SUPPLEMENTARY INFORMATION: On Monday, April 29, 1985, there was published in the **Federal Register**, 50 FR 16708, a proposed consent agreement with analysis In the Matter of Hawaii Dental Service Corporation, a corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows: Subpart—Coercing and Intimidating: § 13.350 Customers or prospective customers; §13.367 Members. Subpart—Combining or Conspiring: § 13.384 Combining or conspiring; § 13.388 To control allocation and solicitation of customers; § 13.425 To enforce or bring about resale price maintenance; § 13.475 To restrict competition in buying: §13.497 To terminate or threaten to terminate contracts, dealings, franchises, etc. Subpart—Corrective Actions and/or Requirements: § 13.533 Corrective actions and/or requirements; § 13.533–20 Disclosures; § 13.533–37 Formal regulatory and/or statutory requirements; § 13.533–40 Furnishing information to media; § 13.533–60 Release of general, specific, or contractual constrictions, requirements, or restraints.

List of Subjects in 16 CFR Part 13

Dental services, Trade practices.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 85–19549 Filed 8–15–85; 8:45 am]

BILLING CODE 6750–01–M

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16 CFR Part 13

[Docket No. C–2859]

Salomon/North America, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Modifying Order.

SUMMARY: This order modifies the 1977 consent order (42 FR 6797) issued with respondent by deleting provisions in the original order that prohibited the company from barring transshipment (sales between retailers) or limiting the retail locations from which dealers may sell its products. The modifying order is the result of respondent's request to the Commission for modification of the terms of the original order.

DATES: Consent Order issued Jan. 6, 1977. Modifying Order issued July 30, 1985.

FOR FURTHER INFORMATION CONTACT: FTC/L–301, Daniel P. Ducore, Washington, D.C. 20580. (202) 634–4642.

SUPPLEMENTARY INFORMATION: In the Matter of Salomon/North America, Inc., a corporation. The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are modified by deleting the following: Subpart—Combining or Conspiring: § 13.450 To limit distribution or dealings to regular, established or acceptable channels or classes.

List of Subjects in 16 CFR Part 13

Ski bindings and equipment, Trade practices.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Order Reopening and Modifying Order

Commissioners: James C. Miller III, Chairman; Patricia P. Bailey, George W. Douglas, Terry Calvani, Mary L. Azcuenaga.

In the Matter of Salomon/North America, Inc., Docket No. C–2859.

Issued: January 6, 1977.

On March 25, 1985, respondent Salomon/North America, Inc. ("Salomon") filed its "Request of Salomon/North America, Inc. for Modification of Consent Order" ("Request"), pursuant to section 5(b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), and § 2.51 of the Commission's Rules of Practice. The Request asked the Commission to reopen the proceeding in Docket No. C–2859 and to modify the order issued by the Commission in this case on January 6, 1977, by deleting the provisions that restrict Salomon's ability to limit the transshipping of its products and that prohibit Salomon from limiting the retail locations from which dealers may sell its products. Salomon also requests deletion of Paragraph II of the order which creates a limited exception to the order's provision that restricts Salomon's ability to limit the transshipment of its products. Salomon's Request was on the public record for thirty days and no comments were received.

After reviewing Salomon's request and other available information, the Commission has concluded that the public interest warrants reopening and modification of the order in the manner requested by Salomon. The transshipment and location restriction provisions of the order (subparagraphs I.B and I.C) were adopted principally as "fencing-in" restraints ancillary to the order's ban on resale price maintenance ("RPM") Salomon has shown that it does not fix the prices at which its authorized dealers resell Salomon ski products, that Salomon ski product prices vary from dealer to dealer, and that the transshipment and location restriction provisions therefore have served their purpose to encourage the emergence of intrabrand price competition in Salomon products. To the extent that subparagraphs I.B and I.C were intended as a remedy for the alleged anticompetitive effects of transshipment and location restrictions independent of RPM, the Supreme Court's ruling in *Continental T.V. Inc.* v. *GTE Sylvania, Inc.*, 433 U.S. 26 (1977), constitutes a change in law that justifies reexamination of the provisions. Such a reexamination, based on the record presented by Salomon and other information, demonstrates that transshipment and location restraints by Salomon would pose no threat to interbrand competition.

Salomon's inability to ban transshipping and sales from unauthorized locations would likely cause Salomon significant competitive injury by, among other things, lessening the efficiency of Salomon's distribution system, discouraging dealers from remaining with Salomon, exposing Salomon's customers to increased risk of injury and, consequently, exposing Salomon to personal injury claims.

The transshipment and location restriction provisions in question appear to have served their remedial purpose. There is no indication that Salomon has engaged in RPM (or has breached the order's transshipping and location restriction provisions) from January 6, 1977, to date, and nothing in the record suggests that there is a need to continue the order's transshipment and location restriction provisions to ensure that RPM is not reinstituted by Salomon.

Accordingly, it is ordered that this matter be, and it hereby is, reopened and that subparagraphs I.B, I.C and Paragraph II of the order be, and they hereby are, deleted.

Issued: July 30, 1985.

By the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 85–19547 Filed 8–15–85; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

20 CFR Part 450

42 CFR Parts 400, 405, 408, 409, 442, 456, 481, 485, 488 and 491

[BERC-260-F]

Medicare and Medicaid; Corrections and Conforming Changes

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

ACTION: Final rules and corrections.

SUMMARY: This document—

1. Removes unnecessary rules from the Social Security regulations.

2. Removes reporting requirements that never went into effect because they were not approved by the Office of Management and Budget.

