32-101 Requirement for Plant Site Emission Limits (9-14-82)
32-102 Criteria for Establishing Plant Site Emission Limits (9-14-82)
32-103 Alternative Emission Controls (Bubble) (9-14-82)
32-104 Temporary PSD Increment Allocation (9-14-82)
32-800 Air Conveying Systems (1-8-85)
32-990 Other Emissions (8-2-72)

Title 33 Prohibited Practices and Control of Special Classes

33-020 Incinerator and Refuse Burning Equipment (8-2-72)
33-025 Wigwam Waste Burners (8-2-72)
33-030 Concealment and Masking of Emissions (8-2-72)
33-045 Gasoline Tanks (8-2-72)
33-055 Sulfur Content of Fuels (8-2-72)
33-060 Board Products Industries (8-2-72)
33-065 Charcoal Producing Plants (5-15-79)
33-070 Kraft Pulp Mills (9-14-82)

Title 36 Rules for Open Outdoor Burning (1-30-80)

Title 42 Rules of Practice and Procedure—Hearing Procedure (6-29-79)

Title 44 Rules of Practice and Procedure (6-29-79)

Title 45 Rules of Practice and Procedure—Decision and Appeal (6-29-79)

Title 51 Air Pollution Emergencies

51-005 Introduction (8-2-72)
51-010 Episode Criteria (8-2-72)
51-015 Emission Reduction Plans (8-2-72)
51-020 Preplanned Abatement Strategies (8-2-72)
51-025 Implementation (8-2-72)
51-026 Effective Date (8-2-72)

4. Control Strategies for Nonattainment Areas (1-86)

4.1 Portland-Vancouver AQMA-Total Suspended Particulate (12-19-80)
4.2 Portland-Vancouver AQMA-Carbon Monoxide (7-16-82)
4.3 Portland-Vancouver AQMA-Ozone (7-16-82)
4.4 Salem Nonattainment Area-Carbon Monoxide (7-79)
4.5 Salem Nonattainment Area-Ozone (9-19-80)
4.6 Eugene-Springfield AQMA-Total Suspended Particulate (1-30-81)
4.7 Eugene-Springfield AQMA-Carbon Monoxide (6-20-79)
4.8 Medford-Ashland AQMA-Ozone (1-85)
4.9 Medford-Ashland AQMA-Carbon Monoxide (8-82)
4.10 Medford-Ashland AQMA-Particulate Matter (4-83)
4.11 Grants Pass Nonattainment-Carbon Monoxide (10-84)

5. Control Strategies for Attainment and Nonattainment Areas (1-86)

5.1 Statewide Control Strategies for Lead (1-83)
5.2 Visibility Protection Plan (10-24-86)
5.3 Prevention of Significant Deterioration (1-86)

6. Ambient Air Quality Monitoring Program

6.1 Air Monitoring Network (1-86)
6.2 Data Handling and Analysis Procedures (1-86)
6.3 Episode Monitoring (1-86)

7. Emergency Action Plan (1-86)

8. Public Involvement (1-86)

9. Plan Revisions and Reporting (1-86)

OAR Chapter 629-43-043 Smoke Management Plan Administrative Rule (12-12-86)
Directive 1-4-1-601 Operational Guidance for the Oregon Smoke Management Program (12-86)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 405

[BPD-322-F]

RIN 0938-AB68

Medicare Program; Review of Information Collection and Recordkeeping Requirements for Providers of Outpatient Physical Therapy and/or Speech Pathology Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule changes several regulations to reduce information collection and recordkeeping requirements. The requirements, which were identified by the Office of Management and Budget, are contained primarily in the Medicare conditions of participation for providers of outpatient physical therapy and outpatient speech pathology services, and the Medicare conditions for coverage of the services of physical therapists in independent practice. The purpose of this rule is to remove or make modification of those information collection and recordkeeping requirements and to explain the basis for retaining others.

EFFECTIVE DATE: The rules are effective October 15, 1991.

FOR FURTHER INFORMATION CONTACT: Israel Brauner, (301) 966-4640.

SUPPLEMENTARY INFORMATION:

I. Background

The Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)) and implementing regulations authorize the Office of Management and Budget (OMB) to review all information collection and recordkeeping requirements in Federal regulations. OMB's regulations to implement this authority are at 5 CFR 1320.14.

Under § 1320.14(f), OMB may review agency regulations and question whether reporting or information collection requirements are excessive. Questions may be raised about existing regulations, some of which may have been in place prior to the enactment of the Paperwork Reduction Act of 1980 or publication of implementing regulations, as well as proposed new or changed regulations. When an OMB question is raised, the affected agency must publish in the **Federal Register** a notice informing the public which reporting burden or information collection requirement has been questioned and solicit comments on either retaining or revising the requirement. The agency also informs the public whether OMB has approved continuation of existing requirements during the time needed to consider proposed changes.

In a review of collection of information requirements for Medicare providers of outpatient physical therapy and/or speech pathology services, several requirements were identified as possibly being overly prescriptive. In accordance with the requirements of 5 CFR 1320.14(f), a notice was published in the **Federal Register** on August 9, 1985 (50 FR 32238) to inform the public of this action and to state that OMB had granted approval for continued application of the requirements in the interim.

On December 31, 1986, we published in the **Federal Register** (51 FR 47266), a proposed rule in which we suggested removal or modification of certain information collection and recordkeeping requirements, and retention of others, and solicited public comments on the proposals for elimination, change or retention. The requirements identified were contained primarily in the Medicare conditions of participation for home health agencies and providers of outpatient physical therapy and outpatient speech pathology services, and the Medicare conditions for coverage of the services of independent laboratories and physical therapists in independent practice.

Since publication of our proposal, a number of regulations with questioned information collection requirements were significantly revised, usually in response to legislation affecting the program area (see 53 FR 12010, April 12, 1988, and 54 FR 38677 September 20, 1989). Any information collection requirements in those regulations were subject to OMB clearance under 5 CFR 1320.14 and that action superseded our December 31, 1986 proposal.

In response to the December 31, 1986 proposed rule, we received 34 timely items of correspondence on the portion of the rule that pertained to outpatient physical therapy and speech pathology. Some or all of the comments made by five respondents were unrelated to the subject matter of the proposed revisions. These comments addressed concerns about timeframes for social/vocational reevaluation, the importance of physicians' certifications, State versus Federal qualifications for social workers, whether home health agencies can be considered public health agencies, how homebound status is met for home health agencies, and the timing of progress notes. We are not responding to those comments in this regulation because they relate to issues and requirements outside the scope of the proposed rule, which was limited to information collection issues.

II. Comments and Responses

Two commenters generally favored the proposed revisions and did not raise specific concerns.

The comments made by three commenters were so broad and nonspecific that we could not relate them to any particular part of the proposed revisions. These comments expressed the views that government regulations are too restrictive and unfair, that surveyor criteria are antiquated, and that Medicare regulations are blatantly discriminatory. The remaining comments and our responses are discussed below.

Section 405.1720(b). Condition of Participation-Rehabilitation Program. Standard: Arrangements for Social or Vocational Services.

This standard permits rehabilitation agencies to provide social or vocational adjustment services under a written contract with others (that is, other than salaried employees), provided the agency retains responsibility for, and control and supervision of, these services. The terms of the contract must be specified in detail.

Statutory Basis

The introductory phrase of section 1861(p) of the Social Security Act (the Act) defines "outpatient physical therapy services" as services furnished by the agency "or by others under an arrangement with, and under the supervision of," such agency. Section 1861(p)(4)(A)(v) of the Act requires that each clinic or agency meet other health and safety requirements that the Secretary finds necessary.

Proposal

We proposed to revise the regulations by removing explicit contractual requirements such as the geographic areas in which services are to be furnished, the completion and submission of clinical record information, and the participation in conferences required to coordinate patient care. We proposed instead to require that personnel under contract be held accountable for meeting the same agency requirements as salaried personnel, as set forth in 42 CFR part 405, subpart Q, and that the agency be responsible for control and supervision of services.

Comment: One commenter expressed concern that the requirement may conflict with the conditions of participation for skilled nursing facilities (SNFs) that require SNFs to retain responsibility for social and vocational services that are provided to their inpatients under contract.

Response: New requirements for Medicare SNFs and Medicaid nursing facilities (NFs) are effective October 1, 1990 (see final rules published February 2, 1989 at 54 FR 5316 and December 29, 1989 at 54 FR 53611). There is no conflict. Under the new requirements, § 483.45 requires a facility that does not provide specialized rehabilitative services needed by its residents to obtain those services from an outside provider in accordance with § 483.75(j). A rehabilitation agency could be the outside provider. Section 483.75(j) requires a Medicare SNF to make arrangements for services furnished to its residents by an outside resource. This means that the SNF, rather than the rehabilitation agency, becomes responsible as the provider of services. A Medicaid NF, under the same section, is required to make an arrangement or an agreement and assume responsibility for obtaining services that meet applicable standards and principles, and for the timeliness of the services. Consequently, when a Medicare SNF or Medicaid NF obtains services for its residents from a rehabilitation agency as an outside resource, the SNF or NF assumes responsibility for the services.

