economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Parts 180, 185, and 186

Environmental protection, Administrative practice and procedure, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 21, 1994.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 180—[AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. In § 180.449, by revising paragraph (a), to read as follows:

§ 180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

(a) Tolerances, to expire on April 30, 1996, are established for the combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer (a mixture of avermectins containing ≧ 80 percent avermectin B_{1a} (5-O-demethyl avermectin B_{1a}) and < 20 percent avermectin B_{1a} (5-O-demethyl-25-di (1-methylpropyl)-25-1(1-methylethyl) avermectin A_{1a}) in or on the following commodities:

Commodity	Parts per million
Citrus, whole fruit	0.02
Cattle, meat	0.02
Cattle, mbyp	0.02
Cottonseed	0.005
Milk	0.005

* * * * *

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. By revising § 185.300, to read as follows:

§ 185.300 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

Tolerances, to expire on April 30, 1996, are established for the combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer (a mixture of avermectins containing ≧ 80 percent avermectin B_{1a} (5-O-demethyl avermectin B_{1a}) and < 20 percent avermectin B_{1a} (5-O-demethyl-25-di (1-methylpropyl)-25-1(1-methylethyl) avermectin A_{1a}) in or on the following commodity:

Commodity	Parts per million
Citrus oil	0.10

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 348.

b. In § 186.300, by revising paragraph (a) to read as follows:

§ 186.300 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

(a) Tolerances, to expire on April 30, 1996, are established for the combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer (a mixture of avermectins containing ≧ 80 percent avermectin B_{1a} (5-O-demethyl avermectin B_{1a}) and < 20 percent avermectin B_{1a} (5-O-demethyl-25-di (1-methylpropyl)-25-1(1-methylethyl) avermectin A_{1a}) in or on the following commodity:

Commodity	Parts per million
Dried citrus pulp	0.10

* * * * *

[FR Doc. 94-24249 Filed 9-29-94; 8:45 am]
BILLING CODE 6560-50-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 410, 411, 413, and 494

[BPD-724-F]

RIN 0938-AF26

Medicare Program; Medicare Coverage of Screening Mammography

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

ACTION: Final rule.

SUMMARY: This final rule revises interim final regulations on Medicare coverage of screening mammography that were published in the **Federal Register** on December 31, 1990 (55 FR 53510). Those regulations implemented section 4163 of the Omnibus Budget Reconciliation Act of 1990, setting forth payment limitations and conditions for coverage of screening mammography. The conditions consist of quality standards to ensure the safety and accuracy of screening mammography services performed by qualified physicians and other suppliers of these services.

As a result of the implementation of the Mammography Quality Standards Act of 1992 (MQSA) by the Food and Drug Administration (FDA), we are conforming the conditions for coverage to the applicable FDA certification requirements that all Medicare suppliers of services must meet effective October 1, 1994. The revisions in this final rule also respond to certain comments we received on the interim final rule published on December 31, 1990; they provide clarification of certain of its provisions; and they establish conditions for coverage of diagnostic mammography that are similar to those we have established for screening mammography. In addition, this final rule reflects changes resulting from the final rule on the fee schedule for physicians' services, which was published in the **Federal Register** on December 2, 1993 (58 FR 63626).

DATES: These regulations are effective October 1, 1994.

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FOR FURTHER INFORMATION CONTACT: William Larson (Conditions for Coverage), (410) 966–4639. William Morse (Payment Limits), (410) 966–4520.

SUPPLEMENTARY INFORMATION:

I. Background

On December 31, 1990, we published interim final regulations concerning Medicare coverage of screening mammography in the **Federal Register** (55 FR 53510). These regulations implemented section 4163 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Public Law 101–508), which was enacted on November 5, 1990. Section 4163 amended sections 1833, 1834, 1861, 1862, 1863, 1864, 1865, 1902, and 1915 of the Social Security Act (the Act) to provide coverage of screening mammography (including a physician's interpretation of the images or films produced by the radiologic procedure) effective January 1, 1991, subject to frequency limitations, quality standards, and special payment rules.

Before we could follow up on the interim final rule and publish a final rule on Medicare coverage of screening mammography, the Mammography Quality Standards Act of 1992 (MQSA) (Public Law 101–539) was enacted on October 27, 1992, establishing new national quality standards for all mammography services. The MQSA amended part F of title III of the Public Health Service Act (the PHS Act) (42 U.S.C. 263b) to establish a comprehensive statutory mechanism for certification and inspection of all mammography facilities in the United States, except facilities of the Department of Veterans Affairs (VA). The authority to implement the provisions of the MQSA was delegated by the Secretary to the Food and Drug Administration (FDA), which published interim final regulations in this regard in the **Federal Register** (58 FR 67558 and 58 FR 67565) on December 21, 1993, with an effective date of February 22, 1994.

The MQSA did not explicitly repeal section 1834(c) of the Act, which contains the provisions governing Medicare standards for screening mammography. Furthermore, conforming provisions that would tie Medicare coverage for both screening and diagnostic mammography to MQSA standards were initially included in the Omnibus Budget Reconciliation Act of 1993 by the House of Representatives, but subsequently had to be dropped along with other nonbudget provisions in response to Senate procedural rules. These provisions were included again in a technical corrections bill that the Congress attempted to pass late in 1993, but did not pass for reasons unrelated to the substance of the bill.

The MQSA, however, as it was enacted, specifically provides that the standards under the PHS Act apply to all facilities in the country furnishing mammography, except VA facilities. Thus section 354(b) of the PHS Act, added by the MQSA, states that "No facility may conduct an examination or procedure * * * involving mammography * * * unless the facility obtains * * * a certificate issued * * * by the Secretary." Similarly, the MQSA defines a facility in the broadest terms: It includes "a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility * * * that conducts breast cancer screening or diagnosis through mammography activities."

The plain language of the PHS Act requires that facilities furnishing mammography to Medicare beneficiaries meet the standards promulgated under the MQSA. Moreover, we believe that the language of the law indicates that the Congress intended that all facilities furnishing mammography meet a consistent set of national standards. When the Congress wished to exclude facilities from these standards, it did so explicitly; thus, VA facilities are specifically not subject to the Federal standards under the MQSA. Finally, we have compared the requirements contained in the MQSA and quality standards in section 1834(c) of the Act and believe that the Medicare requirements are substantially subsumed in the PHS Act. For the reasons stated above, we believe that it was the Congress' intent that facilities have to meet only one set of Federal mammography standards and that the MQSA standards supersede the previous Medicare standards.

II. Provisions of the Interim Final Rule

The interim final rule, published in the **Federal Register** on December 31, 1990 (55 FR 53510), implemented section 4163 of OBRA '90 by setting forth Medicare payment limitations and establishing conditions for coverage of screening mammography to ensure the safety and accuracy of the screening process.

III. Discussion of Public Comments

We received 42 timely items of correspondence in response to the December 31, 1990 interim final rule. The comments were from professional organizations, State governments, hospitals, consumer organizations, suppliers of mammography equipment, and individual practitioners.

Of these 42 items, 30 of them dealt exclusively with the quality standards described in 42 CFR part 494, subpart B, and only 12 of them offered any comments on the other provisions of the interim regulations relating to the payment, coverage frequency, and other provisions. Since we are deleting the quality standards in subpart B and are replacing them with a cross-reference to the applicable FDA requirements, as discussed in section IV. of this preamble, it is no longer necessary to respond in this rule to the comments that were received on those standards. The other comments and our responses to those comments, however, are discussed below.

A. Payment Limitations

Comment: One commenter suggested that the allocation between the professional and technical components for the screening mammogram should be the same as for a diagnostic mammogram.

Response: In the interim final rule (55 FR 53512), we used the same allocation between the two components of a screening mammogram that we had in place under the Medicare radiologist fee schedule for diagnostic mammograms because it was the best information we had available at the time and because of the lack of a persuasive argument that there should be different allocations for the two types of mammograms. In this final rule, we are changing the apportionment between the professional component and the technical component, effective for services furnished beginning January 1, 1995, to reflect the relationship between the relative value units established for a diagnostic bilateral mammogram under the fee schedule for physicians' services

for the year in question. We will not include the percentages for the professional component and the technical component in this final rule because the specificity requires a time-consuming rulemaking process when we modify the apportionment. We will announce the apportionment of the payment limits between the two components for 1995, and each year thereafter, at the same time as we announce the statutory payment limit in effect for that year. At this time, we anticipate that the apportionment of the payment limit in 1995 will be 32 percent professional component and 68 percent technical component.

Comment: One commenter objected to the discussion in the preamble of the interim final rule (55 FR 53513) of the difficulty rural hospitals have in furnishing the technical component of a screening mammogram within the payment limit because the rural hospitals may have a low volume of services. The commenter believed that, if a hospital and a radiologist entered into an agreement stating that the radiologist would accept a lower amount for the interpretation than Medicare would pay the radiologist directly for the interpretation, the agreement would constitute a "kickback" of a portion of the radiologist's fee to the hospital.

Response: We acknowledge that this agreement could constitute a kickback under the Medicare and Medicaid anti-kickback statute (42 U.S.C. 1320a–7b(b)). That statute makes it a felony to offer, pay, solicit, or receive remuneration with the intention of inducing the referral of Medicare, Medicaid, Maternal and Child Health Services Block Grant, or Social Services Block Grant program business. Activities that come within the purview of the statute are not subject to prosecution if they fit within specified safe harbors, as set forth in the regulation published in the **Federal Register** July 29, 1991 (56 FR 35952). Consequently, an organization or individual should enter into an agreement such as that referenced in the December 1990 interim final rule only if the agreement does not violate the anti-kickback statute.

Comment: Several commenters suggested that the rule should be modified so that a portion of the professional component of a screening mammogram be determined to represent the contribution of the primary care physician if the screening mammogram is taken in the primary care physician's office but interpreted by another physician. The commenters believed that the allocation of 37 percent of the payment limit to the interpreting physician's role overcompensates that physician and ignores the primary care physician's role in furnishing the mammogram. One commenter stated that the Physician Payment Reform Commission report entitled "The Costs of Providing Screening Mammography" allocates a flat $12 for the interpretation. As an alternative, the commenter suggested that the primary care physician be permitted to contract with the interpreting physician for payment at a rate less than 37 percent of the payment limit. Another commenter recommended that the interpretation represent 20 percent of the total fee.

Response: Medicare does not pay for referrals, and exacting a fee for referrals is against the law. A qualified physician who furnishes the interpretation of the screening mammogram receives payment for the professional component of the screening mammogram. If the primary care physician furnishes neither the professional component nor the technical component of the screening mammogram, he or she is entitled to no payment for the screening mammogram.

The apportionment of the screening mammography payment limit between the professional component and the technical component will reflect the payment split for the corresponding components for diagnostic mammography under the fee schedule for physicians' services. The weights of the factors reflect historical payment data, and we have no reason to believe that the apportionment is not appropriate for a screening mammography procedure.