3. Corrects errors and omissions in final rules published in December 1982 and March 1983.

4. Makes technical corrections and conforming changes in other Medicare and Medicaid regulations that deal with payment of benefits, exclusions from Medicare, beneficiary appeals, and physician certification. These changes are needed primarily to conform certain rules to changes made in other regulations since the rules were last published.

5. Redesignates Parts 481 and 488 to make possible a more logical organization of Subchapter E—Standards and Certification.

EFFECTIVE DATE: These rules are effective September 16, 1985.

FOR FURTHER INFORMATION CONTACT: Luisa V. Iglesias, (202) 245-0383.

SUPPLEMENTARY INFORMATION: Part 450 of Chapter III of Title 20 of the Code of Federal Regulations, which deals with grants to demonstrate the effectiveness of health care rate regulation, as authorized under section 1526 of the Public Health Service Act, is removed as unnecessary because—

- We have never approved any demonstration projects under these rules;
- For the past several years, Congress has not appropriated any funds to implement the section 1526 authority; and
- Section 1886(c) of the Medicare statute, enacted in September 1982 and amended in April 1983, allows States to request HCFA approval of a State's hospital reimbursement control system under which payment for services provided by hospitals in the State may be made in accordance with the State's system, rather than in accordance with other provisions of title XVIII. Thus, demonstration projects for health care rate regulation are unnecessary.

Two sets of final rules are corrected by this document. The first, published on December 15, 1982 (47 FR 56282), established Part 488, the rules for the comprehensive outpatient rehabilitation facility (CORF) services authorized under section 1861(cc) of the Social Security Act. Part 488 (which is being redesignated as Part 485) needed only the correction of the statement that a CORF psychologist must hold a master's degree "from a training program approved by the State." Since training programs are not approved by the State and do not grant degrees, we corrected the statement to read ". . . a master's degree in psychology from an educational institution approved by the State in which it is located."

The second was published on March 25, 1983 (48 FR 12526) to implement 13 statutory provisions and to clarify, reorganize, and renumber a major portion of the Medicare hospital insurance regulations. Most of the corrections are required because of unintended omissions. In one case (§ 409.12) it was necessary to revise the language because it did not clearly describe the statutory exclusion of private duty nursing. The definition of "provider" is amended to include a hospice; and the definition of "State", to reflect the extension of Medicaid funding to American Samoa.

A third set of final rules, published on September 1, 1983 (48 FR 39752) implemented sections 602 (e), (h), and (k) of Pub. L. 98-21 (the Social Security Amendments of 1983), which amended the Act to (1) exclude from Medicare payment any service (other than physicians' services) furnished to hospital inpatients unless the service is furnished by, or under arrangements made by, the hospital; (2) require hospitals to agree, as a condition for approving a provider agreement, to furnish directly or under arrangements any inpatient hospital services (except physicians services) that are covered by Medicare; and (3) provide that the first two requirements may be waived for any cost reporting period that begins before October 1986, if a hospital has, since before October 1982, allowed direct billing under Part B so extensively that immediate implementation of the exclusion would threaten the stability of the care furnished to the hospital's inpatients. The rules published on September 1, 1983 added a new paragraph (m) to § 405.310 to reflect the new exclusion and the exceptions to that exclusion. Because the language of that paragraph (m) is unclear and could be misleading, we are revising it to ensure proper understanding and application. We are also updating other paragraphs of § 405.310 as explained below in the discussion of changes to Subpart C of Part 405 of the Medicare rules. This document also corrects and conforms other Medicare regulations in Subparts A, C, F, G, K, and P of Part 405, and in Parts 456 and 474, as explained below:

1. In Subpart A, which deals with payment of hospital insurance benefits, we:

a. Revised § 405.165 to —

- Substitute the term "posthospital SNF care" for "posthospital extended care services" wherever it appears, and add "participating hospital that has a swing-bed approval" as a place (in addition to a SNF) where Medicare pays for SNF care. (These changes are needed for consistency with the rules published on March 25, 1983 at 48 FR 12541-12546, which change the terminology and specify coverage of SNF care furnished in any hospital that has an agreement to use some of its beds to furnish SNF type care.)
- Delete the parenthetical statement "(other than a doctor of podiatry or surgical chiropody)" because, under section 1861(r)(3) of the Social Security Act (the Act) as amended by section 951 of the Omnibus Reconciliation Act of 1980 (Pub. L. 96-499), a doctor of podiatric medicine is recognized as a physician for purposes of certifying need for services, if specified conditions are met.
- Delete the reference to Part 463 Professional Standards Review Organization (PSRO) because those organizations no longer function to review Medicare claims.
- Substitute reference to "§§ 409.20 and 409.30-409.36" for reference to §§ 405.125 through 405.128a", because the latter sections were renumbered by the March 25, 1983 regulations cited above.
- Delete the reference to § 405.133 because that section was removed from the Medicare regulations by the March 25, 1983 publication. Section 405.133 dealt with the "presumed coverage" provision that was formerly contained in section 1814 of the Act, and was repealed by section 941 of Pub. L. 96-499.
- Conform the content on inpatient hospital services (required before admission to the SNF) to §§ 409.3 and 409.30 of the March 25, 1983 regulations (48 FR 12542 and 12544).

b. Revised § 405.166 to —

• Change "posthospital extended care services" to "posthospital SNF care".

• Indicate briefly the content of cited § 405.1137.

• Revise paragraph (b) to reflect the fact that it is PROs rather than PSROs that may now assume responsibility for review of SNF care.

c. Revised § 405.167 to—

• Change "posthospital extended care services" to "posthospital SNF care".

• Update the content to show that—

(1) HCFA (rather than the Secretary) makes the determination, as is set forth in § 489.50 of the Medicare regulations.