In addition, although the commenter did not mention hospitals, sections 1862(a)(14) and 1866(a)(1)(H) of the Act require that a Medicare hospital must make arrangements for all Medicare covered services (other than the services of physicians and certified registered nurse anesthetists) furnished to its patients by an outside resource.

The basic requirements in § 405.1720 that a rehabilitation agency provide "social or vocational adjustment services to all patients in need of such services" applies only to the agency's own patients, not to patients of hospitals, SNFs or NFs, that have an arrangement or agreement with the agency as an outside resource. In the latter case, the primary provider is responsible for seeing that the needs of its patients are met. We are adding a clarifying statement to remove any confusion on this point. Therefore, the responsibility required in § 405.1720(b) pertains only to services furnished to the agency's own patients.

Provisions in Final Rule

We are revising proposed § 405.1720(b) to remove the 6 numbered contract requirements, and substituting a general statement to specify the requirements of this standard.

Section 405.1721(a). Condition of Participation-Arrangements for Physical Therapy and Speech Pathology Services to be Performed by Other than Salaried Organization Personnel. Standard: Contract Provisions

This standard contains specific requirements for the terms of a contract under which an organization provides outpatient physical therapy or speech pathology services under an arrangement with others.

Statutory Basis

Section 1861(p)(4)(A)(i) of the Act requires that each clinic or agency have the necessary personnel to carry out the program offered. Sections 1861(p)(4)(A)(v) and (B) provide that the clinics and agencies must meet the health and safety requirements the Secretary finds necessary.

Proposal

We proposed to delete the list of contractual provisions and instead require that all nonsalaried personnel furnishing services meet the same requirements as salaried personnel. We also proposed to make a conforming change to this section to make it consistent with other proposed changes published in the **Federal Register** on February 24, 1986 (51 FR 6429) that would include "podiatrist" in the definition of "physician."

Comment: One commenter expressed concern about the requirement that services be furnished at a specific site and that the survey verify what equipment is available, while another commenter expressed concern that too much time is required for reviewing records and keeping records not related to patient care and outcomes.

Response: We agree that parts of § 405.1721(a) concerning the site of contracted services and associated recordkeeping appear to be overly burdensome and unnecessary in terms of assuring patient health and safety and we are further revising this section to delete paragraphs (a)(4) and (a)(5). Requirements for adequate facilities and equipment are addressed in §§ 405.1718(b), 405.1719(b), 405.1724 and 405.1732.

Provisions in Final Rule

We are revising the content of § 405.1721(a) as proposed, and in addition, are also deleting the recordkeeping requirements in paragraphs (a)(4) and (a)(5) of that section. For editorial clarity, we are designating the introductory text as paragraph (a) and redesignating existing paragraph (a) as paragraph (b).

Since the clinical records requirements are similar for both providers and independent therapists, we will discuss §§ 405.1722 and 405.1736 together.

Section 405.1722. Conditions of Participation-Clinical Records

This section specifies requirements for maintaining records for providers of outpatient physical therapy and speech pathology services.

Statutory Basis

Section 1861(p)(4)(A)(iii) of the Act requires that providers of outpatient physical therapy and outpatient speech pathology services must maintain clinical records on all patients.

Proposal

We planned no changes to § 405.1722, because the recordkeeping requirements are consistent with accepted standards of care. However, we requested comments on which of the requirements are still needed to ensure that medically necessary services of acceptable quality are furnished to program beneficiaries.

Comment: Three commenters objected to the requirements that clinical records be maintained for all patients, but they did not specify alternatives. Two other commenters stated that clinical records should be maintained on all patients.

Response: We believe that health and safety of all patients can be assured only if adequate clinical records are maintained. As noted above, this view is expressly stated in the statute at section 1861(p)(4)(A)(iii), which excludes any service furnished by a clinic or rehabilitation agency unless the provider "maintains clinical records on all patients."

Comment: Two commenters objected to the requirements pertaining to maintaining documentation for all patients, in that individuals participating in other insurance programs or who submit bills to private pay carriers do not need to have their documents reviewed by HCFA personnel.

Response: We disagree. We believe that adequate documentation of each patient's condition is necessary in order to ensure the health and safety of the patient. Furthermore, as noted earlier, the recordkeeping requirements are consistent with accepted standards of care.

Comment: One commenter stated that to have detailed treatment noted for each patient visit is excessive, expensive and inappropriate. The state of art for professional documentation has changed over the last decade and documentation every two weeks of patients' progress would be more appropriate.

Response: This comment appears to relate to the requirement that the medical record contain documentation of the care and services provided. However, we do not believe a clinical record would be adequate if it did not document each occasion of service. Progress notes, on the other hand, are only required to be completed periodically.

Section 405.1736(b) and (d) Condition for Coverage-Clinical Records. Standard: Content, and Standard: Retention and Preservation

These standards specify requirements for the content and retention of clinical records by physical therapists in independent practice.

Statutory Basis

Section 1861(p) of the Act provides that independently practicing physical therapists must meet those requirements that the Secretary may find necessary.

Proposal

We planned no changes to § 405.1736(b) and (d) because the recordkeeping activities described therein are consistent with accepted standards of practice. Nevertheless, we requested comments on which of the requirements may still be necessary to ensure the quality and appropriateness of services and which may no longer be necessary. The majority of commenters shared a general view that requirements for specific clinical records documentation of physician involvement should not be applied to non-Medicare patients.

On March 28, 1990 (55 FR 11372), we published a final rule that revised 42 CFR 405.1717 and 405.1733 to remove the requirements that physicians provide the referrals, periodic visits, and direction of treatment for non-Medicare patients. That final rule was based on section 1861(p) of the Act, as amended by section 8424 of the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100–647). Accordingly, there is no need for further revision.

Provisions in Final Rule

We did not propose changes to §§ 405.1722 and 405.1736(b) and (d) but merely published to solicit comments. No changes to the rules are required.

III. Regulatory Impact Statement

Executive Order (E.O. 12291) requires us to prepare and publish a final regulatory impact analysis for any final regulation that meets any of the E.O. 12291 criteria for a "major rule"; that is, that would be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all physical therapists, and all providers of outpatient physical therapy and outpatient speech pathology services are treated as small entities.

We examined each provision in this preamble as to potential effects on affected providers. Several changes will benefit providers by reducing certain recordkeeping requirements, such as those relating to personnel records and contractual provisions. However, we are retaining those currently existing requirements we believe are necessary to assure compliance. The time and manpower required by providers during the survey process to demonstrate

compliance with the retained requirements will be minimal.

Therefore, we have determined that this final rule, in itself, will not produce any effects that will meet any of the criteria of E.O. 12291. For the same reasons, we have determined and the Secretary certifies that this final rule will not have significant effect on a substantial number of small entities. Thus, a regulatory impact analysis under E.O. 12291 and a regulatory flexibility analysis under the RFA are not required.

Section 1102(b) of the Act requires the Secretary to prepare a regulatory analysis if a final rule 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 define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area (MSA) and has fewer than 50 beds.

We are not preparing a rural impact statement since we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on the operations of a substantial number of small rural hospitals.

IV. Information Collection Requirement

Sections 405.1720 and 405.1721 of this rule contain information collection requirements subject to the Office of Management and Budget review under to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501). These requirements will be sent to OMB for review, and a notice will be published in the **Federal Register** after approval is obtained.

List of Subjects in 42 CFR Part 405

Administrative practice and procedure, Certification of compliance, Clinics, Contracts (Agreements), End-Stage Renal Disease (ESRD), Health care, Health facilities, Health maintenance organizations (HMO), Health professions, Health suppliers, Home health agencies, Hospitals, Inpatients, Kidney diseases, Laboratories, Medicare, Nursing homes, Onsite surveys, Outpatient providers, Reporting and Recordkeeping requirements, Rural areas, X-rays.

For reasons set forth in the preamble, 42 CFR chapter IV, part 405, subpart Q is amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart Q—Conditions of Participation: Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and/or Speech Pathology Services; and Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice

Subpart Q—[Amended]

1. The authority citation for subpart Q continues to read as follows:

Authority: Secs. 1102, 1861(p), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(p), 1395hh).

2. In § 405.1720, the introductory text and paragraph (b) are revised to read as follows:

§ 405.1720 Condition of participation-rehabilitation program.

At a minimum, a rehabilitation agency provides physical therapy or speech pathology services, and a rehabilitation program that in addition to physical therapy or speech pathology services, includes social or vocational adjustment services to all its patients in need of such services by making provision for special, qualified staff to evaluate the social or vocational factors involved in a patient's rehabilitation, to counsel and advise on social or vocational problems arising from the patient's illness or injury, and to make appropriate referrals for required services.

When hospitals, skilled nursing facilities, or Medicaid nursing facilities obtain services for their patients from the agency this requirement does not apply to those patients.

* * * * *

(b) *Standard: Arrangements for social or vocational services.* If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide such adjustment services by means of a written contract with others who must meet the same requirements and responsibilities as salaried personnel as set forth in this subpart. The contract must specify the period of time the contract is to be in effect and the manner of termination or renewal, and provide for retention by the agency of responsibility for, and control and supervision of, the services.

