**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 417 and 422**

**[CMS–4069–F2]**

**RIN 0938–AN06**

## Medicare Program; Establishment of the Medicare Advantage Program; Interpretation

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

**ACTION:** Final rule; interpretation.

**SUMMARY:** This final rule clarifies our interpretation of the meaning of ''entity'' in the final rule titled ''Medicare Program; Establishment of the Medicare Advantage Program'' published in the **Federal Register** on January 28, 2005 (70 FR 4588). Subsequent to the publication of the Medicare Advantage (MA) final rule on January 28, 2005, we have received inquiries from parties interested in offering an MA Regional Plan concerning whether they could jointly enter into a contract with us to offer a single MA Regional Plan in a multistate region. The participating health plans wish to contract with each other to create a single ''joint enterprise.'' They have asked us whether such a joint enterprise could be considered an ''entity'' under sections 1859(a)(1) and 1855(a)(1) of the Social Security Act, for purposes of offering an MA Regional Plan. The MA final rule is scheduled to take effect on March 22, 2005. Our interpretation of the word ''entity'' that follows in the ''Supplementary Information'' section of this final rule is deemed to be included in that final rule.

**DATES:** *Effective Date:* This regulation is effective on March 22, 2005.

**FOR FURTHER INFORMATION CONTACT:** Jane Andrews, (410) 786–3133.

**SUPPLEMENTARY INFORMATION:**

### I. Background and Clarification of ''Entity''

Subsequent to the publication of the Medicare Advantage (MA) final rule in the **Federal Register** on January 28, 2005 (70 FR 4588), we have received inquiries from parties interested in offering an MA Regional Plan concerning what organizational requirements they must meet in order to be eligible to offer such a plan. Several health plans, each licensed by a State as a risk-bearing entity, have inquired as to whether they could jointly enter into a contract with us to offer an MA Regional Plan in a multistate region. The participating health plans wish to contract with each other to create a single ''joint enterprise.'' They have asked us whether such a joint enterprise could be considered an ''entity'' under sections 1859(a)(1) and 1855(a)(1) of the Social Security Act, for purposes of offering an MA plan.

The statute generally requires that the ''entity'' be licensed by the State as a risk bearing entity where it offers benefits. The health plans seeking jointly to offer an MA Regional Plan propose to meet this requirement through the State license that each participating health plan holds in the State in which it does business. Each plan would be at risk for, and fully responsible for, each MA plan enrollee in its State, or a portion of a State in which it is licensed and operating. Together, the entire region would be covered by an insurer licensed by the State to bear risk where the enrollee lives.

In considering this proposal, we have determined that such a joint enterprise could be treated as a single ''entity'' for purposes of offering an MA Regional Plan, as long as the enterprise as a whole meets all applicable Medicare requirements, and there is no substantive difference between this arrangement and a traditional entity from a Medicare enrollee's perspective. This means that the joint enterprise must, at a minimum—(1) enter into a single contract under which it was accountable, through its participants individually or in the aggregate, for meeting all applicable Medicare requirements, including, since a regional entity cannot continue to operate in a service area that is less than the entire region, providing us with a description of the contracting entity's plan in the event that one or more parties in the joint enterprise terminates their participation (or are terminated by another party) in the enterprise in a contract year; (2) submit a single bid covering the entire MA Region, which would include a uniform benefit, uniform cost-sharing, as well as a uniform premium, and information about how the joint enterprise will allocate risk among the multiple parties in the region; (3) offer a region-wide network of providers that is accessible to all enrollees in the plan, regardless of where in the region they live; (4) market the plan under a single name throughout the region; and (5) provide uniform enrollee customer service and appeal and grievance rights throughout the region. In addition, where the regulations specifically govern the activities of the entity, such as the requirement for fidelity bonds for officers, or certifications associated with receipt of payment, each State-licensed plan comprising the joint enterprise would be required to meet such requirements individually. We will issue operational guidance concerning the process by which we will make payment to these joint enterprise entities. The preamble to the January 28, 2005 MA final rule scheduled to take effect on March 22, 2005 is deemed to include the foregoing clarification concerning our interpretation of the word ''entity.'' We may also issue further guidance on how individual requirements (such as, for example, those related to termination, apportionment of liability, and the imposition of sanctions) will apply to joint enterprises and the plans participating in such enterprises.

*Requirements for Issuance of Regulations*

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule interprets provisions set forth in the January 28, 2005 final regulation. In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

### II. Waiver of 30-Day Delay in Effective Date

We ordinarily provide an effective date 30 days after the publication of a final rule in the **Federal Register**. We can waive this delay, however, if we find good cause that it is impracticable, unnecessary, or contrary to the public interest, and we incorporate a statement of this finding and the reasons for it in the rule issued. The MA final rule sets forth requirements for offering a regional MA plan beginning on January 1, 2006.

Therefore, those wishing to offer a regional MA plan must submit an

application, receive CMS approval, and comply with all applicable requirements in time to offer the plan on January 1, 2006. We believe that delaying the effective date of this interpretation would be contrary to the public interest because it would shorten the already tight time frame for implementing a regional MA plan for some potential applicants. Therefore, we believe it is necessary to have this interpretation of our existing policy take effect at the time as the MA final rule.

Accordingly, we believe there is good cause to waive the 30-day delay in effective date, and this interpretation will be effective on the effective date of the MA final rule, March 22, 2005.

### III. 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. 35).

### IV. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include 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 $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

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 rule will have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**Authority:** Sections 1851 through 1859 of the Social Security Act (42 U.S.C. 1395w–21 through 1395w–28).

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

Dated: March 2, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: March 16, 2005.

**Michael O. Leavitt,**

*Secretary.*

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## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## 50 CFR Part 648

**[Docket No. 050125017–5068–02; I.D. 011905E]**

**RIN 0648–AR57**

## Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Specifications

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** NMFS issues 2005 specifications for the Atlantic bluefish fishery, including state-by-state commercial quotas, a recreational harvest limit, and recreational possession limits for Atlantic bluefish off the east coast of the United States. The final specifications for the fishing year (FY) 2005 are a commercial quota of 10.398 million lb (4.716 million kg), and a recreational harvest limit of 20.157 million lb (9.143 million kg), as adjusted by the research set-aside quota (RSA) of 297,750 lb (135,057 kg). The intent of these specifications is to establish the allowable 2005 harvest levels and possession limits to attain the target fishing mortality rate (F), consistent with the stock rebuilding program in Amendment 1 to the Atlantic Bluefish Fishery Management Plan (FMP).

**DATES:** Effective April 20, 2005, through December 31, 2005.

**ADDRESSES:** Copies of the specifications document, including the Environmental Assessment (EA), Regulatory Impact Review (RIR), and the Initial Regulatory Flexibility Analysis (IRFA) are available from Daniel Furlong, Executive Director, Mid-Atlantic Fishery Management Council, Room 2115, Federal Building, 300 South Street, Dover, DE 19901–6790. The specifications document is also accessible via the Internet at *http://www.nero.nmfs.gov*. The Final Regulatory Flexibility Analysis (FRFA) consists of the IRFA, public comments and responses contained in this final rule, and a summary of impacts and alternatives contained in this final rule. The small entity compliance guide is available from Patricia A. Kurkul, Regional Administrator, Northeast Regional Office, National Marine Fisheries Service, One Blackburn Drive, Gloucester, MA 01930–2298. The 39th Stock Assessment Review Committee