(2) The provisions also apply to SNF care furnished by a hospital that has a swing-bed approval.

• Delete unnecessary cross-references.

d. Revised § 405.170 to—

• Delete the word "posthospital" wherever it appears because the requirement that home health services be related to prior inpatient hospital care was removed from section 1812(b)(3) of the Act by section 930 of Pub. L. 96–499.

• Delete the details of certification requirements because they duplicated the content of § 405.1633, which contains the applicable rules on certification for home health services and is cited in § 405.170.

• Delete content pertinent to the presumed coverage provision that was repealed.

• Include reference to § 409.42, which contains other conditions for coverage of home health services.

• Remove paragraph (c) which dealt with the revoked "presumed coverage" provision explained above in the discussion of § 405.165.

e. Made other minor editorial changes and corrections.

2. In Subpart C, which deals with exclusions from Medicare and exceptions to those exclusions, we have, in addition to revising the recently added paragraph (m) of § 405.310, as discussed above, made the following kinds of changes:

a. *Updating to reflect statutory changes already in effect.* Sections 936 and 939 of Pub. L. 96–499 amended section 1862 of the Act to broaden benefits by (1) extending coverage of inpatient hospital care in connection with dental procedures to situations in which hospitalization is required because of the severity of the dental procedures, and (2) encompassing treatment of warts of the foot. Section 1 of Pub. L. 96–611 added sections 1861(s)(10) and 1862(a)(1)(B) to the Act to provide coverage for pneumococcal vaccine and vaccination to the extent that it is reasonable and necessary for the prevention of illness. These additional services are covered as exceptions to specific exclusions from Medicare. Accordingly, they are reflected, respectively, in revised paragraphs (i), (1), and (e) of § 405.310.

b. *Updating to reflect statutory changes already implemented by final rules.* Section 122 of Pub. L. 97–248 amended section 1812 of the Act to expand Medicare Part A coverage to include hospice care. Implementing rules were published on December 16, 1983 (48 FR 56008). The hospice rules provide exceptions to three of the § 405.310 exclusions: custodial care (paragraph (g)), personal comfort services (paragraph (j)), and services not reasonable and necessary (paragraph (k)).

c. *Conforming and clarifying editorial changes.* We made minor editorial changes in paragraphs (a) through (d), (f), and (h) of § 405.310, to achieve consistency of style and terminology with the paragraphs that required the substantive changes discussed above.

d. *Removal of duplicative content.* We removed paragraph (n) of that section because its content was transferred to § 409.30 by the final rules published on March 25, 1983, and discussed above.

3. In Subpart D, which deals with principles of reimbursement, we have:

• Removed reporting requirements that never became effective because they were not approved by the Executive Office of Management and Budget (EOMB). (Paragraph (h) of § 405.421, which is removed, contained reporting requirements applicable to providers that receive grants for primary care training programs. It was published with a note indicating that it would not go into effect until approved by EOMB).

4. In Subpart F, in § 405.658, which deals with emergency services furnished by nonparticipating hospitals, we have corrected cross-references.

5. In Subpart G, which sets forth the policies and procedures for beneficiary appeals under the hospital insurance program, we have made the following changes:

• Removed the appendix that reproduced the Social Security regulations that contain provisions applicable to beneficiary appeals (20 CFR Part 404, Subparts J and R). We supplied the appendix so that users of HCFA regulations could get the complete picture without having to refer to another title of the CFR. However, when the Social Security regulations were revised, our appendix became outdated. We have concluded that the cost of maintaining the appendix outweighs the advantages that it might provide.

• Deleted a reference to that appendix (§ 405.701).

• Corrected cross-references in § 405.710(b).

6. In Subpart K, which sets forth the conditions of participation for skilled nursing facilities (SNFs), we amended §405.1121 to—

• Remove reporting requirements that have never gone into effect because they were not approved by the Office of Management and Budget; and

• Substitute language that reflects only the provisions of section 1861(j)(14) of the Act, which is clear, and sufficient to ensure the protection of funds belonging to SMF patients.

7. In Subpart P, which sets forth the requirements for physician certification and recertification, we removed an outdated cross-reference in § 405.1625–1, revised §§ 405.1629 and 405.1632 to conform their terminology to previously published revisions of §§ 405.1627, 405.1633, and 405.1634. In addition —

We amended § 405.1632 to —

• Substitute the term "posthospital SNF care" for "posthospital extended care services" wherever it appears.

• Delete content pertaining to the "presumed coverage" provisions that were repealed by section 941 of Pub. L. 96–499 and removed from other Medicare regulations by the final rules published on March 25, 1983.

• Make clear that the rules of the section apply to SNF care furnished by a swing-bed hospital as well as that furnished by a SNF.

• Conform the "content of certification" rule to §§ 409.3 and 409.30 of the March 25, 1983 regulations (48 FR 12542 and 12544).

• Provide captions that make the section easier to use and understand.

We amended § 405.1634 to —

• Clarify who must sign a plan for speech pathology service.

• Reflect the provisions of sections 2341 and 2342 of the Deficit Reduction Act of 1984 (Pub. L. 98–369), as they affect outpatient physical therapy (OPT) services. Section 2341 provides that, if specified conditions are met, a doctor of podiatric medicine is considered a physician for the requirement that OPT services be furnished while the beneficiary is under the care of a physician. Section 2342 provides that a physical therapist (as well as a physician) may establish a plan of treatment for OPT services. The plan must be reviewed by a physician.

• Incorporate the content of § 405.250–1, which is more appropriate to this section.

8. In part 408, Subpart A, which deals with eligibility and entitlement to

hospital insurance (Medicare Part A), we have substituted designated subpart titles for undesignated headings, to facilitate references to these rules.