3. Section 405.1721 is revised to read as follows:

§ 405.1721 Condition of participation-arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.

(a) *Conditions.* When an organization provides outpatient physical therapy and/or speech pathology services under an arrangement with others, such services are to be furnished in accordance with the terms of a written contract, which provides for retention by the organization of professional and administrative responsibility form and control and supervision of, such services.

(b) *Standard: Contract provisions.* The terms of the contract:

(1) Require that personnel furnishing services must meet the same requirements as salaried personnel as set forth in this subpart;

(2) Specify the financial arrangements that provide that the contracting outside resource may not bill the patient or the health insurance program for covered services (because, pursuant to section 1861(w)(1) of the Act (42 U.S.C. 1395x(w)(1)), covered services furnished under arrangements must be billed through the provider exclusively and receipt of payment by the provider for such services on behalf of an entitled individual discharges the liability of such individual or any other person to pay for such services); and

(3) Specify the period of time the contract is to be in effect and the manner of termination or renewal.

(Catalog of Federal Domestic Assistance Program No. 13.774, Medicare-Supplementary Medical Insurance Program)

Dated: March 11, 1991.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: May 16, 1991.

Louis W. Sullivan,

Secretary.

[FR Doc. 91-21802 Filed 9-12-91; 8:45 am]

BILLING CODE 4120-01-M

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42 CFR Part 417

[BPD-422-F]

RIN 0938-AD-14

Medicare Program; Explanation of Enrollee Rights and Other Provisions Applicable to Health Maintenance Organizations and Competitive Medical Plans

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This rule revises current Medicare requirements relating to health maintenance organizations and competitive medical plans. It eliminates the requirement that an organization enroll two new Medicare beneficiaries for each present Medicare enrollee converted from a cost to a risk contract (the "two-for-one" rule), expands the amount and type of information which an organization must provide to enrollees, and requires annual notice of enrollees' rights under the plan. This rule also authorizes HCFA to terminate a contract with an organization for noncompliance with the composition of enrollment standard requiring that no more than 50 percent of an organization's membership be comprised of Medicare or Medicaid enrollees (hereinafter referred to as the "50/50 rule") and authorizes sanctions when an organization fails to comply with the 50/50 rule or the terms of any waiver or exception to that rule.

These provisions conform our regulations with changes made by the Omnibus Budget Reconciliation Acts of 1986, 1987 and 1989.

EFFECTIVE DATE: These regulations are effective October 15, 1991, except for the definition of "affiliated organization" at § 417.401, which is effective September 14, 1992.

FOR FURTHER INFORMATION CONTACT: Joan Mahanes at (301) 966–4642 for two-for-one rule, and explanation of enrollee rights. Jean LeMasurier at (202) 619–2070 for 50 percent composition of enrollment rule.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

Section 1876 of the Social Security Act (the Act) as amended by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Public Law 97–248, provides for Medicare payment on a predetermined, per capita basis to eligible organizations that have entered into risk contracts with HCFA, and for payment on an interim basis subject to annual adjustments based on reasonable costs to eligible organizations that have reasonable cost contracts. The definition of an eligible organization includes health maintenance organizations (HMOs) that have been Federally qualified under title XIII of the Public Health Service (PHS) Act, and competitive medical plans (CMPs) that meet the requirements of section 1876(b)(2) of the Act. Eligible organizations which choose to contract on a risk basis assume financial risk for providing health care services to enrolled members, in exchange for a prospectively determined periodic payment made by the member or on the member's behalf. Medicare enrollees of organizations with risk contracts generally are required to receive covered services only through the organization, except for emergency services and urgently needed out-of-area services. Medicare enrollees of organizations with cost contracts may receive covered services through the organization or through any other Medicare qualified provider or supplier.

B. Two-for-One Rule

Section 114(c)(2)(A) of TEFRA provided that HMOs that had enrolled individuals under an existing cost contract could convert such individuals to enrollment under a new risk contract only under limited circumstances. This provision, known as the two-for-one rule, required the organization to enroll two "new"Medicare enrollees under its risk contract for each "current non-risk Medicare enrollee" it converted to enrollment under the risk provisions of its contract. As defined in section 114(c)(2)(D) of TEFRA, a Medicare enrollee was "new" if the individual was not enrolled in the organization either prior to the time that the organization entered into a risk contract or prior to the time that the individual became entitled to Medicare. Regulations implementing the two-for-one rule and the established procedures for conversion are at 42 CFR 417.446. The Omnibus Budget Reconciliation Act of 1986 (OBRA 86), Public Law 99–509, repealed this conversion requirement.

C. Enrollment Restrictions

Section 1876(c)(3)(B) of the Act provides that an eligible Medicare beneficiary may enroll with an eligible organization which has a contract with Medicare in the manner prescribed in regulations and may terminate his enrollment with the organization as of the beginning of the first calendar month after the beneficiary requests that his enrollment be terminated.

D. Enrollee Rights

Section 1876(c)(3)(C) of the Act provides that the Secretary may prescribe the proceduress and conditions under which an eligible organization under contract with HCFA may advertise its product and enroll eligible Medicare beneficiaries. Prior to OBRA 86, there were no specific statutory provisions pertaining to disclosure of benefits, services and patient rights for Medicare beneficiaries enrolling in an HMO or CMP, although our regulations at 42 CFR 417.436 require that the organization maintain membership rules explaining certain matters, such as procedures for paying premiums and other charges and for obtaining services from the organization. The membership rules must also explain the organization's procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and enrolled Medicare beneficiaries, as required by section 1876(c)(5)(A) of the Act. Our regulations also require that the organization provide a copy of the rules to each Medicare enrollee and that it notify enrollees at least 30 days prior to any change in the rules.

Section 4011(b) of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), Public Law 100–203, amended section 1876(c)(3) of the Act by requiring that organizations with risk contracts notify individuals considering enrollment or already enrolled with the organization of the organization's option to terminate or fail to renew the contract at the conclusion of its term, and that non-renewal of the contract may result in termination of the individual's enrollment in the organization.

E. Fifty Percent Composition of Enrollment

Section 1876(f) of the Act requires that an HMO or CMP with a Medicare contract maintain an enrollment consisting of no more than 50 percent Medicare beneficiaries and Medicaid recipients. Prior to the enactment of OBRA 86, this section also authorized the Secretary to modify or waive the 50/50 rule if he or she determined that special circumstances warranted a modification or exception and the organization was making reasonable efforts to enroll individuals not entitled to Medicare or Medicaid. Regulations at 42 CFR 417.413 implemented the statutory requirement for composition of enrollment and the waiver or exception authority.

II. Notice of Proposed Rulemaking

On July 22, 1988 we published a proposed rule with a 60 day comment period (53 FR 27718) that would revise subpart C of 42 CFR part 417. The proposed rule would incorporate OBRA 86 and OBRA 87 provisions essentially without elaboration and make additional clarifying revisions. Briefly, these proposed changes to the regulations would—

Two-for-One Rule—

• Delete all reference to the two-for-one rule.

Enrollment Restrictions

• Require organizations converting from a cost to a risk contract to inform current non-risk Medicare enrollees within 60 days of signing a risk contract of their right to remain as cost members until HCFA determines, for administrative reasons or because there are fewer than 75 current nonrisk Medicare enrollees remaining in the organization, that remaining cost enrollees must be covered under the risk provisions of the contract. Current nonrisk Medicare enrollees must also be informed of their right to convert at any time to a risk enrollment.

Composition of Enrollment

• Provide that HCFA may waive compliance with composition of enrollment requirements for an organization where Medicare beneficiaries and Medicaid recipients constitute more than 50 percent of the population in the geographic area.

• Provide a waiver of the composition of enrollment requirements for a government owned and operated organization that has taken and is making reasonable efforts to enroll individuals who are not entitled to Medicare or Medicaid. Such a waiver may not exceed a period of up to three years after the date the organization first enters into a Medicare contract.

• Specify that an organization which has received a waiver or exception to the composition of enrollment rule on or before October 21, 1986 may continue its waiver or exception if it makes reasonable efforts to meet scheduled enrollment goals approved by HCFA.

• Specify and describe the sanctions that HCFA may apply against an organization not in compliance with the composition of enrollment rule prior to instituting termination proceedings.

• Specify that HCFA may terminate an organization's contract if the organization does not substantially comply with the composition of enrollment requirements.

Enrollee Rights

• Require organizations to inform eligible individuals in their marketing materials that the organization's contract with HCFA is subject to termination at any time during the year, or to nonrenewal at the expiration of the contract's term, and that termination or expiration and nonrenewal of an organization's contract will result in termination of an individual's enrollment.

• Add additional requirements to make clear that a copy of the membership rules must be furnished to each Medicare enrollee at the time of enrollment and at least annually thereafter.

• Require that the membership rules include an explanation of the benefits provided by the organization, the amount of any premium or other charges imposed on the beneficiary, restrictions on coverage for non-emergency services that are not received through the organization, the organization's coverage of emergency services and services which are urgently needed while the enrollee is absent from the organization's geographic area, and appeal rights of enrollees.