Comment: One commenter stated that the purchased service limitation set forth in section 1842(n) of the Act should not apply to the technical component of a screening mammography procedure furnished in a primary care physician's office that customarily uses a temporary or leased technologist because—

- The technologist is under the direct control and supervision of the primary care physician and, as such, meets the common law rules for an employer/employee relationship applied under the Internal Revenue Code; and
- The screening mammography procedure is performed under the supervision of the primary care physician in conformance with the definition of "direct supervision" set forth in § 410.32(a).

Response: The purchased service limitation does not apply to screening mammography services because the procedures are not included in the definition of diagnostic tests under section 1861(s)(3) of the Act, as required by section 1842(n) of the Act, the statutory basis of the purchased service limitation. Section 1861(s)(13) of the Act provides for Part B coverage of screening mammography services, which are not subject to the requirements of section 1842(n) of the Act.

Comment: Two commenters stated that a "screening mammogram" is no different from a "diagnostic mammogram" and therefore should be paid at the same level.

Response: A screening mammogram and a diagnostic mammogram are similar in many respects, but the purposes of the two tests are distinctly different. A screening mammogram is a routine medical check; a diagnostic mammogram is made to diagnose a specific complaint or medical problem already identified by the patient or her attending physician. Section 1834(c)(4)(A) of the Act clearly establishes a $55 overall limit applicable to a screening mammography procedure in 1991 with increases in subsequent years limited to the percentage increase in the Medicare Economic Index for the subsequent year. Section 1834(b)(4)(B) of the Act authorizes the Secretary of the Department of Health and Human Services (the Secretary) to reduce this limit, after appropriate review, but does not authorize the Secretary to raise the limit. If we decide to establish the same payment for the two procedures, we might have to lower the payments for most diagnostic mammograms.

Comment: Two commenters recommended that the interim final rule be amended to waive the beneficiary's copayment liabilities so that older women will not have to bear out-of-pocket costs for the screening mammography procedure.

Response: A waiver of copayment liabilities would have to be authorized by the Congress. Section 1834(c)(1)(C) of the Act specifically limits Medicare payments to 80 percent of the least of the actual charge, the radiologist fee schedule or the physicians' fee schedule established under section 1848 of the Act as applicable, or the statutory limit for the service.

Comment: One commenter stated that insufficient payment levels should not be a deterrent to women having access to screening mammography services and that the relationship between current charges, payment levels, and access to the service should be taken into consideration in determining payment levels.

Response: We have to apply the overall payment limit established in

section 1834(c)(4) of the Act. There is no provision for exceptions to ensure access to these services in special circumstances.

Comment: One commenter believed that it is critical that any changes to the Medicare Part B payment system not be counter to physician payment reform. The existence of an overall national payment limit concerned another commenter who believed that the limit is inconsistent with the premise of a resource-based relative value scale payment schedule adjusted for geographic cost variations.

Response: Section 1834(c)(1)(C) of the Act requires that the amount of payment for screening mammography services be equal to 80 percent of the least of the actual charge, the radiologist fee schedule, or the physicians' fee schedule established under section 1848 of the Act, as applicable, or the statutory limit for the service.

Comment: One commenter, while conceding that we had no choice under the statute in imposing an overall $55 limit, stated that a single national rate without any recognition of geographic variations is inappropriate. The commenter believed that we should establish a price for screening mammograms within the context of other radiology services and ask the Congress to repeal the separate limit for these procedures.

Response: If it becomes apparent that the statutory limit is inadequate, we may make the proposal.

Comment: One commenter stated that radiologists would charge $32 for their interpretation, leaving only about $23 for the hospital, an amount which would cover only the cost of the film.

Response: Under the statutory allocation methodology implemented in the interim final rule (55 FR 53512), the professional component of the procedure in 1991 was limited to $20.35 (37 percent of $55), while the technical component was limited to $34.63 (63 percent of $55). The 1991 limiting charges for nonparticipating physicians and suppliers were: $68.75 (global), $25.44 (professional component), and $43.31 (technical component). Therefore, payment to hospitals for the technical component of screening mammography services is not determined by subtracting the amount billed for the professional component charge from the overall limit, but rather on the basis of the allocation methodology described in the interim final rule (55 FR 53512).

Comment: One commenter stated that the payment limit in section 1834(c)(4) of the Act is lower than the costs for screening mammography services furnished by a mobile unit in rural areas. The commenter believed that the operating costs of a mobile unit are higher than those of a stationary unit. Another commenter expressed concern that the processing of Medicare claims will increase the costs of mobile facilities and other screening centers that previously have not handled Medicare claims.

Response: Section 1834(c)(4) of the Act does not provide for any exception to the overall limit. Nonparticipating physicians and suppliers may bill beneficiaries higher amounts for the procedure up to the limiting charge set forth in § 405.535.

B. Limitations on Screening Mammography Services

Comment: One commenter believed that the screening mammography radiologic procedure covered under the Medicare program should not be limited to the four-view procedure specified in § 410.34(b)(1) of the interim final rule, but that additional views should be allowed as necessary in the case of particular patients.

Response: As we indicated in the preamble to the interim final rule (55 FR 53513), the basis for specifying that the screening mammography service must be a bilateral four-view procedure (that is, cranio-caudal and a medial lateral oblique view of each breast) is congressional intent as expressed in the Report of the Committee of Conference that accompanied Public Law No. 100–360 (H.R. Rep. No. 100–661, 100th Congress, 2nd Sess. 171 (1988)). In that report, the conferees stated that they "understood that a bilateral four-view procedure is currently considered to be the standard of care in the United States for screening mammography * * * [and] therefore anticipate that this would be initially included in the quality standards to be developed by the Secretary as a requirement for coverage."

We recognize that it may be necessary in the case of some patients to perform more than a bilateral four-view procedure. In view of the possibility that more than four images will need to be taken in the case of a particular patient, we have revised § 410.34(b)(1) (redesignated in this final rule as § 410.34(d)(1)) to state that generally "the service must, at a minimum, be a four-view exposure * * *." The need to do additional images will not have any effect on the payment amount that will be allowed for the Medicare screening mammography services because the payment amount is prescribed by statute.

To accommodate postmastectomy screening of certain women, however, we will allow, at a minimum, a two-view exposure (that is, a cranio-caudal and a medial lateral oblique view) of the remaining breast for those individuals, and still permit the facility to meet the standard. We are setting that standard as a two-view exposure.

Comment: Several commenters expressed concern about the limitations on the frequency of coverage of mammography screenings.

Response: As explained in the interim final rule (55 FR 53513), the frequency limitations specified in § 410.34 reflect the provisions imposed by section 1834(c)(2) of the Act, except for the high risk factors that were identified in § 410.34(b)(4)(i) (redesignated in this final rule as § 410.34(d)(4)(i)). As provided in section 1834(c)(2)(B) of the Act, the frequency limitations may be revised by the Secretary in consultation with the National Cancer Institute (NCI). This matter is under consideration, and will be addressed in a later notice, as appropriate.

Comment: One commenter suggested that this final rule discuss the importance of women having a clinical breast examination performed by a physician that would supplement the preventive value of using the Medicare screening mammography benefit. The commenter acknowledged that Medicare law authorizing screening mammography coverage does not provide for coverage and payment for a clinical breast examination as part of the screening mammography benefit. However, the commenter suggested that this final rule, at a minimum, indicate that a supplementary clinical breast examination performed by a physician be recommended in conjunction with a screening mammography examination and related physician's interpretation of the results of that radiologic examination.

Response: The commenter is correct. We do not have the legal authority under the screening mammography benefit to provide for coverage and payment for a clinical breast examination performed by a physician in conjunction with the use of screening mammography services. We understand, however, that NCI, ACS, the American Medical Association (AMA), the American Society of Internal Medicine, the National Medical Association, the American Academy of Family Physicians, the American College of Radiology, and other specialty groups recommend that a combination of screening mammography and a clinical breast examination is necessary for a complete early breast cancer detection

program. In this regard, NCI publishes public information brochures that explain screening mammography and strongly advise that a doctor also perform a clinical breast examination to supplement the value of the screening service. Information about breast cancer screening, including information regarding the importance of clinical breast examinations, can be obtained, free of charge, by calling the NCI-funded Cancer Information Service at 1–800–4–CANCER.

Comment: One commenter questioned the inclusion of "not given birth prior to age 30" as a factor indicating a high risk of developing breast cancer.

Response: We included "not given birth prior to age 30" as a factor indicating a high risk of developing breast cancer in the interim final rule based upon advice we received from NCI, and, in response to the comment, we have consulted further with NCI. NCI staff have advised us that the relative risk of women who have "not given birth prior to age 30" developing breast cancer is 1.4; that is, a woman who has not given birth prior to age 30 has a 40 percent higher chance of developing breast cancer over her lifetime than would otherwise be the case. This elevated risk applies over the age range of 40 to 49 that is subject to the high risk factor provision specified in the Medicare statute. Based on the advice of NCI, we have decided to retain in this final rule "not given birth prior to age 30" as a factor indicating a high risk of developing breast cancer.

Comment: One commenter believed that there is a need to clarify the meaning of the term "personal history of breast cancer" that is cited in § 410.34(b)(4) as one of the factors indicating a high risk of developing breast cancer. The commenter also requested clarification as to whether a biopsy that reveals a lump to be benign is reasonable evidence of "a history of breast cancer."

Response: The use of the term "a personal history of breast cancer" in § 410.34(b)(4) of the interim final rule was intended to mean that there is documented evidence in the woman's medical record that she has tested positive for breast cancer. Thus, a woman who has a biopsy of a lump in her breast that is determined to be benign would not be considered to have "a history of breast cancer."

Comment: One commenter expressed concern that the interim final rule made no reference to the possibility that the Medicare program may pay for certain medically necessary mammograms that are performed more often than the frequencies stated in the statute and the interim final rule for screening mammograms. The commenter suggested that we clarify this.

Response: The commenter is correct that the Medicare program may pay for certain medically necessary mammograms (also referred to as diagnostic mammograms as distinguished from screening mammograms) that are performed more frequently than the frequencies stated in the law and the interim final rule for screening mammograms. We stated this fact in the interim final rule (55 FR 53511). Under this policy, mammograms are covered if medically necessary to diagnose a specific complaint or medical problem that has been identified by the patient or her attending physician, including medical problems that may have been identified on the basis of a previous screening mammogram. This coverage is based on sections 1861(s)(1) and (s)(3) of the Act, which provide for Medicare coverage of interpretation of diagnostic X-ray tests by a physician.

Comment: Three commenters observed that a diagnostic mammogram requires essentially the same level of professional attention and professional expertise as does a screening mammogram, and one of these commenters suggested that similar quality standards be applied to both types of mammography services under the Medicare program.

Response: We agree. As we noted in response to a previous comment, a diagnostic mammogram and a screening mammogram are similar in many respects, and the Congress recognized this fact when it enacted the MQSA, which authorized the application of quality standards to both types of mammograms, effective October 1, 1994. Accordingly, we are including a condition for coverage in this rule at § 410.34(b)(2) that, in order to qualify for payment for diagnostic mammograms under the Medicare program, suppliers of these services must meet the same FDA certification requirements that we are adopting in this final rule for screening mammograms. (These certification requirements are set forth in section 354 of the PHS Act, implemented by 21 CFR part 900, subpart B.)