9. In Part 409, Subpart A, which deals with Medicare Part A benefits, we amended §409.42(b)(2) to provide that, if specified conditions are met, a doctor of podiatric medicine (as well as a doctor of medicine or osteopathy) is considered a physician to fulfill the requirements that home health services be provided while the beneficiary is "under the care of a physician". We have also substituted a designated subpart title for each undesignated heading, to facilitate reference to these rules.

10. In Part 442, which sets forth standards for Medicaid payment for skilled nursing and intermediate care facility services, we revised three sections to conform to the changes made in the Medicare rules on protection of patients' funds. Previous proposals to revise §§ 442.311, 442.404, 442.406, and to remove 442.320 did not go into effect because they would have made applicable to Medicaid the Medicare information collection requirements (§ 405.1121(m)) that EOMB did not approve. Now that § 405.1121(m) has been revised to include only the statutory requirements, there is no reason no to make it applicable to Medicaid. We have removed the effective date note at the end of § 442.320. Section 442.320 was to be deleted effective October 22, 1980, upon EOMB approval of the regulations at § 405.1121(m) Since EOMB did not approve those regulations, § 442.320 will remain and the effective date note will be removed.

11. In Part 456, Subpart F, which deals with utilization control activities in SNFs, we amended § 456.360 to reflect the amendment to section 1903(g)(1)(A) of the Act by section 137(b)(12) of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97-248). The amendment extends to private ICFs for the mentally retarded (ICFs/MR) timing of recertification provisions previously applicable only to public ICFs/MR.

12. We redesignated Part 481 as Part 491, and Part 488 as Part 485, to permit a more logical organization of Subchapter E.

Impact Analysis Statement

Executive Order 12291

Executive Order 12291 requires agencies to prepare a regulatory analysis for any rule that is likely to have an annual impact of $100 million or more on the general economy; cause a major increase in costs or prices; or meet other thresholds specified in section 1(b) of the Order. We have determined tht none of the conforming amendments will affect the economy by more than $100 million. These provisions were self-implementing upon date of enactment. Therefore, these regulations have no additional impact beyond that which results from the statutory provisions.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)) requires agencies to prepare and publish a regulatory flexibility analysis (RFA) for any regulation that will have "a significant impact on a substantial number of small entities". A small entity is a small business, a nonprofit enterprise, or a government jurisdiction (such as a county or township) with a population of less than 50,000. The purpose of the analysis would be to anticipate the impact and to seek alternatives that would have a less negative effect.

An RFA is not required for these rules because we have determined, and the Secretary certifies, that they will not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act

Section 405.1632(b) through (f) of this final rule contains information collection requirements subject to approval by the Office of Management and Budget (OMB) under section 3507 of the Paperwork Reduction Act of 1980. When approval is obtained, we will publish a notice in the **Federal Register** to that effect.

Waiver of Proposed Rulemaking

The changes made by these rules are of three types:

- Minor technical corrections, such as the removal of rules that never went into effect.
- Minor clarifying editorial revisions.
- Minor amendments needed to conform the rules to changes in the law or in other regulations. In no instance does any of the amendments affect the substance of the Medicare or Medicaid rules, apart from the changes in the law or other regulations. Therefore we find that the usual notice and opportunity for public comment are unnecessary.

List of Subjects

42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 408

Health facilities, Kidney diseases, Medicare.

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 442

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 456

Administrative practice and procedure, Grant programs-health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 481 (Redesignated as Part 491)

Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 488 (Redesignated as Part 485)

Health facilities, Medicare, Reporting and recordkeeping requirements.

Title 20—Employees' Benefits

20 CFR Chapter III is amended as set forth below:

PART 450—RESEARCH GRANTS AND CONTRACTS [REMOVED]

20 CFR Part 450 is removed as outdated and unnecessary, and the table of contents of Chapter III is amended to reflect this change.

Title 42—Public Health

42 CFR Chapter IV is amended as set forth below:

I. PART 400—INTRODUCTION; DEFINITIONS

A. The authority citation for Part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

B. *§ 400.203 [Amended]*

In § 400.203, in the definition of "*State*", "American Samoa," is added immediately after "Guam,".

II. PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Subpart A—Hospital Insurance Benefits

1. The authority citation for Subpart A continues to read as follows:

Authority: Secs. 1102, 1814, 1815, 1861, 1866(d), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395g, 1395x, 1395cc(d), and 1395hh).

2. *§ 405.150 [Amended]*

In § 405.150, reference to "§ 405.156" is removed, and reference to "Subpart F of this Part 405" is changed to "Part 489 of this chapter".

3. *§ 405.152 [Amended]*

a. In § 405.152(a), introductory text, reference to "§ 405.151" is changed to "§ 409.69", and the phrase "—see § 405.606)" is changed to "and Part 489 of this chapter)".

b. § 405.152(a)(2), the phrase "meets the requirements of § 405.102;" is removed, and "is entitled to hospital insurance benefits;" is inserted.

c. In § 405.152(a)(4), reference to "Subpart F of this Part 405" is changed to "Part 489 of this chapter".

d. In § 405.152(a)(7), reference to "§ 405.606" is changed to "Part 489 of this chapter."

e. In § 405.152(b), the phrase "(see § 405.116)" is removed.

4. *§ 405.157 [Amended]*

In § 405.157, introductory text, the phrase "(see § 405.102)" is removed.

5. *§ 405.158 [Amended]*

In § 405.158(a)(1), reference to "§§ 405.113 through 405.115" is changed to "§§ 409.80, 409.82, 409.83, and 409.87".

6. *§ 405.160 [Amended]*

In § 405.160(d), reference to "§ 405.116" is changed to "§§ 409.10 through 409.18".