• Require that membership rules state that the organization's contract with HCFA may be terminated, either by HCFA or the organization, for various reasons such as failure by either party to renew the contract at the expiration of its term, and that beneficiaries will, if the contract is terminated, be terminated as well as from their enrollment in the organization.

Clarifications of Previous Regulations

• Define extended absence from the organization's geographic area as absent for a period of more than 90 days but less than one year.

• Clarify that the exception permitting continued enrollment of beneficiaries during an extended absence is available to all CMPs, but only to those Federally qualified HMOs that are affiliated with another eligible organization serving the geographic area where the beneficiary will be located temporarily.

• Define an "affiliated organization," for purposes of the exception permitting continued enrollment of beneficiaries during an extended absence, as an organization which has a contract under section 1876 of the Act, and (1) is under the common ownership or control of another organization seeks to retain absent members, or (2) has written agreement in effect with that organization to furnish items and services to enrollees who are on an extended absence from the geographic area of the original organization.

III. Analysis of and Response to Public Comments

In response to the July 22, 1988 proposed rule, we received eight timely items of correspondence. The comments were from groups health associations, a medical school, health insurance plans and a law firm. A summary of these comments and our responses to them are discussed below:

A. Two-for-One Rule

We received no public comments on this area.

B. Enrollee Rights

Comment: One commenter suggested that § 417.436(a) be revised to state that organizations should maintain membership rules "for any other matters related to membership which HCFA may prescibe" rather than "any other matters that HCFA may prescribe", because this modification more accurately states the intended scope of this provision "which assures rules which are reasonable and necessary for the member to make well informed decisions".

Response: We do not agree that such a modification is necessary. We do not intend to require plans to include in membership rules matters which are of no interest or utility to Medicare enrollees, but we want to assure that the scope of membership rules includes all matters which Medicare enrollees need to know.

Comment: One commenter stated that it is meaningless to include premium information in membership rules because, for enrollees who are also enrolled under another group, the operative figure would be the actual out-of-pocket expenses for the enrollee, and that figure would vary depending on the group's contribution and/or the benefit level selected by or for the enrollee. The commenter suggested that membership rules simply state the source from which the permium amount could be obtained.

Response: As a result of this comment we have reevaluated our proposal. Section 1876(c)(3)(E) of the Act does not require that premium information be included in membership rules. Therefore, we are accepting the recommended change and revising § 417.436 to permit organizations to omit the actual premium from the membership rules, if it is not feasible to include it, as long as the source for the information is clearly identified and a telephone number is included. However, this change does not affect the organization's obligation to inform HCFA and enrollees of changes to the premium in a timely fashion, as required by § 417.436(c).

Comment: One Commenter requested clarification of HCFA's requirement that enrollees be informed of any services that the organization chooses to furnish outside of the organization's own providers.

Response: As requested, we are clarifying § 417.436(a)(5) to include an additional example of the services

which should be disclosed. Organizations contracting on a risk basis must disclose any exceptions to the lock-in restriction permitted under § 417.448, such as, any that may apply in a "preferred provider organization," which permits members to choose to receive specified services from providers with whom the organization does not have arrangements.

Comment: One commenter stated that HCFA's requirement that plans include in membership rules the fact that the organization's contract with the Medicare program may end may be confusing to beneficiaries who have coverage from a group contract as well as from the Medicare contract. The organization suggested that continuing coverage under other contract should be described as well.

Response: We have no objection to including additional information not strictly pertinent to the Medicare contract in the membership rules, as long as the information will alleviate confusion among enrollees, and as long as the organization submits the language for review according to § 417.436(c).

C. Fifty-percent Composition of Enrollment Requirement

Comment: One commenter stated that there are certain factors beyond its control which may cause the organization to violate the rule requiring that no more than 50 percent of an organization's members be comprised of Medicare and Medicaid enrollees. For instance, an employer group could drop the plan without sufficient notice, the expected number of commercial enrollees could fail to enroll, or a higher number of retirees of a commercial plan, who are also Medicare beneficiaries, could enroll in the plan. The organization requested that Medicare beneficiaries who are members of employer group health plans or other commercial groups be permitted to enroll even though the plan is in violation of the 50/50 rule.

Response: The 50/50 rule affords protections to all Medicare beneficiaries whether they are enrolled in an HMO or CMP through an employer plan or on their own. These protections would be nullified if group members were allowed to enroll in violation of the 50/50 rule.

While we intend to enforce the 50/50 rule as required by the law, we do not intend to impose sanctions arbitrarily. If an organization inadvertently violates the 50/50 rule, it should notify HCFA immediately and advise HCFA of how it intends to rectify the violation, such as closing Medicare enrollment or seeking more commercial enrollees.

Comment: One commenter questioned the provision of § 417.313(d)(2)(ii) which states that a waiver of the 50/50 rule for organizations which are owned and operated by a government entity may not be extended beyond 3 years, since the statute at section 1876(f)(2) of the Act does not prohibit extensions of the waiver.

Response: We disagree. The statute clearly states that the Secretary may waive the requirement "only" with respect to the first three contract years, thus implicitly prohibiting any extensions.

D. Termination of Contract for Failure to Comply with 50/50 Rule

Comment: Several commenters questioned HCFA's authority to terminate the contract of a plan that substantially fails to meet the 50/50 rule or the terms of any waiver or exception to that rule. The commenters stated that such a termination goes beyond the legislative intent and is an excessive penalty.

Response: The requirement in section 1876(f) of the Act is that an organization must meet the 50/50 requirement. Under the plain language of section 1876(i)(1)(C) of the Act, the Secretary is expressly authorized to terminate the contract of any organization that substantially fails to comply with the requirements of section 1876(f). If an organization's failure to comply with the rule, or the conditions of any modification or waiver of the rule, is determined to be insubstantial, HCFA may take interim sanctions permitted under the law, i.e., suspension of enrollment, under the provisions of section 1876(f)(3) of the Act. Suspension of enrollment protects beneficiaries enrolled in the organization by preventing the violation of the 50/50 rule from becoming worse. If the violation is so substantial that suspension of enrollment will not make a significant improvement, termination of the contract is the only other method available to HCFA to protect beneficiaries from the effects of an organization's failure to comply with contract conditions.

Comment: One commenter requested that HCFA be more specific concerning the requirement that organizations "substantially" meet the 50/50 composition of enrollment requirement, and give examples of what efforts to meet the 50/50 requirement HCFA would find "reasonable."

Response: The number of Medicare and Medicaid recipients enrolled in an organization should never be above 50 percent of the total enrolled population in order to meet the 50/50 rule, as required under section 1876(f) of the Act. The organization must ensure that this is the case and must notify HCFA when it is in jeopardy of violating the rule. The organization that is diligent in following the rules, keeping HCFA informed, and correcting temporary enrollment imbalances quickly, will be considered to be in substantial compliance with the rule. HCFA expects organizations to devise plans for correcting violations of the 50/50 rule. Examples of efforts HCFA would find reasonable to correct violations would be documented efforts, with a likelihood of success, to recruit private enrollees or employer groups for enrollment and/or voluntary closure of enrollment of Medicare and Medicaid recipients. Lack of diligence in informing HCFA of enrollment imbalances, or in devising and pursuing corrective action, and/or inability to demonstrate success in, or the likelihood of success of, corrective action, will be considered "substantial" violation of the 50/50 rule.

Comment: One commenter was concerned that it is prevented from enrolling the number of Medicaid recipients it might otherwise wish to because the 50/50 rule counts Medicaid enrollees against the 50 percent limit and because its request to HCFA for a waiver was denied. The organization stated that it should be the mission of publicly sponsored organizations to serve publicly sponsored patients.

Response: The statutory requirements are clear on this issue. We have no authority to make an exception on the basis suggested by the commenter.

E. Distribution of Membership Rules

Comment: One commenter suggested that annual distribution of complete membership rules may be too costly and that HCFA consider an abbreviated booklet or newsletter article as meeting the requirement of the statute at section 1876(c)(3) of the Act. The commenter also requested an interpretation of the requirement that membership rules be distributed at the time of enrollment.

Response: We recognize that organizations will incur additional administrative costs because of annual distribution of membership rules. However, we cannot agree as a general rule that abbreviated booklets or addenda to previously published material would satisfy the intent of the law. Each case would have to be judged on its merit according to whether the presentation of the material will serve the purpose of formally notifying enrollees of their rights and responsibilities as enrollees of the organization. We suggest that each organization consult with its contract officer before incurring unnecessary

expense in reprinting all handbooks. HCFA will advise organizations, if requested, whether less expensive alterations will suffice. Newsletter articles would not be acceptable because they are likely to be overlooked or discarded by enrollees.

Marketing material must contain an explanation of membership rules and other information sufficient for the beneficiary to make an informed decision about enrollment. The purpose of membership rules, on the other hand, is to inform beneficiaries of their rights and responsibilities once enrolled in the organization. We encourage organizations to give enrollees the membership rules as early as possible after the application for enrollment is received. However, in every case the enrollee should be given the membership rules prior to the effective date of the enrollment.