IV. Provisions of the Final Rule

In this final rule, we are deleting the conditions for coverage specified in 42 CFR part 494, subpart B, which screening mammography suppliers must meet to qualify for coverage of the services under the Medicare program. Instead, we are cross-referencing the applicable FDA certification requirements, published in the Federal Register on December 21, 1993 (58 FR 67558 and 58 FR 67565), that suppliers of the services must meet effective October 1, 1994.

Based on our analysis of section 354 of the PHS Act, as added by the MQSA, and the related FDA interim regulations, we believe that we have fulfilled our responsibility to establish quality standards under section 1834(c)(3) of the Act by adopting the quality standards and related certification requirements specified in the FDA regulations.

Section 1834(c)(3) of the Act requires the Secretary to establish standards to ensure the safety and accuracy of screening mammography services performed under Medicare Part B. The quality standards that must be established include: (1) Standards that require the use of equipment specifically designed for mammography and that meet other radiological standards established by the Secretary for mammography; (2) standards that require that the mammography be performed by individuals who are licensed by a State to perform radiological procedures, or who are certified as qualified to perform radiological procedures by an appropriate program as the Secretary specifies in regulations; (3) standards that require that the results of the mammography be interpreted by a physician who is certified as qualified to interpret radiological procedures by such an appropriate board (or program) as the Secretary recognizes in regulations; and (4) requirements that, with respect to a woman's first screening mammography performed for which payment is made under the program, the results of the mammography will be placed in the woman's permanent medical records.

In the FDA interim final rule, 21 CFR subpart B, § 900.11 ("Requirements for certification"), paragraph (a) provides that after October 1, 1994, "a certificate issued by FDA will be required for lawful operation of all facilities" and that in order to obtain a certificate from FDA, facilities "are required to meet the quality standards in § 900.12 and to be accredited by an accrediting body approved by FDA" as described in 21 CFR part 900, subpart A, §§ 900.1 through 900.7. In § 900.12 of the interim final rule, FDA established standards for mammography equipment, personnel, and practices. These standards are substantially the same as the Medicare interim quality standards that were published on December 31, 1990, but when they do differ from the existing Medicare standards, they still appear to

be consistent with our mandate under section 1834(c)(3) of the Act. Thus, this final rule will remove the existing Medicare interim quality standards and, instead, will cross-refer to applicable interim FDA certification requirements for mammography services.

In addition, we are making several technical and other clarifying revisions in the remaining provisions of the existing interim regulations that we published in the **Federal Register** on December 31, 1990 (55 FR 53510). With the exception of two points of clarification, a technical change, and certain conforming changes to part 405, subpart E ("Criteria for Determination of Reasonable Charges; Payment for Services of Hospital Interns, Residents, and Supervising Physicians"), the rationale for these revisions is discussed in the "Discussion of Public Comments" in section III. of this rule.

In § 405.534 ("Limitation on payment for screening mammography services"), we are making technical changes to cross-refer to the fee schedule for physicians' services. The current § 405.534 refers to § 405.533. The latter was removed from the CFR on November 25, 1991, with the publication of the fee schedule for physicians' services in the **Federal Register** (56 FR 59622). We are also revising paragraphs (c) and (d) so that, effective for a screening mammography procedure furnished beginning January 1, 1995, the payment for the screening mammography procedure reflects the relationship between the relative value units for the professional and technical components established for a diagnostic mammography procedure under the physicians' fee schedule. Effective January 1, 1995, the apportionment of the payment limit between the professional and technical components will be changed to reflect the relationship of the two components for diagnostic bilateral mammograms under the fee schedule for physicians' services for 1995.

We are revising the title of § 405.535 to add the words "and suppliers." It will read, "Special rules for nonparticipating physicians and suppliers furnishing screening mammography services." We are also making technical changes in this section to cross-refer the reader to the fee schedule for physicians' services. Additionally, we are setting forth in § 405.535 requirements for the limiting charge if the screening mammography services are furnished by a nonparticipating physician or supplier who does not accept assignment.

Conditions for Coverage

In accordance with section 354 of the PHS Act, regarding coverage conditions for diagnostic and screening mammography, we are amending 42 CFR by revising § 410.34(a) to specify definitions of the terms (1) "diagnostic mammography," (2) "screening mammography," (3) "supplier of diagnostic mammography," (4) "supplier of screening mammography," (5) "certificate," (6) "provisional certificate," and (7) "meets the certification requirements of section 354 of the Public Health Services (PHS) Act."

In § 410.34, we are redesignating paragraph (b) as paragraph (d). We are adding a heading to paragraph (d), "Limitations on coverage of screening mammography services." In newly redesignated paragraph (d)(1) of § 410.34, we are clarifying that the current requirement that a mammogram "must, *at a minimum* [emphasis added], be a four-view exposure (that is, a cranio-caudal and a medial lateral oblique view of each breast)" is the minimum requirement that must be met, except in the case of a woman who is having a postmastectomy screening, when we will allow a two-view exposure (that is, a cranio-caudal and a medial lateral oblique view) of the remaining breast.

We are adding a new paragraph (b) to § 410.34 to set forth conditions for coverage of diagnostic mammography, which essentially cross-reference the same FDA certification requirements that suppliers of screening mammography must meet on October 1, 1994. Medicare Part B pays for diagnostic mammography services if the diagnostic mammography services are ordered by a doctor of medicine or osteopathy and if they are furnished by a supplier of diagnostic mammography services that meets the certification requirements of section 354 of the PHS Act, as described in 21 CFR part 900 ("Mammography"), subpart B ("Quality Standards and Certification").

We are also adding a new paragraph (c) to § 410.34 to set forth the conditions for payment of screening mammography. Medicare Part B pays for screening mammography services only if they are furnished by a supplier of screening mammography services that meets the certification requirements of section 354 of the PHS Act, as described in 21 CFR part 900, subpart B.

We are revising § 411.15 ("Particular services excluded from coverage") to replace the cross reference to subpart B of part 494 (which is being removed and reserved) with a reference to the certification requirements in section 354 of the PHS Act, as set forth in 21 CFR part 900, subpart B.

The current § 413.123(b) states that payment to hospitals for screening mammography services performed on an outpatient basis is determined in accordance with § 405.534(c). We are changing this to refer to § 405.534(d) to correct an error.

V. Information Collection Requirements

Due to the enactment of the MQSA and its implementation by FDA, we are requesting cancellation of the information collection requirements approved under OMB control number 0938–0608 for Medicare coverage of screening mammograms, effective October 1, 1994. The latter information collection document was previously required as a result of the enactment of section 4163 of OBRA '90.

In implementing section 4163 of OBRA '90, we published interim final regulations on December 31, 1990 (55 FR 53510), including certain minimum safety and accuracy standards set forth in 42 CFR subpart B, which suppliers of screening mammography services had to meet in order to participate under Medicare, effective January 1, 1991. With the enactment of the MQSA, however, all mammography facilities in the United States, except for VA facilities, will be required, effective October 1, 1994, to have a certificate issued by FDA regardless of their source of payment. Therefore, under its delegation of authority from the Secretary of the Department of Health and Human Services, FDA will replace HCFA on October 1, 1994, as the Federal agency responsible for surveying and certifying suppliers of screening mammography services in accordance with the new MQSA standards.

VI. Delay in the Effective Date

As required by the Administrative Procedure Act (APA), we generally provide for final rules not to be effective until 30 days after the date of publication unless we find good cause to waive the delay. As a result of the implementation of the MQSA by FDA, we are conforming the conditions for Medicare coverage of screening mammography services to the applicable FDA certification requirements, published in the **Federal Register** on December 21, 1993 (58 FR 67558 and 58 FR 67565), that all Medicare suppliers of services must meet effective October 1, 1994. We view the changes made by this rule as merely interpretative. The APA does not require that there be a delayed effective

date for an interpretative rule. Accordingly, this rule will be effective October 1, 1994, the effective date of the FDA requirements on mammography services.

VII. Regulatory Impact Analysis

A. Introduction

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all physicians and suppliers of screening mammography services and equipment are considered to be small entities.

This final rule revises interim regulations on Medicare coverage of screening mammography that were published in the **Federal Register** on December 31, 1990 (55 FR 53510). Those regulations implemented section 4163 of OBRA '90, setting conditions for coverage for and limitations on screening mammography.

In the interim final rule, we presented an analysis of the various effects that the screening mammography benefit would have on beneficiaries, physicians, and suppliers (55 FR 53518). We received no comments on the impact analysis. Below, we present revised estimates of projected Medicare costs and utilization rates and the effects, as far as they can be foreseen, of the changes we have adopted as a result of public comment. Our estimates of projected additional costs and services are lower than those we anticipated when the interim final rule was published in the **Federal Register**. One explanation for lower than anticipated costs and services for this service may be that physicians have been furnishing screening mammography services but have been billing for the services using the CPT code for diagnostic mammography.

We anticipate that Medicare coverage of screening mammography services will result in the following costs:

TABLE I.—PROJECTED BUDGET IMPACT AS A RESULT OF MEDICARE COVERAGE OF SCREENING MAMMOGRAPHY

[in millions]

	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999
Benefit costs	$90	$95	$100	$110	$115

TABLE II.—PROJECTED NUMBER OF SCREENING MAMMOGRAPHIES PERFORMED AS A RESULT OF MEDICARE COVERAGE

[in millions]

CY 1995	CY 1996	CY 1997	CY 1998	CY 1999
1.4	1.4	1.5	1.6	1.6

Beginning October 1, 1994, FDA replaces HCFA as the Federal agency responsible for surveying and certifying suppliers of all mammography services, both diagnostic and screening. Beginning on that date, all facilities furnishing mammography services will be expected to meet only one set of national standards. This provision should benefit mammography facilities and help ensure the safety and accuracy of screening mammography services performed under Medicare Part B. The Medicare program will no longer be responsible for funding this cost.

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

B. Rural Hospital Impact Statement

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. We do not believe small rural hospitals will be required to make any operational changes to comply with this final rule. Therefore, we are not preparing a rural impact analysis because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

VII. List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 494

Medicare, Reporting and recordkeeping requirements, X-rays.

For the reasons set forth in the preamble and under the authority of 42 U.S.C. 1302 and 1395hh, 42 CFR chapter IV is amended as follows:

A. Part 405, subpart E is amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart E—Criteria for Determination of Reasonable Charges; Payment for Services of Hospital Interns, Residents, and Supervising Physicians

1. The authority citation for subpart E, part 405, is revised to read as follows:

Authority: Secs. 1102, 1814(b), 1832, 1833(a), 1834(a), (b), and (c), 1842(b) and (h), 1848, 1861(b), (s), (v), (aa), and (jj), 1862(a)(14), 1866(a), 1871, 1881, 1886, 1887, and 1889 of the Social Security Act as amended (42 U.S.C. 1302, 1395f(b), 1395k, 1395l(a), 1395m(a), (b), and (c), 1395u(b) and (h), 1395w-4, 1395x(b), (s), (v), (aa), and (jj), 1395y(a)(14), 1395cc(a), 1395hh, 1395rr, 1395ww, 1395xx, and 1395zz).