7. Section 405.165 is revised to read as follows:

§ 405.165 Payment for posthospital SNF care.

Medicare Part A pays for posthospital SNF care furnished in a SNF or a participating hospital that has a swing-bed approval if the following requirements are met:

(a) *Request for payment.* A written request for payment is filed by or on behalf of the individual to whom the services were furnished.

(b) *Physician certification.* A physician provides certification and recertification in accordance with § 405.1632.

(c) *Other requirements.* (1) The conditions for coverage set forth in §§ 409.20 and 409.30 through 409.36 of this chapter are met.

(2) Payment is not prohibited under §§ 405.166 and 405.167.

8. Section 405.166 is revised to read as follows:

§ 405.166 Prohibition against payment for posthospital SNF care after a utilization review finding that further care is not medically necessary.

(a) *SNF system of utilization review (UR).* If a finding has been made, under a SNF UR system required by § 405.1137, that further posthospital SNF care is not medically necessary, payment may be made only for care furnished before the fourth day following the day the SNF received notice of the finding.

(b) *PRO system of review.* If a PRO has assumed review responsibility and has found that further SNF care is not medically necessary, or should be furnished more economically or on an outpatient basis or in an inpatient facility of a different type, payment may be made for up to two days after the SNF receives notice of the PRO finding, but only if—

(1) The PRO has determined that additional time is required to arrange for post-discharge care; and

(2) It is determined, under § 405.332, that the SNF did not know, and could not reasonably have been expected to know that Medicare payment would not be made.

9. Section 405.167 is revised to read as follows:

§ 405.167 Prohibition against payment for posthospital SNF care furnished by a facility that fails to make timely utilization review (UR).

(a) *Determination and notice.* If HCFA determines that the facility has failed substantially to make timely UR of long-stay cases, it will notify the SNF and any hospital with which the SNF has a transfer agreement (or the hospital that has a swing-bed approval) and the public, that payment to the facility will be limited, and specify the effective date of the determination.

(b) *Limitation on payment.* Payment may not be made for SNF care furnished after the 20th consecutive day of care furnished to an individual admitted to the facility after the effective date of HCFA's determination.

10. Section 405.170 is revised to read as follows:

§ 405.170 Payment for home health services: Conditions.

Medicare Part A pays for home health services if the following conditions are met:

(a) *Request for payment.* A written request for payment is filed by or on behalf of the individual to whom the services were furnished.

(b) *Physician certification.* A physician provides certification and recertification in accordance with § 405.1633.

(c) *Other conditions.* The requirements of § 409.42 of this chapter are met.

11. *§ 405.195 [Amended]*

In § 405.195(d)(1), reference to "§ 405.106" is changed to "§ 405.196".

12. *§ 405.196 [Amended]*

In § 405.196(a), the phrase "(see § 405.131)" is removed.

B. Subpart B—Supplementary Medical Insurance Benefits; Enrollment, Exclusions, and Payments

1. The authority citation of Subpart B is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

2. *§ 405.250 [Redesignated]*

§ 405.250–1 is redesignated as § 405.1634(b) and revised elsewhere in this document. The table of contents of Subpart B is amended to reflect this change.

C. Subpart C—Exclusions, Recovery of Overpayments, Liability of a Certifying Officer and Suspension of Payment

1. The authority citation of Subpart C is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

2. Section 405.310 is revised to read as follows:

§ 405.310 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; or

(2) Examinations required by insurance companies, business establishments, government agencies, or other third parties.

(b) *Eyeglasses or contact lenses, except for* post-surgical lenses customarily used during convalescence from eye surgery in which the lens of the eye was removed (e.g., cataract surgery); or prosthetic lenses for patients who lack the lens of the eye because of congential absence or surgical removal.

(c) *Eye examinations* for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive error only and procedures performed in the course of any eye

examination to determine the refractive state of the eyes, without regard to the reason for the performance of the refractive procedures. Refractive procedures are excluded even when performed in connection with otherwise covered diagnosis or treatment of illness or injury.

(d) *Hearing aids* or examinations for the purpose of prescribing, fitting, or changing hearing aids.

(e) *Immunizations, except for*—

(1) Vaccinations or inoculations directly related to the treatment of an injury or direct exposure such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenom sera, or immune globulin; and

(2) Pneumococcal vaccinations that are reasonable and necessary for the prevention of illness.

(f) *Orthopedic shoes* or other supportive devices for the feet, *except when* shoes are integral parts of leg braces.

(g) *Custodial care, except as necessary* for the palliation or management of terminal illness, as provided in Part 418 of this chapter. (Custodial care is any care that does not meet the requirements for coverage as posthospital SNF care as set forth in §§ 409.30 through 409.35 of this chapter.)

(h) *Cosmetic surgery* and related services, *except* as required for the prompt repair of accidental injury or to improve the functioning of a malformed body member.

(i) *Dental services* in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth, *except for* inpatient hospital services in connection with such dental procedures when hospitalization is required because of—

(1) The individual's underlying medical condition and clinical status; or

(2) The severity of the dental procedures.[1]

(j) *Personal comfort services, except* as necessary for the palliation or management of terminal illness as provided in Part 418 of this chapter. The use of a television set or a telephone are examples of personal comfort services.

(k) *Any services that are not reasonable and necessary* for one of the following purposes:

(1) For the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(2) In the case of hospice services, for the palliation or management of terminal illness, as provided in Part 418 of this chapter.

(3) In the case of pneumococcal vaccine, for the prevention of illness.