Comment: One commenter requested that HCFA specifically state the meaning of the requirement that organizations "furnish" a copy of membership rules to enrollees. The commenter suggested that distribution of membership rules be left up to employer and other groups, when appropriate, rather than distributed directly by the organization, and that the timing of the annual distribution similarly be left up to groups.

Response: We see no problem with organizations coordinating the preparation of membership rules with groups when Medicare enrollees are also enrolled under another contract with an employer or other group. We also see no problem with the group distributing the rules, as long as the organization recognizes that it remains responsible if the group fails to comply with the rule. We are not changing the proposed rule, as we prefer that organizations consult individually with their contract officers on appropriate methods and procedures for distribution. If membership rules vary group by group, each version should be submitted for review under the provisions of § 417.436(c).

F. Absence of the Enrollee from the Geographic Area

Comment: One commenter objected to the proposed limitation of one year on "extended absence" from the geographic area during which an enrollee would be permitted to retain membership in the organization. The commenter termed such limitation "unduly restrictive" because there may be some instances when absences could extend beyond one year and the organization may be willing to retain the beneficiary. Two commenters objected because the 90 day limit on temporary absences after which disenrollment would be warranted and the one year limit on retention of enrollees who are absent from the geographic area are not "statutorily based", and they disadvantage Medicare enrollees.

Response: We disagree. The provision in § 417.460(a)(2)(iv) was originally intended to assist beneficiaries who take extended vacations in other areas of the country, and did not wish to disenroll from the "mother" organization. However, it was never meant to include persons who would be leaving the geographic area for more than a few months or those who leave permanently. We believe the time limits we proposed, 90 days and one year respectively, are more than enough time to accommodate seasonal preferences and other extended, but nonpermanent, absences from the geographic area, and are advantagous to enrollees. The statute at section 1876(d) requires enrollees to reside within the organization's geographic area. It is within our authority to define by regulation the length of absence which indicates the beneficiary no longer lives in that area.

Beneficiaries must be disenrolled if they "permanently move" out of the service area. There are two ways to determine whether a permanent move has occurred: First, as described in § 417.460(a)(2)(i)(A), if there is a written statement from the beneficiary, or "other evidence acceptable to HCFA", and second, if an extended absence extends beyond a certain period of time, the beneficiary may be "deemed" to have made a permanent move. Previously, this period of time was defined to be 90 days.

This regulation amends this provision, and makes a new distinction. If a beneficiary is on an "extended absence," which is defined as more than 90 days, the HMO may deem the absence to be permanent, and disenroll the beneficiary, or if the HMO determines that the beneficiary does not intend to make a permanent move, it may retain the beneficiary if the various conditions in §§ 417.460(a)(2)(iv) are met. However, HCFA has determined that for Medicare purposes, a beneficiary who is absent for more than a year cannot reasonably be considered to "reside" in the service area, and must be disenrolled. Accordingly, §§ 417.460(a)(2)(iv)(B) has been revised to make clear that beneficiaries may remain enrolled during extended absences, but not if they "reside" outside the service area.

Comment: One commenter stated that HCFA should reconsider rules concerning retention of members who are absent from the geographic area, depending on whether the enrollee is a member of the organization under another group contract. The organization stated that enrollees who are absent for more than one year and must be disenrolled under the Medicare contract may lose the other group membership as well, because the group does not cover enrollment in an organization outside a specific geographic area.

Response: These rules govern only Medicare enrollment in an HMO/CMP and are being promulgated to afford all Medicare beneficiaries protection, whether they are enrolled by virtue of their relationship with a former employer or on their own. We understand that a group retiree's situation may be different from an individual enrollee's. It is true, for example, that a group retiree may suffer consequences beyond the individual's control if he or she is disenrolled after a one year absence. The former employer might cease coverage of health benefits altogether or reduce the amount it pays on the group retiree's behalf. The HMO/CMP should clearly state in its marketing material the need for group retirees to consult with their former employers if they will be absent from the geographic area.

If the employer group would terminate coverage if it knew that the beneficiary had left the area, then the beneficiary should be made aware of the implication of his or her decision to leave. Group retirees who lose group coverage because their former employer does not cover enrollment in an organization outside a specific geographic area have several options. Sometimes employers offer other kinds of group coverage outside of the specific area (such as Medigap policies) which a retiree might elect. The group retiree could also join the affiliated organization, or any other organization with a Medicare contract as an individual enrollee.

G. Geographic Limitation

Comment: One commenter pointed out that § 417.460(a)(2)(iv)(D), which requires that organizations that wish to limit the geographic areas in which they will retain members during an extended absence may do so only if there is an "affiliated organization" in that area, does not contain a definition of the term "affiliated organization". The commenter suggested that an affiliated organization should be defined as one where a contract exists, where a second organization agrees to provide or arrange services of the first organization, or alternatively, plans

should be free to "lock-in" beneficiaries to any provider with which it has made arrangements. The same commenter stated that the legislative and regulatory history does not support a definition which would require "affiliated organizations" to be under common ownership or control.

Response: We agree with the commenter that it is desirable to define the term "affiliated organization," and have revised the regulations accordingly. We also agree with the commenter that the definition should not be limited to organizations under common ownership or control of the original organization, although we do not agree that the statute or legislative history mandates such a result, or would prevent HCFA from exercising its rulemaking authority to implement a different policy. Therefore, under the new definition, an organization may be "affiliated" if it is under common ownership or control of, or has a written agreement with, the organization which wishes to retain members who leave its geographic area.

However, we believe that written agreements or common ownership alone would not provide sufficient protections to beneficiaries who exercise the option of remaining enrolled in an organization during an extended absence. Therefore, we have chosen to impose an additional limitation on the definition of "affiliated organization." The affiliated organization must also have a Medicare contract under section 1876. Since the affiliated organization must therefore meet the qualifying conditions in §§ 417.410 through 417.418 and all the other requirements of subpart C which the original organization must meet, it will ensure that beneficiaries receive the same quality of services from the affiliated organization as from the original organization. We have chosen to delay the implementation date for the definition for one year in order to give organizations an opportunity to comply with the rule.

Comment: The same commenter and several other commenters stated that the limitation we proposed, to confine the extended absences which could be covered under the provisions of § 417.460(a)(2)(iv), to absences in which the enrollee remains within the United States, should be stricken. One commenter stated that disenrollment should be an option but not a requirement.

Response: We disagree. Section 417.460(a)(2)(iv)(B) permits a beneficiary to remain enrolled if he or she is absent from the geographic area for more than 90 days, but only if the HMO or CMP provides the enrollee with the full scope of Medicare covered services as well as any additional or supplemental benefits. There are at least two reasons why it is impossible for any HMO or CMP to comply with this requirement if the beneficiary is absent from the United States for an extended period.

First, section 1862(a)(4) of the Act has the effect of precluding Medicare coverage for any service provided outside the United States (with narrow exceptions for certain services in Canada and Mexico). Therefore, since no services provided outside the United States are considered to be covered, it is not possible for an HMO or CMP to meet the requirement to provide an enrollee with Medicare covered services if that enrollee is outside the United States. We note that if there were any basis for concluding that this prohibition did not apply to services provided by an HMO or CMP, it would mean that all HMOs and CMPs would be required to provide emergency and out-of-area urgently-needed services to all of their Medicare enrollees anywhere in the world.

Second, it is not possible to provide Medicare covered physicians' services (or any other Medicare covered services which require the involvement of a physician) outside the United States. Section 1861(r) of the Act defines a physician as someone "legally authorized to practice medicine and surgery by the State in which he performs such function * * *" (emphasis added). Thus, even if services are performed by physicians licensed in the United States, they would not be performing the services in the States which license them. Furthermore, the statutory definition of a State under sections 1861(x) and 210(h) of the Act clearly does not include a foreign country.

Comment: One commenter felt that HCFA should permit HMOs/CMPs to retain enrollees who leave the country for more than 90 days because: (1) HCFA may not object to an organization's selection of additional benefits (beyond the scope of Medicare covered services) except if the Secretary determines that the additional services will substantially discourage enrollment of Medicare beneficiaries in the organization (section 1876(c)); (2) the exclusion of payment for items and services furnished outside the United States does not apply to HMOs/CMPs, since HCFA does not pay HMOs/CMPs for items and services furnished to enrollees; (3) the rule has a discriminatory impact on ethnic Americans who travel outside the United States during their retirement years; (4) the rule infringes on the beneficiary's constitutional right to travel and prevents Medicare contracting HMOs/CMPs from bridging this coverage gap in the Medicare program; (5) HMOs/CMPs may be subject to unfair recoupment of monthly payments by HCFA if the enrollee leaves the country without informing the organization; and (6) HCFA cannot enforce the rule.