2. In § 405.534, the introductory text of paragraphs (b), (c), and (d), and paragraphs (b)(2), (b)(3), (c)(2), (c)(3),

(d)(2), and (d)(3) are revised to read as follows:

§ 405.534 Limitation on payment for screening mammography services.

* * * * *

(b) *Global or complete service billing representing both the professional and technical components of the procedure.* If a fee is billed for a global service, the amount of payment subject to the deductible is equal to 80 percent of the least of the following:

* * * * *

(2) The amount established for the global procedure for a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at part 414, subpart A.

(3) The payment limit for the procedure. For screening mammography services furnished in CY 1994, the payment limit is $59.63. On January 1 of each subsequent year, the payment limit is updated by the percentage increase in the Medicare Economic Index (MEI) and reflects the relationship between the relative value units for the professional and technical components of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(c) *Professional component billing representing only the physician's interpretation for the procedure.* If the professional component of screening mammography services is billed separately, the amount of payment for that professional component, subject to the deductible, is equal to 80 percent of the least of the following:

* * * * *

(2) The amount established for the professional component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The professional component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

(d) *Technical component billing representing other resources involved in furnishing the procedure.* If the technical component of screening mammography services is billed separately, the amount of payment, subject to the deductible, is equal to 80 percent of the least of the following:

* * * * *

(2) The amount established for the technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The technical component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

3. Section 405.535 is revised to read as follows:

§ 405.535 Special rules for nonparticipating physicians and suppliers furnishing screening mammography services.

If screening mammography services are furnished to a beneficiary by a nonparticipating physician or supplier that does not accept assignment, a limiting charge applies to the charges billed to the beneficiary. The limiting charge is the lesser of the following:

(a) 115 percent of the payment limit set forth in § 405.534(b)(3), (c)(3), and (d)(3) (limitations on the global service, professional component, and technical component of screening mammography services, respectively).

(b) The limiting charge for the global service, professional component, and technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at § 414.48(b)(3) of this chapter.

B. Part 410, subpart B is amended as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart B—Medical and Other Health Services

1. The authority citation for part 410 is revised to read as follows:

Authority: Secs. 1102, 1832, 1833, 1834, 1835, 1861(r), (s), (aa), (cc), (ff), and (mm), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395k, 1395l, 1395m, 1395n, 1395x(r), (s), (aa), (cc), (ff), and (mm), 1395hh, and 1395rr).

2. In § 410.10, the introductory text is republished, and paragraph (e) is revised to read as follows:

§ 410.10 Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, "medical and other health services" includes the following services:

* * * * *

(e) Diagnostic laboratory and X-ray tests (including diagnostic mammography that meets the conditions for coverage specified in § 410.34(b) of this subpart) and other diagnostic tests.

* * * * *

3. Section 410.34 is amended by revising the heading, removing the introductory text, revising paragraph (a), redesignating paragraphs (b)(1) through (b)(6) as paragraphs (d)(1) through (d)(6), adding a heading to newly redesignated paragraph (d), revising newly redesignated paragraph (d)(1), and adding new paragraphs (b) and (c) to read as follows:

§ 410.34 Mammography services: Conditions for and limitations on coverage.

(a) *Definitions.* As used in this section, the following definitions apply:

(1) *Diagnostic mammography* means a radiologic procedure furnished to a symptomatic woman for the purpose of detecting breast disease and includes a physician's interpretation of the results of the procedure.

(2) *Screening mammography* means a radiologic procedure furnished to an asymptomatic woman for the purpose of early detection of breast cancer and includes a physician's interpretation of the results of the procedure.

(3) *Supplier of diagnostic mammography* means a facility that is certified and responsible for ensuring that all diagnostic mammography services furnished to Medicare beneficiaries meet the conditions for coverage of diagnostic mammography services as specified in paragraph (b) of this section.

(4) *Supplier of screening mammography* means a facility that is certified and responsible for ensuring that all screening mammography services furnished to Medicare beneficiaries meet the conditions and limitations for coverage of screening mammography services as specified in paragraphs (c) and (d) of this section.

(5) *Certificate* means the certificate described in 21 CFR 900.2(b) that may be issued to, or renewed for, a facility that meets the requirements for conducting an examination or procedure involving mammography.

(6) *Provisional certificate* means the provisional certificate described in 21 CFR 900.2(m) that may be issued to a facility to enable the facility to qualify to meet the requirements for conducting an examination or procedure involving mammography.

(7) The term *meets the certification requirements of section 354 of the Public Health Service (PHS) Act* means that in order to qualify for coverage of its services under the Medicare program, a supplier of diagnostic or screening mammography services must meet the following requirements:

(i) Must have a valid provisional certificate, or a valid certificate, that has been issued by FDA indicating that the supplier meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(ii) Has not been issued a written notification by FDA that states that the supplier must cease conducting mammography examinations because the supplier is not in compliance with certain critical certification requirements of section 354 of the PHS

Act, implemented by 21 CFR part 900, subpart B.

(iii) Must not employ for provision of the professional component of mammography services a physician or physicians for whom the facility has received written notification by FDA that the physician (or physicians) is (or are) in violation of the certification requirements set forth in section 354 of the PHS Act, as implemented by 21 CFR 900.12(a)(1)(i).

(b) *Conditions for coverage of diagnostic mammography services.* Medicare Part B pays for diagnostic mammography services if they meet the following conditions:

(1) They are ordered by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

(2) They are furnished by a supplier of diagnostic mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(c) *Conditions for coverage of screening mammography services.* Medicare Part B pays for screening mammography services if they are furnished by a supplier of screening mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(d) *Limitations on coverage of screening mammography services.* The following limitations apply to coverage of screening mammography services:

(1) The service must be, at a minimum—

(i) A four-view exposure (that is, a cranio-caudal and a medial lateral oblique view of each breast); or

(ii) In the case of a postmastectomy patient, a two-view exposure (that is, a cranio-caudal and a medial lateral oblique view) of the remaining breast.

* * * * *

C. Part 411, subpart A is amended as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

Subpart A—General Exclusions and Exclusion of Particular Services

1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1834, 1842(l), 1861, 1862, 1866, 1871, 1877, and 1879 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395u(l), 1395x, 1395y, 1395cc, 1395hh, 1395nn, and 1395pp).

2. In § 411.15, the introductory text for the section is republished, and paragraph (a)(1) is revised to read as follows:

§ 411.15 Particular services excluded from coverage.

The following services are excluded from coverage.

(a) Routine physical checkups such as—

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptom, complaint, or injury, except for screening mammography (including a physician's interpretation of the results) that meets the conditions for coverage and limitations on coverage of screening mammography specified at § 410.34 of this chapter and the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

* * * * *

D. Part 413, subpart F is amended as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES

Subpart F—Specific Categories of Costs

1. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1122, 1814(b), 1815, 1833 (a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act as amended (42 U.S.C. 1302, 1320a–1, 1395f(b), 1395g, 1395l (a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww).

2. In § 413.123, paragraph (b) is revised to read as follows:

§ 413.123 Payment for screening mammography performed by hospitals on an outpatient basis.

* * * * *

(b) *Payment to hospitals for outpatient services.* Payment to hospitals for screening mammography services performed on an outpatient basis is determined in accordance with the technical component billing requirements in § 405.534(d) of this chapter.

PART 494—[REMOVED AND RESERVED]

E. Part 494 is removed and reserved.

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

Dated: August 3, 1994.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: September 8, 1994.

Donna E. Shalala,

Secretary.

[FR Doc. 94–24335 Filed 9–29–94; 8:45 am]

BILLING CODE 4120–01–P

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42 CFR Part 417

[OMC–009–FC]

RIN: 0938–AG92

Medicare Program; Qualified Health Maintenance Organizations: Technical Amendments

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

ACTION: Final rule with comment period.

SUMMARY: This rule clarifies and updates portions of the HCFA regulations that pertain to Federal qualification and continued regulation of health maintenance organizations (HMOs), inclusion of qualified HMOs in employee health benefits plans, and the administration of outstanding loans and loan guarantees that were awarded before October 1, 1986, under the Public Health Service Act (PHS Act). This rule is part of a special project to clarify and update all of 42 CFR part 417, which contains the regulations applicable to all entities that provide prepaid health care, that is, HMOs, CMPs (competitive medical plans) and HCPPs (health care prepayment plans).

These are technical and editorial changes that do not affect the substance of the regulations. They are intended to make it easier to find particular provisions, to provide overviews of the different program aspects, and to better ensure uniform understanding of the rules.

DATES: *Effective Date:* These regulations are effective on October 31, 1994.

Comment Date: We will consider all comments received at the appropriate address as provided below no later than 5 p.m. on November 29, 1994.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: OMC–9–FC, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (an original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or
Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, MD 21207.

Due to staff limitations, we cannot accept facsimile (FAX) transmission of comments. Comments will be available for public inspection as they are received, beginning approximately 3 weeks from date of publication in the **Federal Register**, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Tracy Jensen, (202) 619–2158.

SUPPLEMENTARY INFORMATION:

A. Background

This rule revises subparts D, E, F, and V of part 417 of the HCFA rules as part of the special project noted in the **SUMMARY.**

The first two steps in the project to clarify and update part 417 were the publication of two final rules identified as OCC–22–F and OCC–15–FC. The first was published in the **Federal Register** on October 17, 1991, at 56 FR 51984; the second, on July 15, 1993, at 58 FR 38062.

The regulation identified as OCC–22–F—

- Removed most of the outdated content;
- Redesignated certain portions of part 417 to free section numbers needed so that new rules can be incorporated in logical order; and
- Designated the remaining text under subpart headings that identify the different program aspects so that it is easier to refer to those aspects and to find particular rules.

The second regulation, identified as OCC–15–F—

- Through nomenclature and definition changes, established certain terms to be used throughout part 417 with the aim of avoiding confusion, making clear that responsibility for the prepaid health care programs has been delegated to HCFA, and ensuring use of the most precise terms available.
- Established a separate subpart C with four sections to set forth the many requirements that apply to the organization and operation of HMOs, and that were previously compressed into a single section (§ 417.107).

As a result of the redesignations made by OCC–22–F and OCC–15–FC, §§ 417.107 through 417.119 are now available for new rules that are required because of statutory amendments that affect the furnishing of services by qualified HMOs or may be needed because of future changes in the statute.

B. Changes in the Regulations

In order to clarify and update subparts D, E, F, and V, this rule makes the following changes:

- Uses terminology established by OCC–15–FC or that reflects accepted usage in all HCFA regulations.
- Revises long unbroken columns of text to designate separate provisions and to provide headings that help the reader to get an overview and to find particular provisions.
- Uses the active voice and the present indicative (rather than the future tense) to describe what HCFA or its employees, agents, or contractors do, and uses the most precise terms available.

A specific goal is to complete the separation of the rules that pertain to assurances required of entities applying for Federal qualification from those that pertain to assurances given in applying for financial assistance (grants, loans, and loan guarantees) that was available under the PHS Act before October 1986. To achieve this goal, we have—

- Removed the portion of § 417.160 applicable to financial assistance that is no longer available; and
- Added a new § 417.940 in subpart V to reference § 417.163(g) as applicable to entities that have outstanding loans or loan guarantees, and that fail to comply with assurances they gave in applying for the loan or loan guarantee. (Section 417.163(g) provides that HCFA may bring civil action to enforce compliance with assurances.)

