FR Doc. 02–15971 Filed 6–27–02; 8:45 am]

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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:

7. Office of Operations Management (FAY)

• Analyzes and evaluates project time lines, schedules, and new methodologies. Evaluates and recommends project management alternatives to the Deputy Administrator/Chief Operating Officer (COO) and the Agency.

• Prepares and presents recommendations to the Administrator, Deputy Administrator/ COO, other high level CMS, and Department officials on planning, leadership, implementation, and policy issues concerning modifications to existing and proposed operating policies that will improve the administration and operations of programs and the Agency as a whole.

• With appropriate CMS components to collect and disseminate data on health care and insurance market trends that affect CMS's business risk profile. The Risk Management Staff has the lead for monitoring indicators of risk associated with the operations of CMS and our business partners.

• Surveys risk assessment techniques in use in the private and public sectors and identifies and applies the most useful ones for CMS. Helps develop new risk assessment techniques and keeps abreast of methodological developments in the professional literature.

• Promotes and teaches risk assessment methods to business owners throughout CMS. Promotes awareness of the importance of risk analysis as a component of business planning and trains CMS staff in specific techniques and their applicability in particular situations.

• Educates and reaches out to the public and internal CMS staff on the Health Insurance Portability and Accountability Act (HIPAA) issues. Formulates and coordinates a public relations campaign, prepares and delivers presentations and speeches, responds to inquires on HIPAA issues, and liaisons with industry representatives.

• Provides technical coordination regarding development of HIPAA tools, including transaction testing, and coordinates requirements for Enumeration systems.

• Provides consulting services internally to Agency management and staff to identify processes or contracts that need improvement, to develop improvement strategies, and to monitor processes and improvements over time.

• Participates in Agency-wide initiatives to streamline operations, improve accountability and performance, and implement management best practices. Provides leadership, training, and coaching in the implementation of the initiatives. Promotes a continuous improvement ethos.

Specific Project Management Functions

• Develops, in conjunction with staff in CMS centers and offices, major project plans, implementation schedules and post implementation evaluations.

• Promotes project planning principles throughout the Agency and provides technical guidance to the Agency on project planning and management techniques.

• Reports to the Deputy Administrator/COO and senior officials on progress of Agency priority projects. Negotiates with and supports project and component heads regarding project schedules, progress, etc.

• Prepares and presents recommendations to senior officials regarding major projects.

• Analyzes and evaluates project time lines, schedules, and new methodologies. Evaluates and recommends project management alternatives to the Deputy Administrator/COO and the Agency.

• Conducts process control analysis and tracking to ensure projects are running smoothly.

• Prepares and presents recommendations to the Administrator, Deputy Administrator/COO, and other high level CMS and Department officials on planning, leadership, implementation and policy issues concerning modifications to existing and proposed operating policies that will improve the administration and operations of programs and the Agency as a whole.

Specific Operational Review Functions

• Plans and conducts targeted operational reviews and recommends process and policy improvements to improve the operations of the Agency. The subjects of these reviews will be determined through regular periodic consultation with the Project Management Staff, Risk Management Staff, the Director of the Office of Operations Management, and the Deputy Administrator/COO. Drafts written reports summarizing conclusions and presents findings to appropriate officials for follow-up actions.

• Reviews and evaluates enterprise-wide programs, projects, and processes to assess their effectiveness and efficiency, compliance with laws and regulations, or adequacy of management processes.

• Provides consulting services internally to Agency management and staff to identify processes or contracts that need improvement, to develop improvement strategies, and to monitor processes and improvements over time.

• Participates in agency-wide initiatives to streamline operations, improve accountability and performance, and implement management best practices. Provides leadership, training, and coaching in the implementation of the initiatives. Promotes a continuous improvement ethos.

• Collaborates with the Risk Management Staff, Project Management Staff, and CMS senior management to identify and address enterprise-wide risk factors that lead to ineffective or inefficient operations.

• Identifies operational vulnerabilities in CMS and develops and executes an operational review plan for each fiscal year, subject to approval by the Deputy Administrator/COO and other senior leadership of CMS.

Dated: June 5, 2002.

Ruben J. King-Shaw, Jr.,

Deputy Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. 02–14949 Filed 6–27–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0102]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 29, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235,