(l) *Foot care.*—(1) *Basic rule.* Except as provided in paragraph (1)(2) of this section, any services furnished in connection with the following:

(i) *Routine foot care,* such as the cutting or removal of corns, or calluses, the trimming of nails, routine hygienic care (preventive maintenance care ordinarily within the realm of self care), and any services performed in the absence of localized illness, injury, or symptoms involving the feet.

(ii) *The evaluation or treatment of subluxations of the feet,* regardless of underlying pathology. (Subluxations are structural misalignments of the joints, other than fractures or complete dislocations, that require treatment only by nonsurgical methods.)

(iii) *The evaluation or treatment of flattened arches* (including the prescription of supportive devices) regardless of the underlying pathology.

(2) *Exception.* Treatment of warts is covered, and the services excluded under paragraph (l)(1), of this section are covered if they are furnished—

(i) As an incident to, at the same time as, and as a necessary integral part of a primary covered procedure performed on the foot; or

(ii) As initial diagnostic services (regardless of the resulting diagnosis), in connection with a specific symptom or complaint that might arise from a condition whose treatment would be covered.

(m) *Services to hospital inpatients.*—(1) *Basic rule.* Except as provided in paragraph (m)(2) of this section, any service furnished to an inpatient of a hospital by an entity other than the hospital, unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital's inpatients.[2]

(2) *Exceptions.* (i) Physicians' services that meet the criteria of § 405.550(b) for payment on a reasonable charge basis, and services of an anesthetist employed by a physician that meet the conditions of § 405.553(b)(4), are not excluded.

(ii) The exclusion may be waived temporarily by HCFA, in accordance with § 489.23 of this chapter.

(Services subject to exclusion under this paragraph include, but are not limited to, clinical laboratory services, pacemakers, artificial limbs, knees, and hips, intraocular lenses, total parenteral nutrition, and services incident to physicians' services.)

(n) [Removed]

D. Subpart F—Notice, Election, and Agreements

1. The authority citation of Subpart F is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

2. *§ 405.658 [Amended]*

In § 405.658, the following references are corrected:

a. In paragraph (b)(1), "§§ 405.607 through 405.610" is changed to "Subpart C of Part 489 of this chapter".

b. In paragraph (b)(2), "§§ 405.618 through 405.621" is changed to "Subpart D of Part 489 of this chapter".

E. Subpart G—Reconsiderations and Appeals Under the Hospital Insurance Program

1. The authority citation of Subpart G is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) unless otherwise noted.

2. *§ 405.701 [Amended]*

In § 405.701(c), the comma following the parenthesis and the phrase "reprinted in the appendix to this subpart" are removed.

3. *§ 405.710 [Amended]*

In § 405.710(b), reference to "§ 405.704(b)" is changed to "§ 405.704(c)" wherever it appears.

4. *Appendix—[Removed]*

The Appendix to Subpart G is removed and the table of contents of the subpart is amended to reflect this change.

F. Subpart K—Conditions of Participation; Skilled Nursing Facilities

1. The authority citation for Subpart K is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) unless otherwise noted.

2. *§ 405.1121 [Amended]*

Section 405.1121 is amended by adding a new paragraph (m) to read as follows:

* * * * *

(m) *Standard: Protection of patients' funds.* The facility establishes and maintains a system that—

(1) Ensures full and complete accounting of its patients' personal funds; and

(2) Precludes commingling of a patient's funds with funds of the facility or of any person other than another patient.

3. The Effective Date Note at the end of § 405.1121 and the small print

[1] Paragraph (i)(2) is effective for services furnished after June 30, 1981.

[2] This exclusion was effective as of October 1, 1983.

paragraphs (k)(6) and (m) following the Note are removed.

G. Subpart P—Certification and Recertification; Claims and Benefit Payment Requirements; Check Replacement Procedures

1. The authority citation for Subpart P is revised to read as follows:

Authority: Secs. 1102, 1814, 1835, 1871, and 1883 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395h, 1395hh, and 1395tt).

2. *§ 405.1625–1 [Amended]*

Section 405.1625–1 is amended by removing the reference to § 405.133.

3. *§ 405.1629 [Amended]*

Section 405.1629 is amended by substituting "must" for "should" wherever it appears.

4. Section 405.1632 is revised to read as follows:

§ 405.1632 Posthospital SNF care: Certification and recertification.

(a) *General provisions.* As a condition for Medicare Part A payment for posthospital SNF care furnished in a SNF or in a hospital with a swing-bed approval, the requirements of this section must be met. As used in this section, the term "facility" means either a SNF, or a hospital that has approval to furnish SNF care.

(b) *Content of certification.* A physician must certify that—

(1) Posthospital SNF care is or was required because the individual needs or needed on a daily basis skilled nursing care (furnished directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in a SNF or a swing-bed hospital on an inpatient basis.

(2) The SNF care is or was needed for a condition for which the individual received inpatient care in a participating hospital or a qualified hospital, as defined in § 409.3 of this chapter.

(c) *Timing of certification.* The certification must be obtained at the time of admission or as soon thereafter as is reasonable and practicable.

(d) *Content of recertification.* The recertification statement must certify continued need for services and contain the following information:

(1) An adequate explanation of the reasons for the continued need for SNF care.

(2) The estimated period of time the individual will need to remain in the facility.

(3) Plans for home care, if appropriate.

(4) If the continued need for SNF care is for a condition that arose after the individual's transfer to the facility and while he or she was still in the facility for treatment of a condition for which he or she had received inpatient hospital services, a statement to that effect.

(e) *Timing of recertification.*—(1) *Initial recertification.* The first recertification is required no later than the 14th day of SNF care. A facility, may, at its option, provide for an earlier date or vary the timing of the first recertification within the 14-day period, by diagnostic or clinical categories.