In addition, we have—

- Removed the definitions of the three types of "qualified" HMOs (§ 417.141) because definitions are not used for substantive content, and in this case simply constituted a partial duplication of the rules themselves;
- Incorporated paragraph (a) of § 417.143 into § 417.140 to set forth the scope of the whole subpart D; and
- Removed §§ 417.168 and 417.169 from subpart F because their content is being transferred to § 417.142(g) and (h).

Waiver of Proposed Rulemaking

With one exception, the changes made by this rule are technical and editorial in nature. Their aim is to simplify, clarify, and update subparts D, E, F, and V without substantive change.

We have removed from § 417.169 (now redesignated as § 417.142(h)), the words "for purposes of receiving assistance under this subpart." HCFA has consistently interpreted this language (which appears in section 1307(d) of the PHS Act) as applying to continued qualification of HMOs as well as to initial applications for assistance that was available under that Act before October 1986. This interpretation avoids what would be an unintended result: Now that the assistance is no longer available, HMOs that had qualified in connection with their requests for assistance would have to disenroll their Federal Employee Health Benefit Program (FEHBP) enrollees in order to retain qualification and to be able to take advantage of the requirement that employers include qualified HMOs in their employee health benefits plans. It was a mistake to include in § 417.169 the limiting language, which did not appear in the predecessor rule issued in 1974. We have deleted the language to achieve consistency between paragraphs (g) and (h) of § 417.142 and with HCFA's long-standing interpretation of the statute.

Given this justification, we find that there is good cause to waive proposed rule-making procedures as unnecessary. As previously indicated, however, we will consider timely comments from anyone who questions the deletion of the reference to "assistance" or believes that, in making the technical and editorial changes, we have altered the substance of the rules. Although we cannot respond to comments individually, if we revise these rules as a result of comments, we will discuss all timely comments in the preamble to the revised rules.

Paperwork Reduction Act

These regulations contain no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

Regulatory Impact Statement

Regulatory Flexibility Analysis

Consistent with the Regulatory Flexibility Act (RFA) and section 1102(b) of the Social Security Act, we prepare a regulatory flexibility analysis for each rule, unless the Secretary certifies that the particular rule will not have a significant economic impact on a substantial number of small entities, or a significant impact on the operation of a substantial number of small rural hospitals.

We have not prepared a regulatory flexibility analysis because we have determined, and the Secretary certifies, that these rules will not have a significant impact on a substantial number of small entities or on the

operation of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 417

Administrative practice and procedure, Health maintenance organizations (HMOs), Medicare.

42 CFR Part 417 is amended as set forth below.

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

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

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), Title XIII of the Public Health Service Act (42 U.S.C. 300e through 300e–17), and 31 U.S.C. 9701, unless otherwise noted.

B. Subpart D is amended as set forth below.

Subpart D—Application for Federal Qualification

1. Section 417.140 is revised to read as follows:

§ 417.140 Scope.

This subpart sets forth—

(a) The requirements for—

(1) Entities that seek qualification as HMOs under title XIII of the PHS Act; and

(2) HMOs that seek—

(i) qualification for their regional components; or

(ii) Expansion of their service areas;

(b) The procedures that HCFA follows to make determinations; and

(c) Other related provisions, including application fees.

§ 417.141 [Removed]

2. Section 417.141 is removed.

3. Section 417.142 is revised to read as follows:

§ 417.142 Requirements for qualification.

(a) *General rules.* (1) An entity seeking qualification as an HMO must meet the requirements and provide the assurances specified in paragraphs (b) through (f) of this section, as appropriate.

(2) HCFA determines whether the entity is an HMO on the basis of the entity's application and any additional information and investigation (including site visits) that HCFA may require.

(3) HCFA may determine that an entity is any of the following:

(i) An operational qualified HMO.

(ii) A preoperational qualified HMO.

(iii) A transitional qualified HMO.

(b) *Operational qualified HMO.* HCFA determines that an entity is an operational qualified HMO if—

(1) HCFA finds that the entity meets the requirements of subparts B and C of this part.

(2) The entity, within 30 days of HCFA's determination, provides written assurances, satisfactory to HCFA, that it—

(i) Provides and will provide basic health services (and any supplemental health services included in any contract) to its enrollees;

(ii) Provides and will provide these services in the manner prescribed in sections 1301(b) and 1301(c) of the PHS Act and subpart B of this part;

(iii) Is organized and operated and will continue to be organized and operated in the manner prescribed in section 1301(c) of the PHS Act and subpart C of this part;

(iv) Under arrangements that safeguard the confidentiality of patient information and records, will provide access to HCFA and the Comptroller General or any of their duly authorized representatives for the purpose of audit, examination or evaluation to any books, documents, papers, and records of the entity relating to its operation as an HMO, and to any facilities that it operates; and

(v) Will continue to comply with any other assurances that it has given to HCFA.

(c) *Preoperational qualified HMO.* (1) HCFA may determine that an entity is a preoperational qualified HMO if it provides, within 30 days of HCFA's determination, satisfactory assurances that it will become operational within 60 days following that determination and will, when it becomes operational, meet the requirements of subparts B and C of this part.

(2) Within 30 days after receiving notice that the entity has begun operation, HCFA determines whether it is an operational qualified HMO. In the absence of this determination, the entity is not an operational qualified HMO even though it becomes operational.

(d) *Transitional qualified HMO: General rules*—(1) *Basic requirements.* HCFA may determine that an entity is a transitional qualified HMO if the entity—

(i) Meets the requirements of paragraph (d)(2) through (d)(4) of this section; and

(ii) Provides the assurances specified in paragraphs (d)(5) through (d)(7) of this section within 30 days of HCFA's determination.

(2) *Organization and operation.* The entity is organized and operated in accordance with subpart C of this part, except that it need not—

(i) Assume full financial risk for the provision of basic health services as required by § 417.120(b); or

(ii) Comply with the limitations that are imposed on insurance by § 417.120(b)(1).

(3) *Range of services.* The entity is currently providing the following services on a prepaid basis:

(i) Physician services.

(ii) Outpatient services and inpatient hospital services. (The entity need not provide or pay for hospital inpatient or outpatient services that it can show are being provided directly, through insurance, or under arrangements, by other entities.)

(iii) Medically necessary emergency services.

(iv) Diagnostic laboratory services and diagnostic and therapeutic radiologic services.

These services must meet the requirement of § 417.101, but may be limited in time and cost without regard to the constraints imposed by § 417.101(a).

(4) *Payment for services*—(i) *General rule.* The entity pays for basic health services in accordance with § 417.104, except that it need not comply with the copayments limitations imposed by § 417.104(a)(4).

(ii) *Determination of payment rates.* In determining payment rates, the entity need not comply with the community rating requirements of §§ 417.104(b) and 417.105(b).

(5) *Contracts in effect on the date of HCFA's determination.* The entity gives assurances that it will meet the following conditions with respect to its group and individual contracts that are in effect on the date of HCFA's determination, and which are renewed or renegotiated during the period approved by HCFA under paragraph (d)(6) of this section:

(i) Continue to provide services in accordance with paragraph (d)(3) of this section.

(ii) Continue to be organized and operated and to pay for basic health services in accordance with paragraphs (d)(2) and (d)(4) of this section, respectively.

(6) *Time-phased plan.* The entity gives assurances as follows:

(i) It will implement a time-phased plan acceptable to HCFA that—

(A) May not extend for more than 3 years from the date of HCFA's determination; and

(B) Specifies definite steps for meeting, at the time of renewal of each

group or individual contract, all the requirements of subparts B and C of this part.

(ii) Upon completion of this time-phased plan, it will—

(A) Provide basic and supplemental services to all of its enrollees; and

(B) Be organized and operated, and provide services, in accordance with subparts B and C of this part.

(7) *Contracts entered into after the date of HCFA's determination.* The entity gives assurances that, with respect to any group or individual contract entered into after the date of HCFA's determination, it will—

(i) Be organized and operated in accordance with subpart C of this part; and

(ii) Provide basic health services and any supplemental health services included in the contract, in accordance with subpart B of this part.

(e) *Failure to sign assurances timely.* If HCFA determines that an entity meets the requirements for qualification and the entity fails to sign its assurances within 30 days following the date of the determination, HCFA gives the entity written notice that its application is considered withdrawn and that it is not a qualified HMO.

(f) *Qualification of regional components.* An HMO that has more than one regional component is considered qualified for those regional components for which assurances have been signed in accordance with this section.

(g) *Special rules: Enrollees entitled to Medicare or Medicaid.* For an HMO that accepts enrollees entitled to Medicare or Medicaid, the following rules apply:

(1) The requirements of titles XVIII and XIX of the Act, as appropriate, take precedence over conflicting requirements of sections 1301(b) and 1301(c) of the PHS Act.

(2) The HMO must, with respect to its enrollees entitled to Medicare or Medicaid, comply with the applicable requirement of title XVIII or XIX, including those that pertain to—

(i) Deductibles and coinsurance;

(ii) Enrollment mix and enrollment practices;

(iii) State plan rules on copayment options; and

(iv) Grievance procedures.

(3) An HMO that complies with paragraph (g)(2) of this section may obtain and retain Federal qualification if, for its other enrollees, the HMO meets the requirements of sections 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and in subparts B and C of this part.

(h) *Special rules: Enrollees under the Federal employee health benefits program (FEHBP).* An HMO that accepts enrollees under the FEHBP (Chapter 89 of title 5 of the U.S.C.) may obtain and retain Federal qualification if, for its other enrollees, it complies with the requirements of section 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and subparts B and C of this part.

4. Section 417.144 is revised to read as follows:

§ 417.144 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) HCFA evaluates an application for Federal qualification on the basis of information contained in the application itself and any additional information that HCFA obtains through on-site visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, HCFA notifies the entity and allows 60 days from the date of the notice for the entity to furnish the missing information.

(3) After evaluating all relevant information, HCFA determines whether the entity meets the applicable requirements of §§ 417.142 and 417.143.

(b) *Notice of determination.* HCFA notifies each entity that applies for qualification under this subpart of its determination and the basis for the determination. The determination may be granting of qualification, intent to deny, or denial.

(c) *Intent to deny.* (1) If HCFA finds that the entity does not appear to meet the requirements for qualification and appears to be able to meet those requirements within 60 days, HCFA gives the entity notice of intent to deny qualification and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the entity may respond in writing to the issues or other matters that were the basis for HCFA's preliminary finding, and may revise its application to remedy any defects identified by HCFA.

(d) *Denial and reconsideration of denial.* (1) If HCFA denies an application for qualification under this subpart, HCFA gives the entity written notice of the denial and an opportunity to request reconsideration of that determination.

(2) A request for reconsideration must—

(i) Be submitted in writing, within 60 days following the date of the notice of denial;

(ii) Be addressed to the HCFA officer or employee who denied the application; and

(iii) Set forth the grounds upon which the entity requests reconsideration, specifying the material issues of fact and of law upon which the entity relies.