Response: We considered the commenter's arguments and decided not to change the proposed rule for the following reasons: (1) and (2) An organization cannot furnish the full scope of benefits, as required by § 417.460(a)(2)(iv) to enrollees absent from the United States, as stated in the previous response. Therefore, it is not possible for an HMO or CMP to meet the requirement to provide an enrollee with Medicare covered service if that enrollee is outside the United States. (3) section 1862(a)(4) of the Act clearly precludes payment in most instances for any services provided outside the United States to Medicare beneficiaries who are not enrolled in HMOs/CMPs. Therefore, rather than being discriminated against, HMO enrollees who travel abroad are in a better position than other beneficiaries, if the HMO chooses to pay for services during absences of 90 days or less. (4) HMOs/CMPs may provide coverage of services they choose as optional supplemental benefits, including services provided outside the United States, if the enrollee is absent from the country for 90 days or less. However, organizations may not retain as an enrollee a beneficiary who is absent from the United States for more than 90 days as discussed in the previous response. (5) Organizations should include the rule requiring disenrollment of beneficiaries leaving the United States for more than 90 days in their membership rules, but are not responsible for enrollees' failure to notify the organization of such absences. On the other hand, the organization that has been informed of an enrollee's absence from the country, for instance by the presentation of a bill for emergency services received while outside the United States, is expected to follow up to ensure that the enrollee has or will return within 90 days, or to initiate disenrollment according to the procedures outlined in § 417.460(a)(2). (6) HCFA will enforce the rule by requiring HMO/CMP compliance and by monitoring the performance of organizations under the contract.

Comment: Several commenters questioned why the exception in § 417.460(a)(2)(iv) permitting organizations to retain enrollees who

leave the geographic area for 90 days to one year would not be available to Federally qualified HMOs. Additionally, Federally qualified HMOs should be permitted to retain those enrollees who are moving to an area other than where there is an affiliated organization.

Response: We have reviewed the regulations and have reconsidered our position on this question. Under the regulation at § 417.108(a), if a Federally qualified HMO complies with relevant Medicare requirements with respect to its Medicare members, then its Federal qualification will not be jeopardized even if the Medicare requirements are less restrictive than the Federal qualification requirements. Section 417.460(a)(2)(iv) permits an HMO or CMP with a Medicare contract to retain Medicare members who leave its service area, even if they do not move to an area where the HMO or CMP has an affiliate organization. Therefore, we believe that this exception may be used by Federally qualified HMOs with respect to their Medicare members. Further, we believe that the disadvantages in retaining members who move out of the HMO's service area, including added financial risk, provide adequate incentives to utilize this exception with caution.

Comment: One commenter recommended that HCFA consider replacing the current rules on temporary, extended, and permanent moves with a policy which would permit the organization to retain all members regardless of the length of absence from the geographic area. Another commenter suggested that there should be different policies depending on different circumstances, such as how far away the enrollee's new permanent residence is, or whether the enrollee "ages in" to Medicare enrollment because he or she was previously an enrollee of the organization, and is becoming eligible for Medicare.

Response: We disagree with the first comment. We believe it is essential to impose limits on an organization's ability, or obligation, to retain members who are absent from the organization's geographic area. As we stated in the proposed rule, it is important to specify a period during which an enrollee can be absent from the geographic area (such as on a vacation) without fear of being arbitrarily disenrolled. This would prevent organizations from, for example, trying to avoid responsibility for emergency or urgently needed out-of-area services during that time. However, some limits are necessary so that HMO/CMPs are not held responsible indefinitely for an enrollee who has permanently left the geographic area.

At the same time, even if organizations wish to retain enrollees indefinitely, it is not fair to beneficiaries, who do not have access to facilities of the organization in which they are enrolled, or to HCFA, which continues full capitation payments to the organization during the beneficiaries' absences. Accordingly, we continue to believe that the regulations we have proposed allow as much flexibility as possible to organizations and beneficiaries, while protecting all parties from abuse. The rules permit an organization and a beneficiary to establish that an absence of less than a year is not "permanent," but provides that any absence of more than a year must be considered permanent, and the beneficiary must be disenrolled.

With respect to the second two comments, the general rule is that where the beneficiary clearly does not reside in the geographic area covered by the organization's Medicare contract, he or she is not eligible to enroll, or remain enrolled under the contract. There are numerous protections afforded to beneficiaries with respect to area covered by a Medicare contract, which may not apply in other areas served by the organization.

However, with respect to HMO/CMP commercial enrollees who "age-in" to Medicare, there is a specific regulation, at 42 CFR 417.432(a), which requires the organization to retain the members.

H. Application of the Rules

Comment: One commenter criticized the proposed rules' failure to distinguish between cost and risk contracts, and to clarify which rules apply to which type of organization.

Response: All the regulations at §§ 417.400 through 417.694 apply equally to organizations with either a cost or risk contract under section 1876, except for those subsections that specifically identify cost or risk organizations in the title or in the title of a group of subsections. For instance, §§ 417.442 through 417.448 apply only to organizations with risk contracts, and the titles of those sections specifically indicate risk contracting organizations. Sections 417.530 through 417.576, by contrast, are specifically grouped and labeled for cost contracting organizations.

It is possible for an organization to have a risk contract, but to retain cost members from a previous cost contract. Although the organization does not have a separate contract for remaining cost enrollees, in general it applies cost contracting rules to cost enrollees and risk contracting rules to risk enrollees. For instance, an organization may not apply the restriction on obtaining services from outside the organization under § 417.448 to cost enrollees.

IV. Provisions of the Final Regulations

After consideration of the comments received and our further analysis of specific issues we are publishing as final the July 22, 1988 proposed regulations with minor editorial clarifications and the revisions identified below.

In § 417.401, we are adding a definition of "affiliated organization."

In § 417.413(d)(6), we are revising language concerning suspension of enrollment when an organization is found not in compliance with the 50/50 rule, to clarify that organizations must stop accepting new applications for enrollment after a date specified by HCFA, or that HCFA may stop adding new enrollees to its records after a date specified by HCFA.

In § 417.436(a)(3), we are clarifying that the lock-in applies only in risk organizations.

We are revising § 417.436(a)(6) to permit organizations to omit the actual amount of the premium from the membership rules, if it is not feasible to include it, as long as the source for the information is clearly identified and a telephone number for obtaining that information is included.

We are also making conforming changes to § 417.596(a) to remove the deadline for the establishment of new benefit stabilization funds for HMOs/CMPs which have risk contracts under section 1876 of the Act, and deleting § 417.597(e) which specifies the deadline date for HMO/CMP use of these funds.

These changes, which were not included in the proposed rule, are mandated by section 6212(c) of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89), Public Law 101-239, which deleted sections 2350(b) (3) and (4) of the Deficit Reduction Act of 1984, Public Law 98-369 and amended section 1876(g)(5) of the Act. The amendment repealed the time limitations on the establishment of new benefit stabilization funds and on the period for HMO/CMPs to use the fund monies.

We ordinarily publish a notice of proposed rulemaking in the Federal Register and invite prior public comment on the proposal. The notice identifies the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issue involved. The proposed rulemaking can be waived when an agency finds that it is impracticable, unnecessary or

contrary to the public interest, and incorporates a statement of the finding of good cause in the final rule.

This change conforms HCFA regulations to a self-executing amendment to Medicare law (title XVIII of the Social Security Act). This amendment to the Act is so specific that it leaves no room for alternative interpretations or implementation. Accordingly, we find that there is good cause to dispense with a proposed rulemaking on this change.

V. Regulatory Impact Statement and Flexibility Analysis

Executive Order (E.O.) 12291 requires us to prepare and publish a final regulatory impact analysis for any final regulation that meets one of the Executive Order 12291 criteria for a "major rule"; that is, that will be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

We generally prepare a final regulatory flexibility analysis that is consistent with Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a final rule will not have a significant economic impact on a substantial number of small entities.

The final rule generally reflects statutory changes that serve to codify in our regulations those practices which are required by recent legislation. The statutory changes repealing the "two-for-one" requirement, requiring an explanation of enrollee rights, and granting waivers for 50-percent composition of enrollment will increase Medicare program expenditures independently of the promulgation of this final rule. These provisions, in themselves, will have a negligible impact on Medicare expenditures. Although the technical change provisions of this rule are new requirements, we expect that the impact on Medicare expenditures also will be negligible.

Therefore, we have determined that this final rule, in itself, will not produce any effects that will meet any of the criteria of Executive Order 12291. For the same reason, we have determined and the Secretary certifies that this final rule would not have a significant economic impact on a substantial number of small entities. Thus, a regulatory impact analysis under Executive Order 12291 and a regulatory flexibility analysis under the RFA are not required.

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such 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 50 beds. For purposes of the RFA, we treat all providers and fiscal intermediaries as small entities.

We are not preparing a rural impact statement since we have determined, and the Secretary certifies, that this final rule will not have significant economic impact on the operations of substantial number of small rural hospitals.

VI. Information Collection Requirement

Sections 417.428 and 417.436 of this final rule contain information collection requirements that are subject to the Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1980. These final regulations apply to organizations contracting with the Medicare program to provide services to Medicare beneficiaries on a prepaid basis.