(2) *Subsequent recertifications.* Subsequent recertifications are required at least every 30 days, and may be made at shorter intervals established by the utilization review committee and the facility.

(3) *Recertification requirement fulfilled by UR.* At the option of the facility, extended stay review under the facility's UR plan may take the place of the second and subsequent physician recertifications.

(4) *Description of procedures.* The facility must have available in its files a written description of its procedures for timing of recertifications—that is, the intervals at which recertifications are required, and whether review of extended stay cases by the UR committee takes the place of the second and subsequent physician recertifications.

(f) *Signature of certifications and recertifications.* Certifications and recertifications must be signed by the physician responsible for the case or, if authorized by the responsible physician, by a physician on the staff of the facility, or the physician who is available in case of an emergency and who has knowledge of the case.

4. Section 405.1634 is amended by revising paragraph (a)(3), adding (a)(4) and (a)(5), revising paragraph (b) to incorporate the content of § 405.250–1, and redesignating and revising paragraph (b)(2) as (c). As amended, § 405.1634 reads as follows:

§ 405.1634 Medical and other health services furnished by a participating provider or ESRD facility: Certification and recertification.

(a) *Basic rules.*

* * * * *

(3) *Documentation.* The certification may be made on a record retained by the provider or facility, or on a special form, or a physician's written order may be accepted as certification.

(4) *Signature.* (i) For outpatient physical therapy and speech pathology services for which the plan is established by a physician, the certification must be signed by the physician who establishes the plan.

(ii) For outpatient physical therapy and speech pathology services for which the plan is established by a physical therapist or speech pathologist, and for all other services not specified in paragraph (a)(4)(i) of this section, the certification must be signed by a physician who has knowledge of the case.

(5) *Timing.* (i) For outpatient physical therapy and speech pathology services, the certification statement must be obtained at the time the plan of treatment is established or as soon thereafter as possible.

(ii) For other services, the certification statement may be obtained at the time the services are furnished or, if they are furnished on a continuing basis, at the beginning or at the end of a series of visits.

(b) *Content of certification: Outpatient physical therapy and speech pathology services.* With respect to outpatient physical therapy and speech pathology services, the physician must certify that—

(1) The individual needs or needed physical therapy or speech pathology services;

(2) The services are furnished under a written plan of treatment that meets the following requirements:

(i) A physician, or the speech pathologist who will furnish the speech pathology services, or the physical therapist who will furnish the physical therapy services, establishes a written plan before treatment is begun, and promptly signs it.[3]

(ii) The plan prescribes the type, amount, frequency, and duration of the services to be furnished and specifies the diagnosis and anticipated goals.

(iii) The plan is reviewed periodically by a physician as often as the patient's condition requires, but at least as often as the physician recertifies the continued need for services. Each review is dated and initialed by the physician who performs it.

(iv) Any changes in the plan are made by the physician directly or through orders given to a staff physician, or a registered nurse, or a qualified physical therapist or speech pathologist (as appropriate), and promptly entered in the patient's record and signed.

(3) The services are furnished while the individual is under the care of a physician. For physical therapy services, a doctor of podiatric medicine is considered a physician, if the

[3] Before January 1981, only a physician could establish a plan of treatment for speech pathology services. Speech pathologists were authorized to establish plans effective July 1, 1981; occupational therapists, effective July 18, 1984.

requirements of § 405.1633(a)(1)(iii) are met.[4]

(c) Content of certification: Home dialysis support services. With respect to home dialysis support services, a physician must certify that the services are furnished in accordance with a written plan of treatment established and periodically reviewed by a team that includes the patient's physician and other professionals familiar with the patient's condition.

III. PART 408—MEDICARE ELIGIBILITY AND ENTITLEMENT

A. The table of contents and the authority citation are amended as set forth below:

1. The Subpart A title is revised to read: "Subpart A—Hospital Insurance Eligibility and Entitlement: General Provisions".

2. The undesignated heading immediately preceding § 408.10 is revised to read: "Subpart B—Hospital Insurance Without Premiums".

3. The undesignated heading immediately preceding § 408.20 is revised to read: "Subpart C—Premium Hospital Insurance".

4. The undesignated heading immediately preceding § 408.30 is revised to read: "Subpart D—Special Circumstances that Affect Entitlement to Hospital Insurance".

5. The authority citation is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

B. The text of Part 408 is amended as set forth below:

1. *Subparts B, C, and D—[Headings added]*

The undesignated headings preceding §§ 408.10, 408.20 and 408.30 are removed, and §§ 408.10 through 408.13 are designated as Subpart B—Hospital Insurance Without Premiums, §§ 408.20 through 408.26 are designated as Subpart C—Premium Hospital Insurance, and §§ 408.30 and 408.31 are designated as Subpart D—Special Circumstances that Affect Entitlement to Hospital Insurance.

2. *§ 408.2 [Amended]*

In the first line, "Subparts A through D of this part" is substituted for "This subpart".

3. *§ 408.5 [Amended]*

In paragraphs (a)(3) and (b), "Subpart B of this part" is substituted for "Sections 408.10 through 408.13" and "§§ 408.10 through 408.13" respectively.

4. *§ 408.6 [Amended]*

In § 408.6(d)(4), the phrase "under § 408.10 that is" is inserted immediately after "application".

5. *§ 408.11 [Amended]*

In § 408.11(b)(3), "3 months" is changed to "third month".

6. *§ 408.20 [Amended]*

In paragraphs (a) and (b)(3), "Subpart B of this part"is substituted for "§§ 408.10 through 408.13".