(3) HCFA bases its reconsideration upon the record compiled during the qualification review proceedings, materials submitted in support of the request for reconsideration, and other relevant materials available to HCFA.

(4) HCFA gives the entity written notice of the reconsidered determination and the basis for the determination.

(e) *Information on qualified HMOs—*(1) **Federal Register** *notices.* In quarterly **Federal Register** notices, HCFA gives the names, addresses, and service areas of newly qualified HMOs and describes the expanded service areas of other qualified HMOs.

(2) *Listings.* A cumulative list of qualified HMOs is available from the following office, which is open from 8:30 a.m. to 5 p.m., Monday through Friday: Office of Managed Care, Room 4360, Cohen Building, 400 Independence Avenue SW., Washington, DC 20201.

C. Subpart E is amended as set forth below.

Subpart E—Inclusion of Qualified Health Maintenance Organizations in Employee Health Benefits Plans

1. Section 417.150 is amended to revise the introductory text, add definitions of "agreement," "contract," and "qualified HMO," remove the definition of "health benefits," and revise the definitions of "bargaining representative," "collective bargaining agreement," "eligible employee," "employer," "health benefits plan," "public entity," and "to offer a health benefits plan" to read as follows:

§ 417.150 Definitions.

As used in this subpart, unless the context indicates otherwise—

Agreement means a collective bargaining agreement.

Bargaining representative means an individual or entity designated or selected, under any applicable Federal, State, or local law, or public entity collective bargaining agreement, to represent employees in collective bargaining, or any other employee representative designated or selected under any law.

* * * * *

Collective bargaining agreement means an agreement entered into between an employing entity and the bargaining representative of its employees.

Contract means an employer-employee or public entity-employee contract, or a contract for health benefits.

Eligible employee means an employee who meets the employer's requirements for participation in the health benefits plan.

* * * * *

Employer has the meaning given that term in section 3(d) of the Fair Labor Standards Act of 1938, except that it—

(1) Includes non-appropriated fund instrumentalities of the United States Government; and

(2) Excludes the following:

(i) The governments of the United States, the District of Columbia and the territories and possessions of the United States, the 50 States and their political subdivisions, and any agencies or instrumentalities of any of the foregoing, including the United States Postal Service and Postal Rate Commission.

(ii) Any church, or convention or association of churches, and any organization operated, supervised, or controlled by a church, or convention or association of churches that meets the following conditions:

(A) Is an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1954.

(B) Does not discriminate, in the employment, compensation, promotion or termination of employment of any personnel, or in the granting of staff and other privileges to physicians or other health personnel, on the grounds that the individuals obtain health care through HMOs, or participate in furnishing health care through HMOs.

Health benefits plan means any arrangement, to provide or pay for health services, that is offered to eligible employees, or to eligible employees and their eligible dependents, by or on behalf of an employing entity.

Public entity means the 50 states, Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands and American Samoa and their political subdivisions, the District of Columbia, and any agency or instrumentality of the foregoing, and *political subdivisions* include counties, parishes, townships, cities, municipalities, towns, villages, and incorporated villages.

Qualified HMO means an HMO that has in effect a determination, made under subpart D of this part, that the HMO is an operational, preoperational, or transitional qualified HMO.

To offer a health benefits plan means to make participation in a health benefits plan available to eligible employees, or to eligible employees and their eligible dependents regardless of whether the employing entity makes a financial contribution to the plan on behalf of these employees, directly or indirectly, for example, through payments on any basis into a health and welfare trust fund.

2. Sections 417.151 through 417.156 are revised to read as follows:

§ 417.151 Applicability.

(a) *Basic rule.* This subpart applies to any employer or public entity that offers a health benefits plan to its employees and meets the conditions specified in paragraphs (b) through (e) of this section.

(b) *Number of employees.* During any calendar quarter of the preceding calendar year, the employer or public entity employed an average of not less than 25 employees.

(c) *Minimum wage.* During any calendar quarter of the preceding calendar year, the employer was required to pay the minimum wage specified in section 6 of the Fair Labor Standards Act of 1938, or would have been required to pay that wage but for section 13(a) of that Act.

(d) *Federal assistance under section 317 of the PHS Act.* The public entity has a pending application for, or is receiving, assistance under section 317 of the PHS Act.

(e) *Request for inclusion of qualified HMO.* The employer or public entity has received, from at least one qualified HMO, a request to be included in the health benefits plan offered to employees, and the following conditions are met:

(1) The request is in writing and meets the requirements of § 417.152.

(2) At least 25 of the employees of the employer or public entity reside within the HMO's service area.

§ 417.152 Request for inclusion of the HMO in a health benefits plan; employing entity's response.

(a) *Time limitations.* (1) Unless otherwise agreed to by the HMO and the employing entity or its designee, an HMO's request for inclusion in a health benefits plan must be received by the employing entity or designee—

(i) Not more than 365 nor less than 180 days before the expiration or renewal date of—

(A) A health benefits contract or employing entity-employee contract; or

(B) A collective bargaining agreement; or

(ii) In the case of a public entity, any longer period prescribed by State law.

(2) For purposes of this paragraph, the dates are considered to be as follows:

(i) For a collective bargaining agreement that is automatically renewable or without fixed term, the expiration or renewal date is the earliest anniversary date of the agreement.

(ii) For a collective bargaining agreement that is for a fixed term of more than 1 year and provides that its health benefits terms may be renegotiated during the term of the agreement, the expiration date is the date provided by the agreement for discussion of health benefits changes.

(b) *To whom the request must be addressed.* The HMO must direct its written request for inclusion to—

(1) The employer's managing official at the employer site being solicited or the employer's designee; or

(2) The public entity's chief executive officer or designee.

(c) *Required information.* The request must include the following:

(1) Evidence showing that the HMO has been determined to be a qualified HMO in accordance with section 1310(d) of the PHS Act and subpart D of this part.

(2) A description of the HMO's service area or proposed service area and the dates when the HMO will furnish basic and supplemental health services in the area.

(3) Indication of whether the HMO furnishes the basic health services that are the services of health professionals—

(i) Through health professionals who are—

(A) Members of the HMO's staff;

(B) Members of one or more medical groups;

(C) Members of one or more individual practice associations (IPAs); or

(D) Under direct contract with the HMO; or

(ii) Through any combination of the foregoing.

(4) If the HMO provides health services through IPAs, a listing of member physicians by name, specialty, and whether they are accepting new patients from the HMO enrollment. This listing must be current within 90 days of the date of the request for inclusion.

(5) If the HMO provides health services other than through IPAs, for each ambulatory care facility the facility's address, days and hours of operation, a statement whether it is accepting new patients from the HMO enrollment, and the names and specialties of the facility's providers of basic and supplemental health services. This information must be current within 90 days of the date of the request for inclusion.

(6) A list of the hospitals where HMO enrollees will be provided basic and supplemental health services.

(7) Identification of the type of HMO entity specifying, for example, whether for profit or nonprofit, public or private, sole proprietorship, partnership or stock corporation; the members of the HMO's policymaking body; and the principal managing officer of the HMO.

(8) A statement of the HMO's capacity to accept new enrollees and the likelihood of any future limitations on enrollment.

(9) The HMO's most recently audited annual financial statement.

(10) Proposed implementing agreements between the HMO and the employer, public entity, or designee for the HMO offering.

(11) Sample copies of solicitation brochures and enrollment literature that will be used in the offer of the HMO option to employees.

(12) The HMO's current rates, including copayments, for basic and uniformly included supplemental health services and the dates these rates became effective; or the HMO's estimated rates for these services.

(d) *Employing entity's response*—(1) *Timing.* An employing entity or its designee must respond in writing to an HMO's request for inclusion no later than 60 days after receipt of the request.

(2) *Basic statement.* The response must state whether the employing entity has 25 or more employees who reside within the HMO's service area.

(3) *Additional information: Public entities only.* A public entity's response must specify the health benefits, including limitations and exclusions, that are required under State law or regulations for employees of the public entity.

(4) *Additional information: All employing entities.* If the employing entity has 25 or more employees who reside within the HMO's service area, the response must include the following:

(i) Expiration or renewal dates of contracts that cover those employees.

(ii) The amount of the employing entity's current contribution and, if applicable, the employee's contribution, for health benefits, and the dates when those contribution levels became effective.

(iii) The expiration dates of any collective bargaining agreements covering those employees.

(e) *Effect of inadequate request.* If the request for inclusion does not meet the requirements of paragraphs (a) through (c) of this section, the following rules apply:

(1) The employing entity is not required to include the HMO option in its employees' health benefits plan under § 417.154 until the HMO makes its request in accordance with those paragraphs.

(2) The employing entity or its designee must, within 60 days after receipt of the request, notify the HMO in writing of the basis for its conclusion that the request does not meet the requirements of paragraphs (a) through (c) of this section.

(f) *New request for inclusion.* (1) If an employing entity includes the HMO option in a health benefits plan in accordance with a request meeting the requirements of paragraphs (a) through (c) of this section, the employing entity must offer the HMO option to all the eligible employees who reside in the HMO's service area during the entire health benefits year.

(2) However, if no employees enroll during the health benefits year, the HMO seeking inclusion in the health benefits plan for subsequent enrollment periods must submit a new request in accordance with paragraphs (a) through (c) of this section.

§ 417.153 Offer of HMO option to employees.[1]

(a) *Basic rule.* An employing entity subject to this subpart must, at the time it offers a health benefits plan to its eligible employees, include in the plan the option of enrollment in qualified HMOs in accordance with this section.

(b) *Employees to whom the HMO option must be offered.* Each employing entity must offer the option of enrollment in a qualified HMO to each eligible employee and his or her eligible dependents who reside in the HMO's service area.

(c) *Manner of offering the HMO option.* (1) For employees who are represented by a bargaining representative, the option of enrollment in a qualified HMO——

(i) Must first be presented to the bargaining representative; and

(ii) If the representative accepts the option, must then be offered to each represented employee.

(2) For employees not represented by a bargaining representative, the option must be offered directly to those employees.

§ 417.154 HMOs that must be included in a health benefits plan.

(a) *HMOs of different models*—(1) *Categories of HMO models.* The following categories describe the manner in which an HMO furnishes the basic health services that are provided by physicians.

(i) A "staff/group model HMO" provides more than one-half of those services through members of the HMO's staff or of a medical group or groups.

(ii) An "IPA/direct contract model HMO" provides those services through——

(A) An IPA or IPAs; or

(B) A combination of IPAs, medical groups, staff, and individual physicians and other health professionals under contract with the HMO.

(2) *Requirement.* If at least one HMO from each category described in paragraph (a)(1) of this section requests inclusion in a health benefits plan, the employing entity must include at least one HMO from each category.

(3) *Terms.* For purposes of this paragraph (a), "health professionals under contract" does not include health professionals who are members of any of the following:

(i) The HMO's staff.

(ii) Medical groups.

(iii) Entities that would be medical groups if they met the following requirements:

(A) For the group members individually, the coordinated practice of their profession represents more than 50 percent of their professional activity.