There are two requirements which are potential information collection requirements: (1) That organizations include in their marketing materials given to prospective enrollees the fact that the organization's contract with Medicare is subject to periodic termination or nonrenewal, and that the individual's enrollment with the organization will terminate if the contract with Medicare is terminated or not renewed; and (2) the explanation furnished to enrollees of the organization and the fact that these rules now must be furnished on an annual basis rather than only upon enrollment and when changes are made, as was the case previously.

Respondents who provide the information include HMOs and CMPs contracting with Medicare.

HMOs/CMPs will not collect any information in order to comply with the requirements; rather, they will disseminate this information to the public and to enrollees. The reporting burden for the addition to marketing materials required under § 417.428 is very negligible, since the information can be added to previously printed marketing materials by the use of an addendum. The previous rules required that marketing materials be subject to Federal review. The burden for the expanded information which must be included in membership rules under § 417.436 similarly can be provided by printing addenda to previously published materials, and are already subject to review. There are currently about 2 million Medicare beneficiaries enrolled in organizations subject to these rules. Distribution of these rules on an annual basis will require additional expenditure by HMOs/CMPs to print and distribute additional copies of the rules.

List of Subjects in 42 CFR Part 417

Administrative practice and procedure, Health maintenance organizations (HMO), Medicare, Reporting and recordkeeping requirements.

42 CFR part 417 subpart C is amended as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 is revised to read as follows:

Authority: Secs. 1102, 1833(a)(1)(A), 1861(s)(2)(H), 1871, 1874, and 1876 of the Social Security Act as amended (42 U.S.C. 1302, 1395l(a)(1)(A), 1395x(s)(2)(H), 1395hh, 1395kk, and 1395mm); section 114(c) of Public Law 97–248 (42 U.S.C. 1395mm note); section 9312(c) of Public Law 99–509 (42 U.S.C. 1395mm note); and section 1301 of the Public Health Service Act (42 U.S.C. 300e) and 31 U.S.C. 9701.

Subpart C—Health Maintenance Organizations and Competitive Medical Plans

2. The table of contents for part 417, subpart C is amended to remove § 417.446.

3. Section 417.401 is amended by adding in alphabetical order the definition of "Affiliated organization" to read as follows:

§ 417.401 Definitions.

* * * * *

Affiliated organization, for purposes of the exception at § 417.460(a)(2)(iv) permitting continued enrollment of beneficiaries during an extended absence, means an organization which has a contract under section 1876 of the Act, and (1) is under the common ownership or control of the organization which seeks to retain absent members, or (2) has an agreement in effect with

that organization to furnish items and services to enrollees who are on an extended absence from the geographic area of the original organization.

* * * * *

4. In § 417.413 paragraph (d) is revised, paragraph (e) is removed and paragraph (f) is redesignated as (e) and revised as follows:

§ 417.413 Qualifying condition: Operating experience and enrollment.

* * * * *

(d) *Standard: Composition of enrollment*—(1) *Requirement.* Except as specified in paragraphs (d)(2) and (e) of this section, not more than 50 percent of an organization's enrollment may be Medicare beneficiaries and Medicaid recipients.

(2) *Waiver of composition of enrollment standard.* HCFA may waive compliance with the requirements of paragraph (d)(1) of this section if the organization has made and is making reasonable efforts to enroll individuals who are not Medicare beneficiaries or Medicaid recipients, and it meets either of the following requirements:

(i) The organization services a geographic area in which Medicare beneficiaries and Medicaid recipients constitute more than 50 percent of the population.

However, HCFA will not grant a waiver that would permit the percentage of Medicare and Medicaid enrollees to exceed the percentage of Medicare beneficiaries and Medicaid recipients in the organization's geographic area.

(ii) The organization is owned and operated by a government entity. The waiver may be for a period up to three years after the date the organization first enters into a contract under this subpart, and may not be extended.

(3) *Waiver granted on or before October 21, 1986.* An organization (or a successor organization) that as of October 21, 1986, had been granted an exception, waiver, or modification of the requirements of paragraph (d)(1) of this section, but that does not meet the requirements of paragraph (d)(2) of this section, must make (and throughout the period of the exception, waiver, or modification continue to make) reasonable efforts to meet scheduled enrollment goals, consistent with a schedule of compliance approved by HCFA. If HCFA determines that the organization has—

(i) Complied, or made significant progress toward compliance, with the approved schedule of compliance, and that an extension is in the best interest of the Medicare program, HCFA may extend such waiver or modification.

(ii) Not complied with the approved schedule. HCFA may apply the sanctions described in paragraphs (d)(6) and (d)(7) of this section.

(4) *Basis for application of sanctions.* HCFA may, as an alternative to contract termination, apply the sanctions specified in paragraph (d)(6) of this section if HCFA determines that the organization is not complying with the requirements in paragraphs (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(5) *Notice of sanction.* Prior to applying the sanctions specified in paragraph (d)(6) of this section, HCFA will send a written notice to the organization stating the proposed action and its basis. HCFA will give the organization 15 days after the date of the notice to provide evidence establishing the organization's compliance with the requirements in paragraph (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(6) *Sanctions.* If, following review of the organization's timely response to HCFA's notice, HCFA determines that an organization does not comply with the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section, HCFA may apply the following sanctions:

(i) HCFA will require the organization to stop accepting new enrollment applications after a date specified by HCFA, or

(ii) HCFA will not make payment to organizations for individuals who have not yet been formally added or "accreted" to HCFA's records by a date specified by HCFA.

(7) *Termination by HCFA.* In addition to the sanctions described in paragraph (d)(6) of this section. HCFA may decline to renew an organization's contract in accordance with § 417.492(b), or terminate its contract in accordance with § 417.494(b) if HCFA determines that the organization no longer substantially meets the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section.

(e) *Standard: Open enrollment.* (1) Except as specified in paragraph (e)(2) of this section, an organization must enroll Medicare beneficiaries on a first-come, first-served basis to the limit of its capacity and provide annual open enrollment periods of at least 30 days duration for Medicare beneficiaries.

(2) HCFA may waive the requirement of paragraph (e)(1) of this section if compliance would prevent compliance with the limitation on enrollment of Medicare beneficiaries and Medicaid recipients (paragraph (d) of this section) or result in an enrollment substantially nonrepresentative of the population of the organization's geographic area. The enrollment would be "substantially nonrepresentative" if the proportion of a subgroup to the total enrollment exceeded, by 10 percent or more, its proportion of the population in the organization's geographic area, as shown by census data or other data acceptable to HCFA. For purposes of this paragraph, a subgroup means a class of Medicare enrollees as defined in § 417.582.

5. In § 417.428, the introductory text of paragraph (a) is republished and the section is amended by adding a new paragraph (a)(4) to read as follows:

§ 417.428 Marketing activities.

(a) *Required marketing activities.* An organization must meet the following requirements:

* * * * *

(4) Include in the organization's written materials provided to prospective enrollees prior to enrollment, notice that the organization is authorized by law to terminate or refuse to renew its contract with HCFA, that HCFA may also choose to terminate or refuse to renew its contact with the organization and that termination or nonrenewal may result in termination of the individual's enrollment in the organization.

§ 417.432 [Amended]

6. In § 417.432, paragraph (f) is removed.

7. Section 417.436 is revised to read as follows:

§ 417.436 Membership rules for enrollees.

(a) Maintaining rules. An organization must maintain written membership rules that deal with, but need not be limited to—

(1) All benefits provided under the contract, as described in § 417.440;

(2) How and where to obtain services from or through the organization;

(3) The restrictions on coverage for services furnished from sources outside an organization contracting on a risk basis, as described in § 417.448, other than emergency services and urgently needed services (as defined in § 417.401);

(4) The obligation of the organization to assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services as required by § 417.414(c);

(5) Any services the organization chooses to provide, as permitted by this part from sources outside the organization, other than emergency services and urgently needed services. A cost contracting organization must disclose that the enrollee may receive

services through any Medicare providers and suppliers;

(6) Premium information, including the amount, (or if the amount cannot be included, the telephone number of the source from which this information may be obtained) and the procedures for paying premiums and other charges for which enrollees may be liable;

(7) Grievance and appeal procedures;

(8) Disenrollment rights;

(9) The obligation of an enrollee who is leaving the organization's geographic area for more than 90 days to notify the organization of the move or extended absence and the organization's policies concerning retention of enrollees who leave the geographic area for more than 90 days, as described in § 417.460(a)(2);

(10) The expiration date of the organization's contract with HCFA and notice that the organization is authorized by law to terminate or refuse to renew the contract, that HCFA may also terminate or refuse to renew the contract and that termination or nonrenewal of the contract may result in termination of the individual's enrollment in the organization; and

(11) Any other matters that HCFA may prescribe.

(b) *Availability of rules.* The organization must furnish a copy of the rules to each Medicare enrollee at the time of enrollment and at least annually thereafter.

(c) *Changes in rules.* If an organization changes its rules, it must submit the changes to HCFA in accordance with § 417.428(a)(3), and notify its Medicare enrollees of the changes at least 30 days before the effective date of the changes.

8. In § 417.444, the introductory text of paragraph (a) is republished, paragraphs (a)(2) and (b) are revised; paragraph (c) is removed. The section reads as follows:

§ 417.444 Special rules for current nonrisk Medicare enrollees of an organization under a risk contract.

(a) *Condition for additional benefits.* Current nonrisk Medicare enrollees of a risk organization may retain that status indefinitely and, therefore, are not entitled to the additional benefits under § 417.442 unless HCFA determines that the enrollee's status must be changed or a change is requested by the enrollee, as follows:

* * * * *

(2) A current nonrisk Medicare enrollee requests, using the same or a similar form to that described in paragraph (a)(1) of this section, that he or she be covered under the risk portion of the contract.

(b) *Notification.* Organizations converting from a cost to a risk contract must, within 60 days of signing the risk contract, inform current nonrisk medicare enrollees of their right to remain current nonrisk Medicare enrollees or to covert to risk enrollment at any time under the provisions of paragraph (a)(2) of this section.

§ 417.446 [Removed]

9. Section 417.446 is removed.

10. In § 417.448, paragraphs (c) and (d) are revised to read as follows:

§ 417.448 Restriction on payments for services received by Medicare enrollees of risk organizations.

* * * * *

(c) *End of restriction.* The restriction of payments imposed by paragraph (a) of this section ends when a Medicare enrollee leaves the organization's geographic area for an extended period as defined in § 471.460(a)(2) and the organization and enrollee make arrangements for membership to continue as provided in § 417.460(a)(2)(iv).

(d) *Timing.* The effective date for the end of the restriction on payments, as discussed in paragraph (c) of this section is the first day of the first month following the month in which the enrollee notifies the organization as required in § 417.436(a)(9), that he or she has left the organization's geographic area for an extended period.

11. Section 417.460(a)(2)(iv) is revised to read as follows:

§ 417.460 Disenrollment of beneficiaries and termination of payments to an organization.

(a) * * *

(2) * * *

(iv) Exception. An organization may retain a Medicare enrollee who is absent from the organization's geographic area for an extended period, but who remains within the United States as defined in § 400.200, if the enrollee agrees. For purposes of this exception, the following provisions apply:

(A) An absence for an extended period means an uninterrupted absence from the organization's geographic area for more than 90 days but less than one year.

(B) The organization and the enrollee may mutually agree upon restrictions for obtaining services while the enrollee is absent for an extended period from the organization's geographic area. However, restrictions may not be imposed on the scope of services described in § 471.440.

(C) When the enrollee returns to the organization's geographic area, the restrictions under § 417.448(a) prohibiting Medicare payment for services not provided or arranged for by the organization apply again immediately.

(D) Organizations that choose to exercise this exception must make the option available to all Medicare enrollees who are absent for an extended period from the organization's geographic area. (However, organizations may limit this option to enrollees who go to a geographic area served by an affiliated organization.)

(E) If the enrollee fails to return to the organization's geographic area within 1 year of the date he or she left the geographic area, then the organization must disenroll the beneficiary on the first day of the month following the anniversary of the date the enrollee left the geographic area under the provisions of paragraph (a)(2)(i) of this section.

* * * * *

12. Section 417.494 is amended by republishing paragraph (b)(1) introductory text, revising (b)(1)(iii) and adding paragraph (b)(1)(iv) to read as follows:

§ 417.494 Modification or termination of contract.

* * * * *

(b) Termination by HCFA. (1) HCFA may terminate a contract for any of the following reasons:

* * * * *

(iii) The organization has failed substantially to comply with the composition of enrollment requirements specified in § 417.413(d).

(iv) HCFA determines that the organization no longer meets the applicable conditions necessary to qualify as an eligible organization under section 1876 of the Act and this subpart.

* * * * *

13. Section 417.596(a) is revised to read as follows:

§ 417.596 Establishment of a benefit stabilization fund.

(a) *General.* If an organization is required to provide its Medicare enrollees with additional benefits as described in § 417.592, the organization may request that HCFA withhold a part of its monthly per capita payment in a benefit stabilization fund. The fund will be used to prevent excessive fluctuation in the provision of those additional benefits in subsequent contract periods.

* * * * *

14. In § 417.597 paragraph (e) is removed and paragraph (b) is revised to read as follows:

§ 417.597 Withdrawal from a benefit stabilization fund.

* * * * *

(b) *Criteria for HCFA approval.* HCFA will approve an organization's request for a withdrawal from its benefit stabilization fund for use during the next contract period only if—

(1) The organization's average of its per capita rates of payment for the next contract period is less than that of the previous contract period;

(2) The organization's ACR for the next contract period is significantly higher than that of the previous contract period; or

(3) The organization's revenue requirements for the next contract period for providing the additional benefits it provided during the previous contract period is significantly higher than the requirements for that previous period and the ACR for the next contract period results in an additional benefits package that is less in total value than that of the previous contract period.

* * * * *

15. Section 417.640(c) is revised to read as follows:

§ 417.640 Determinations subject to appeal.

* * * * *

(c) A determination to terminate, or to refuse to renew, a contract with an organization because—

(1) The organization has failed substantially to carry out the terms of the contract;

(2) The organization is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of section 1876 of the Act;

(3) The organization no longer meets the applicable conditions necessary to qualify as an eligible organization under section 1876 of the Act and this subpart; or

(4) The organization has failed to comply with the composition of enrollment requirements specified in § 417.413(d).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program; No. 93.714, Medical Assistance)

Dated: March 18, 1991.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: May 16, 1991.

Louis W. Sullivan,

Secretary.

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DEPARTMENT OF TRANSPORTATION

Urban Mass Transportation Administration

49 CFR Part 665

[Docket No. 89-B]

RIN 2132-AA30

Bus Testing

AGENCY: Urban Mass Transportation Administration, DOT.

ACTION: Interim rule.

SUMMARY: On October 9, 1990, the Urban Mass Transportation Administration (UMTA) published an Interim Final Rule for its bus testing facility program. At that time, UMTA anticipated publishing a final rule on July 1, 1991. Because of the complex nature of the issues involved, however, UMTA believes that additional time is required to draft a final rule. Today's document amends the termination date of the interim final rule and gives notice of continued effectiveness of the interim procedures.

DATES: These procedures, which became effective on August 23, 1989 (54 FR 35158), with further modifications published on October 9, 1990 (55 FR 41174), remain in effect until further notice.

FOR FURTHER INFORMATION CONTACT: For technical issues, Steven A. Barsony, Director, Office of Engineering Evaluations, Office of Technical Assistance and Safety, (202) 366-0090; for legal issues, Douglas G. Gold, Assistant Chief Counsel for General Law, Office of the Chief Counsel, (202) 366-1936. The test facility can be reached by contacting James C. Wambold, Director of Automotive Research, (814) 863-1889.

SUPPLEMENTARY INFORMATION: On May 25, 1989, UMTA published a notice of proposed rulemaking (NPRM) to implement section 317 of the Surface Transportation and Uniform Relocation Assistance Act of 1987 (STURAA). Section 317 directs the Secretary of DOT (as delegated to UMTA) to establish a bus testing facility at Altoona, Pennsylvania, and provides that no funds obligated by UMTA after September 30, 1989, under the Urban Mass Transportation Act of 1964, as amended, may be used to purchase a "new bus model" unless a bus of such model has been tested at the facility.

To ensure that bus testing procedures were in place before the statutory deadline of October 1, 1989, the agency indicated in the NPRM that it would issue interim guidance in advance of the agency's final rule. The guidance was provided in the interim final rule issued on August 23, 1989 (54 FR 35158). UMTA invited comments on the interim procedures.

While the NPRM proposed the testing of all vehicles used in mass transit after April 2, 1987 (the effective date of STURAA), the interim final rule narrowed the scope of the proposed rule. It provided that only certain larger-sized buses would be subject to the testing procedures. The interim final rule also stated that the agency, after appropriate notice and as conditions warranted, might expand the scope of vehicles to be tested at the facility during the interim period.

On October 9, 1990 (55 FR 41174), the agency modified the interim final rule and invited comments on the changes. The modification extended the interim period to July 1, 1991; added medium-duty body-on-chassis designs to the category of buses to be tested; and modified the definition of "new bus model" to include a bus being produced with a major change in configuration or components. Examples of a major change in configuration and a major change in components were provided. UMTA received numerous comments on these modifications to the interim final rule.

The bus testing rule involves complex and technical issues. UMTA requires additional time to examine and consider these issues and to make a careful review of the public comments received as a result of the October 1990 modifications. As a result, UMTA is extending the effective date of the interim final rule until further notice. The agency continues to reserve the right, after appropriate notice, to make further modifications to the interim final rules.

UMTA does not consider the extension of the effective date of this rule an action which requires an additional notice of proposed rulemaking. Since its first NPRM, the agency's intent has remained clear—to implement the provisions of the UMT Act relating to bus testing in the most effective and efficient manner. The agency has effected this policy through a staged implementation of these provisions, in a series of interim rules.

Because this rule merely extends the effective date of the current regulation, the agency has determined that a recitation of compliance with the various rulemaking executive orders and statutes is unnecessary. Information on the agency's compliance with these requirements may be reviewed in its