(B) For the group as a whole, the delivery of health services to HMO enrollees represents more than 35 percent of their professional activity.

(b) *Additional HMOs that must be included.* An employing entity that is subject to this subpart must offer its eligible employees the option of enrollment in additional qualified HMOs if the HMOs demonstrate that at least 25 of those eligible employees reside in the HMO's service areas and meet either of the following conditions:

(1) They do not reside in the service areas of other HMOs already included in the employing entity's health benefits plan.

(2) They cannot enroll in any other HMO included in the plan because those HMOs have closed their enrollment to additional eligible employees of the employing entity.

(c) *Optional inclusion of alternative HMOs.* An employing entity may include in its health benefits plan, instead of an HMO that made a timely request for inclusion, one or more other HMOs that may not have made a request within the established time limits but are willing to be included, if the following conditions are met:

(1) The alternative HMOs are of the same type (as described in paragraph (a) of this section) as the HMO that submitted the timely request.

(2) All of the eligible employees who reside in the service area of the HMO

[1] The statutory requirement for the employing entity to include the HMO option has a sunset date of October 24, 1995. Accordingly, the statutory requirement expires on that date unless Congress extends it.

that made the timely request reside in the service areas of the alternative HMOs.

§ 417.155 How the HMO option must be included in the health benefits plan.

(a) *HMO access to employees*—(1) *Purpose and timing.*

(i) *Purpose.* The employing entity must provide each HMO included in its health benefits plan fair and reasonable access to all employees specified in § 417.153(b), so that the HMO can explain its program in accordance with § 417.124(b).

(ii) *Timing.* The employing entity must provide access beginning at least 30 days before, and continuing during, the group enrollment period.

(2) *Nature of access.* (i) Access must include, at a minimum, opportunity to distribute educational literature, brochures, announcements of meetings, and other relevant printed materials that meet the requirements of § 417.124(b).

(ii) Access may not be more restrictive or less favorable than the access the employing entity provides to other offerors of options included in the health benefits plan, whether or not those offerors elect to avail themselves of that access.

(b) *Review of HMO offering materials.* (1) The HMO must give the employing entity or designee opportunity to review, revise, and approve HMO educational and offering materials before distribution.

(2) Revisions must be limited to correcting factual errors and misleading or ambiguous statements, unless—

(i) The HMO and the employing entity agree otherwise; or

(ii) Other revisions are required by law.

(3) The employing entity or designee must complete revision of the materials promptly so as not to delay or otherwise interfere with their use during the group enrollment period.

(c) *Group enrollment period; prohibition of restrictions; effective date of HMO coverage*—(1) *Prohibition of restrictions.* If an employing entity or designee includes the option of enrollment in a qualified HMO in the health benefits plan offered to its eligible employees, it must provide a group enrollment period before the effective date of HMO coverage. The employing entity may not impose waiting periods as a condition of enrollment in the HMO or of transfer from HMO to non-HMO coverage, or exclusions, or limitations based on health status.

(2) *Effective date of coverage.* Unless otherwise agreed to by the employing entity, or designee, and the HMO, coverage under the HMO contract for employees selecting the HMO option begins on the day the non-HMO contract expires or is renewed without lapse.

(3) *Coordination of benefits.* Nothing in this subpart precludes the uniform application of coordination of benefits agreements between the HMOs and the other carriers that are included in the health benefits plan.

(d) *Continued eligibility for "free-standing" health benefits*—(1) *Basic requirement.* At the request of a qualified HMO, the employing entity or its designee must provide that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for free-standing dental, optical, or prescription drug benefits for which they were previously eligible or would be eligible if selecting a non-HMO option and that are not included in the services provided by the HMO to its enrollees as part of the HMO prepaid benefit package.

(2) *"Free-standing" defined.* For purposes of this paragraph, the term "free-standing" refers to a benefit which—

(i) Is not integrated or incorporated into a basic health benefits package or major medical plan, and

(ii) Is—

(A) Offered by a carrier other than the one offering the basic health benefits package or major medical plan; or

(B) Subject to a premium separate from the premium for the basic health benefits package or major medical plan.

(3) *Examples of the employing entity's obligation with respect to the continued eligibility.* (i) The health benefits plan includes a free-standing dental benefit. The HMO does not offer any dental coverage as part of its health services provided to members on a prepaid basis. The employing entity must provide that employees who select the HMO option continue to be eligible for dental coverage. (If the dental coverage is not optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be made optional for employees selecting the HMO option. Conversely, if this coverage is optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be mandatory for employees selecting the non-HMO option.) -

(ii) The non-HMO option provides free-standing coverage for optical services (such as refraction and the provision of eyeglasses), and the HMO does not. The employing entity must provide that employees who select the HMO option continue to be eligible for optical coverage.

(iii) The non-HMO option includes dental coverage in its major medical package, with a common deductible applied to dental as well as non-dental benefits. The HMO provides no dental coverage as part of its pre-paid health services. Because the dental coverage is not free-standing, the employing entity is not required to provide that employees who select the HMO option continue to be eligible for dental coverage, but is free to do so.

(e) *Opportunity to select among coverage options: Requirement for affirmative written selection*—(1) *Opportunity other than during a group enrollment period.* The employing entity or designee must provide opportunity (in addition to the group enrollment period) for selection among coverage options, by eligible employees who meet any of the following conditions:

(i) Are new employees.

(ii) Have been transferred or have changed their place of residence, resulting in—

(A) Eligibility for enrollment in a qualified HMO for which they were not previously eligible by place of residence; or

(B) Residence outside the service area of a qualified HMO in which they were previously enrolled.

(iii) Are covered by any coverage option that ceases operation.

(2) *Prohibition of restrictions.* When the employees specified in paragraph (e)(1) of this section are eligible to participate in the health benefits plan, the employing entity or designee must make available, without waiting periods or exclusions based on health status as a condition, the opportunity to enroll in an HMO, or transfer from HMO coverage to non-HMO coverage.

(3) *Affirmative written selection.* The employing entity or designee must require that the eligible employee make an affirmative written selection in any of the following circumstances:

(i) Enrollment in a particular qualified HMO is offered for the first time.

(ii) The eligible employee elects to change from one option to another.

(iii) The eligible employee is one of those specified in paragraph (e)(1) of this section.

(f) *Determination of copayment levels and supplemental health services.* The selection of a copayment level and of supplemental health services to be contracted for must be made as follows:

(1) For employees represented by a collective bargaining representative, the selection of copayment levels and supplemental health services is subject to the collective bargaining process.

(2) For employees not represented by a bargaining representative, the selection of copayment levels and supplemental health services is subject to the same decisionmaking process used by the employing entity with respect to the non-HMO option in its health benefits plan.

(3) In all cases, the HMO has the right to include, with the basic benefits package it provides to its enrollees for a basic health services payment, on a non-negotiable basis, those supplemental health services that meet the following conditions:

(i) Are required to be offered under State law.

(ii) Are included uniformly by the HMO in its prepaid benefit package.

(iii) Are available to employees who select the non-HMO option but not available to those who select the HMO option.

§ 417.156 When the HMO must be offered to employees.

(a) *General rules.* (1) The employing entity or designee must offer eligible employees the option of enrollment in a qualified HMO at the earliest date permitted under the terms of existing agreements or contracts.

(2) If the HMO's request for inclusion in a health benefits plan is received at a time when existing contracts or agreements do not provide for inclusion, the employing entity must include the HMO option in the health benefits plan at the time that new agreements or contracts are offered or negotiated.

(b) *Specific requirements.* Unless mutually agreed otherwise, the following rules apply:

(1) *Collective bargaining agreement.* The employing entity or designee must raise the HMO's request during the collective bargaining process—

(i) When a new agreement is negotiated;

(ii) At the time prescribed, in an agreement with a fixed term of more than 1 year, for discussion of change in health benefits; or

(iii) In accordance with a specific process for review of HMO offers.

(2) *Contracts.* For employees not covered by a collective bargaining agreement, the employing entity or designee must include the HMO option in any health benefits plan offered to eligible employees when the existing contract is renewed or when a new health benefits contract or other arrangement is negotiated.

(i) If a contract has no fixed term or has a term in excess of 1 year, the contract must be treated as renewable on its earliest anniversary date.

(ii) If the employing entity or designee is self-insured, the budget year must be treated as the term of the existing contract.

(3) *Multiple arrangements.* In the case of a health benefits plan that includes multiple contracts or other arrangements with varying expiration or renewal dates, the employing entity must include the HMO option, in accordance with paragraphs (b)(1) and (b)(2) of this section,—

(i) At the time each contract or arrangement is renewed or reissued; or

(ii) The benefits provided under the contract or arrangement are offered to employees.

3. Sections 417.158 and 417.159 are revised to read as follows:

§ 417.158 Payroll deductions.

Each employing entity that provides payroll deductions as a means of paying employees' contributions for health benefits or provides a health benefits plan that does not require an employee contribution must, with the consent of an employee who selects the HMO option, arrange for the employee's contribution, if any, to be paid through payroll deductions.

§ 417.159 Relationship of section 1310 of the Public Health Service Act to the National Labor Relations Act and the Railway Labor Act.

The obligation of an employing entity subject to this subpart to include the HMO option in any health benefits plan offered to its eligible employees must be carried out consistently with the obligations imposed on that employing entity under the National Labor Relations Act, the Railway Labor Act, and other laws of similar effect.

D. Subpart F is amended as set forth below.

Subpart F—Continued Regulation of Federally Qualified Health Maintenance Organizations

1. The heading of subpart F is revised to read as set forth above.

2. Section 417.160 is revised to read as follows:

§ 417.160 Applicability.

This subpart applies to any entity that has been determined to be a qualified HMO under subpart D of this part.

3. Section 417.163 is revised to read as follows:

§ 417.163 Enforcement procedures.

(a) *Complaints.* Any person, group, association, corporation, or other entity may file with HCFA a written complaint with respect to an HMO's compliance with assurances it gave under subpart D of this part. A complaint must—

(1) State the grounds and underlying facts of the complaint;

(2) Give the names of all persons involved; and

(3) Assure that all appropriate grievance and appeals procedures established by the HMO and available to the complainant have been exhausted.

(b) *Investigations.* (1) HCFA may initiate investigations when, based on a report, a complaint, or any other information, HCFA has reason to believe that a Federally qualified HMO is not in compliance with any of the assurances it gave under subpart D of this part.

(2) When HCFA initiates an investigation, it gives the HMO written notice that includes a full statement of the pertinent facts and of the matters being investigated and indicates that the HMO may submit, within 30 days of the date of the notice, a written report concerning these matters.

(3) HCFA obtains any information it considers necessary to resolve issues related to the assurances, and may use site visits, public hearings, or any other procedures that HCFA considers appropriate in seeking this information.

(c) *Determination and notice by HCFA*—(1) *Determination.* (i) On the basis of the investigation, HCFA determines whether the HMO has failed to comply with any of the assurances it gave under subpart D of this part.

(ii) HCFA publishes in the **Federal Register** a notice of each determination of non-compliance.

(2) *Notice of determination: Corrective action.* (i) HCFA gives the HMO written notice of the determination.

(ii) The notice specifies the manner in which the HMO has not complied with its assurances and directs the HMO to initiate the corrective action that HCFA considers necessary to bring the HMO into compliance.

(iii) The HMO must initiate this corrective action within 30 days of the date of the notice from HCFA, or within any longer period that HCFA determines to be reasonable and specifies in the notice. The HMO must carry out the corrective action within the time period specified by HCFA in the notice.

(iv) The notice may provide the HMO an opportunity to submit, for HCFA's approval, proposed methods for achieving compliance.

(d) *Remedy: Revocation of qualification.* If HCFA determines that a qualified HMO has failed to initiate or to carry out corrective action in accordance with paragraph (c)(2) of this section—(1) HCFA revokes the HMO's qualification and notifies the HMO of this action.

(2) In the notice, HCFA provides the HMO with an opportunity for reconsideration of the revocation,

including, at the HMO's election, a fair hearing.

(3) The revocation of qualification is effective on the tenth calendar day after the day of the notice unless HCFA receives a request for reconsideration by that date.

(4) If after reconsideration HCFA again determines to revoke the HMO's qualification, this revocation is effective on the tenth calendar day after the date of the notice of reconsidered determination.

(5) HCFA publishes in the **Federal Register** each determination it makes under this paragraph (d).

(6) A revocation under this paragraph (d) has the effect described in § 417.164.

(e) *Notice by the HMO.* Within 15 days after the date HCFA issues a notice of revocation, the HMO must prepare a notice that explains, in readily understandable language, the reasons for the determination that it is not a qualified HMO, and send the notice to the following:

(1) The HMO's enrollees.

(2) Each employer or public entity that has offered enrollment in the HMO in accordance with subpart E of this part.

(3) Each lawfully recognized collective bargaining representative or other representative of the employees of the employer or public entity.

(f) *Reimbursement of enrollees for services improperly denied, or for charges improperly imposed.* (1) If HCFA determines, under paragraph (c)(1) of this section, that an HMO is out of compliance, HCFA may require the HMO to reimburse its enrollees for the following—

(i) Expenses for basic or supplemental health services that the enrollee obtained from other sources because the HMO failed to provide or arrange for them in accordance with its assurances.

(ii) Any amounts the HMO charged the enrollee that are inconsistent with its assurances. (Rules applicable to charges for all enrollees are set forth in §§ 417.104 and 417.105. The additional rules applicable to Medicare enrollees are in § 415.454.)

(2) This paragraph applies regardless of when the HMO failed to comply with the appropriate assurances.

(g) *Remedy: Civil suit*—(1) *Applicability.* This paragraph applies to any HMO or other entity to which a grant, loan, or loan guarantee was awarded, as set forth in subpart V of this part, on the basis of its assurances regarding the furnishing of basic and supplemental services or its operation and organization, as the case may be.

(2) *Basis for action.* If HCFA determines that the HMO or other entity has failed to initiate or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, HCFA may bring civil action in the U.S. district court for the district in which the HMO or other entity is located, to enforce compliance with the assurances it gave in applying for the grant, loan, or loan guarantee.

4. Section 417.164 is revised to read as follows:

§ 417.164 Effect of revocation of qualifiers on inclusion in employee's health benefit plans.

When an HMO's qualification is revoked under § 417.163(d), the following rules apply:

(a) The HMO may not seek inclusion in employees health benefits plans under subpart E of this part.

(b) Inclusion of the HMO in an employer's health benefits plan—

(1) Is disregarded in determining whether the employer is subject to the requirements of subpart E of this part; and

(2) Does not constitute compliance with subpart E of this part by the employer.

5. Section 417.166 is revised to read as follows:

§ 417.166 Waiver of assurances.

(a) *General rule.* HCFA may release an HMO from compliance with any assurances the HMO gives under subpart D of this part if—

(1) The qualification requirements are change by Federal law; or

(2) The HMO shows good cause, consistent with the purposes of title XIII of the PHS Act.

(b) *Basis for finding of good cause.* (1) Grounds upon which HCFA may find good cause include but are not limited to the following:

(i) The HMO has filed for reorganization under Federal bankruptcy provisions and the reorganization can only be approved with the waiver of the assurances.

(ii) State laws governing the entity have been changed after it signed the assurances so as to prohibit the HMO from being organized and operated in a manner consistent with the signed assurances.

(2) Changes in State laws do not constitute good cause to the extent that the changes are preempted by Federal law under section 1311 of the PHS Act.

(c) *Consequences of waiver.* If HCFA waives any assurances regarding compliance with section 1301 of the PHS Act, HCFA concurrently revokes the HMO's qualification unless the waiver is based on paragraph (a)(1) of this section.

§§ 417.168 and 417.169 [Removed]

6. Sections 417.168 and 417.169 are removed.

E. Subpart V is amended as set forth below:

Subpart V—Administration of Outstanding Loans and Loan Guarantees

1. Section 417.910 is revised to read as follows:

§ 417.910 Applicability.

The regulations in this subpart apply, as appropriate, to public and private entities that have loans or loan guarantees that—

(a) Were awarded to them before October 1986 under section 1304 or section 1305 of the PHS Act; and

(b) Are still outstanding.

2. Section 417.911 is amended to remove the definitions of any *12-month period, health system agency* (including *State health planning and development agency*), and *nonprofit.*

§§ 417.912 through 417.919, 417.921 through 417.926, 417.932, 417.933, 417.935, and 417.936 [Removed]

3. Sections 417.912 through 417.919, 417.921 through 417.926, 417.932, 417.933, 417.935, and 417.936 are removed.

4. Sections 417.934 and 417.937 are revised to read as follows:

§ 417.934 Reserve requirement.

(a) *Timing.* Unless the Secretary approved a longer period, an entity that received a loan or loan guarantee under section 1305 of the PHS Act was required to establish a restricted reserve account on the earlier of the following:

(1) When the HMO's revenues and costs of operation reached the break-even point.

(2) At the end of the 60-month period following the Secretary's endorsement of the loan or loan guarantee.

(b) *Purpose and amount of reserve.* The reserve had to be constituted so as to accumulate, no later than 12 years after endorsement of the loan or loan guarantee, an amount equal to 1 year's principal and interest.

§ 417.937 Loan and loan guarantee provisions.

(a) *Disbursement of loan proceeds.* The principal amount of any loan made or guaranteed by the Secretary under this subpart was disbursed to the entity in accordance with an agreement entered into between the parties to the loan and approved by the Secretary.

(b) *Length and maturity of loans.* The principal amount of each loan or loan guarantee, together with interest

thereon, is repayable over a period of 22 years, beginning on the date of endorsement of the loan, or loan guarantee by the Secretary. The Secretary could approve a shorter repayment period if he or she determined that a repayment period of less than 22 years is more appropriate to an entity's total financial plan.

(c) *Repayment.* The principal amount of each loan or loan guarantee, together with interest thereon is repayable in accordance with a repayment schedule that is agreed upon by the parties to the loan or loan guarantee and approved by the Secretary before or at the time of endorsement of the loan. Unless otherwise specifically authorized by the Secretary, each loan made or guaranteed by the Secretary is repayable in substantially level combined installments of principal and interest to be paid at intervals not less frequently than annually, sufficient in amount to amortize the loan through the final year of the life of the loan. Principal repayment during the first 60 months of operation could be deferred with payment of interest only during that period. The Secretary could set rates of interest for each disbursement at a rate comparable to the rate of interest prevailing on the date of disbursement for marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

5. A new § 417.940 is added, to read as follows:

§ 417.940 Civil action to enforce compliance with assurances.

The provisions of § 417.163(g) apply to entities that have outstanding loans or loan guarantees administered under this subpart.

F. Technical amendments.

1. In § 417.124, a new paragraph (e)(4) is added, to read as follows:

§ 417.124 Administration and management.

* * * * *

(e) *Conversion of enrollment.* * * *

(4) The HMO must offer the enrollment on the same terms and conditions that it makes available to other nongroup enrollees.

§ 417.150 [Amended]

2. In § 417.150, in the definitions of "carrier" and "designee", "membership" is revised to read "enrollment".

§ 417.400 [Amended]

3. In § 417.400, in paragraph (a), "as amended by section 114 of public law 97–248. Section 1876 of the Act," is removed and "which" is added in its place.

§ 417.436 [Amended]

4. In § 417.436, in paragraph (a)(11), "Advanced directives" is revised to read "Advance directives".

§ 417.460 [Amended]

5. In § 417.460, the heading of paragraph (a) is revised to read *"Disenrollment of Medicare beneficiaries."*

§ 417.801 [Amended]

6. In § 417.801, in paragraph (b)(2), ", a beneficiary," is removed, and "individual" is revised to read "enrollee" each time it appears.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare Hospital Insurance Program; No. 93.774, Medicare Supplementary Medical Insurance Program)

Dated: June 23, 1994.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: September 7, 1994.

Donna E. Shalala,

Secretary.

[FR Doc. 94–23281 Filed 9–29–94; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 7088

[CO–930–4210–06; COC–43908]

Withdrawal of National Forest System Land for Breckenridge Ski Area; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order withdraws 280 acres of National Forest System land from mining for protection of recreational resources and facilities at the Breckenridge Ski Area. This withdrawal is an addition to the existing Breckenridge Ski Area. The land has been and remains open to such forms of disposition as may by law be made of National Forest System land and to mineral leasing.

EFFECTIVE DATE: September 30, 1994.

FOR FURTHER INFORMATION CONTACT: Doris E. Chelius, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215–7076, 303–239–3706.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. Subject to valid existing rights, the following described National Forest System land is hereby withdrawn from location and entry under the United States mining laws (30 U.S.C. Ch. 2 (1988)), for protection of facilities at the Breckenridge Ski Area:

Sixth Principal Meridian

Arapaho National Forest

T. 6 S., R. 78 W.,
Sec. 34, Nominal W½W½ (Protraction Diagram No. 9, accepted April 26, 1965).
T. 7 S., R. 78 W.,
Sec. 3, Nominal N½NW¼ and N½S½NW¼ (Protraction Diagram No. 45, accepted August 20, 1986).

The area described contains approximately 280 acres in Summit County.

2. The withdrawal made by this order does not alter the applicability of those public land laws governing the use of National Forest System land under lease, license, or permit, or governing the disposal of their mineral or vegetative resources other than under the mining laws.

3. This withdrawal will expire June 14, 2038, unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land and Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1988), the Secretary determines that the withdrawal shall be extended.

Dated: September 26, 1994.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 94–24266 Filed 9–29–94; 8:45 am]

BILLING CODE 4310–JB–P

43 CFR Public Land Order 7089

[CO–930–4210–06; COC–54072]

Withdrawal of National Forest System Land for the Purgatory Ski Area; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order withdraws 2,360.78 acres of National Forest System land from mining for 50 years to protect recreational resources and facilities at the Purgatory Ski Area. The land has been and remains open to such forms of disposition as may by law be made of National Forest System land and to mineral leasing.

EFFECTIVE DATE: September 30, 1994.

FOR FURTHER INFORMATION CONTACT: Doris E. Chelius, BLM Colorado State