IV PART 409—MEDICARE BENEFITS, LIMITATIONS, AND EXCLUSIONS

A. The table of contents and authority citation of Part 409 are amended as set forth below:

1. The Subpart A title is revised to read: Subpart A—Hospital Insurance Benefits: General Provisions.

2. The undesignated heading immediately preceding § 409.10 is revised to read: Subpart B—Inpatient Hospital Care.

3. The undesignated heading immediately preceding § 409.20 is revised to read: "Subpart C—Posthospital SNF Care".

4. The undesignated heading immediately preceding § 409.30 is revised to read: "Subpart D—Requirements for Coverage of Posthospital SNF Care".

5. The undesignated heading immediately preceding § 409.40 is revised to read: "Subpart E—Home Health Services Under Hospital Insurance".

6. The undesignated heading immediately preceding § 409.60 is revised to read: "Subpart F—Scope of Hospital Insurance Benefits".

7. The undesignated heading immediately preceding § 409.80 is revised to read: "Subpart G—Hospital Insurance Deductibles and Coinsurance".

8. The authority citation is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

B. The text of Part 409 is amended as set forth below:

1. *§ 409.2 [Amended]*

In the first line, "Subparts A through G of this part" is substituted for "This subpart".

2. *§ 409.3 [Amended]*

In the first line, "part" is substituted for "subpart".

3. *§ 409.10 [Amended]*

In paragraph (a), "set forth in this subpart" is substituted for "paragraph (b) of this section and in §§ 409.11 through 409.19".

4. *§ 409.12 [Amended]*

In § 409.12, the phrase "Except as provided in paragraph (b) of this section," is inserted at the beginning of paragraph (a), paragraphs (b) and (c) are removed, and a new paragraph (b) is added to read as follows:

* * * * *

(b) *Exception.* Medicare does not pay for the services of a private duty nurse or attendant. An individual is not considered to be a private duty nurse or attendant if he or she is a hospital employee at the time the services are furnished.

5. *§ 409.20 [Amended]*

In paragraph (a), "this subpart and Subpart D of this part" is substituted for "paragraph (b) of this section and §§ 409.22 through 409.35".

6. *§ 409.27 [Amended]*

In § 409.27, "they are" is inserted immediately after "if".

7. *§ 409.35 [Amended]*

In § 409.35(a), "$100" is changed to "$500".

8. *§ 409.41 [Amended]*

In paragraph (a), "Subpart B of this part" is substituted for §§ 409.11 through 409.18".

9. *§ 409.42 [Amended]*

a. In paragraph (b)(3), a comma is substituted for the word "or", and "or podiatric medicine" is inserted before the semicolon.

b. In paragraph (b)(3), second sentence, the word "continued" is removed.

10. *§ 409.60 [Amended]*

In paragraph (b), "Subpart G of this part" is substituted for "§§ 409.82 through 409.87".

11. *§ 409.68 [Amended]*

a. In the table of contents, in the heading for § 409.68, "before" is substituted for "prior to".

b. In paragraph (a), "Available benefit days" is substituted for "coverage days".

c. In paragraph (a)(1), "available benefit days" is substituted for "available days of coverage".

d. In paragraph (a)(2), "available benefit days" is substituted for "available days of coverage".

e. In paragraph (b)(1), the first "plus" is removed.

V. PART 442—STANDARDS FOR PAYMENT FOR SKILLED NURSING AND INTERMEDIATE CARE FACILITY SERVICES

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

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

B. The text of Part 442 is amended as set forth below:

[4] For the specified purpose, a doctor of podiatric medicine is considered a physician effective July 16, 1984.

1. Section 442.311(e) is revised to read as follows:

§ 442.311 Written policies and procedures: Residents bill of rights.

* * * * *

(e) *Financial affairs.*

The ICF must comply with the requirements specified in § 405.1121(m) of this chapter with respect to the protection of patients' personal funds.

* * * * *

2. The Effective Date Note and the small print paragraph (e) at the end of § 442.311 are removed.

3. The Effective Date Note that follows § 442.320 is removed.

4. Section 442.404(e) is revised to read as follows:

§ 442.404 Residents bill of rights.

* * * * *

(e) *Financial affairs.*

Each resident's personal funds must be protected in accordance with the requirements of § 405.1121(m) of this chapter.

* * * * *

5. The Effective Date Note and the small print paragraph 442.404(e) at the end of § 442.404 are removed.

6. Section 442.406 is revised to read as follows:

§ 442.406 Resident finances.

(a) Each resident must be allowed to possess and use money in normal ways or be learning to do so.

(b) The ICF/MR must comply with the requirements specified in § 405.1121(m) of this chapter with respect to the protection of patients' funds.

7. The Effective Date Note and the small print § 442.406 at the end of § 442.406 are removed.

VI. PART 456—UTILIZATION CONTROL

A. The authority citation for Part 456 is revised to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

B. *§ 456.360 [Amended]*

In paragraphs (b)(2)(i) and (b)(2)(ii), the word "an" is substituted for "a public".

VII. PART 481—CERTIFICATION OF CERTAIN HEALTH FACILITIES

A. The authority citation for Part 481 is revised to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

B. Part 481 is redesignated as Part 491 with no change in content, and all current references throughout Title 42 to Part 481 are changed to refer to Part 491

VIII. PART 488—CONDITIONS OF PARTICIPATION; SPECIALIZED PROVIDERS

A. The authority citation for Part 488 continues to read as follows:

Authority: Secs. 1102, 1861aa, 1861cc, and 1971 of the Social Security Act: 42 U.S.C. 1302 1395x, and 1395hh.

B. Part 488 is redesignated as Part 485, with no change in content, and all current references throughout Title 42 to Part 488 are corrected to refer to Part 485.

C. In redesignated Part 485, § 485.70(g) is revised to read as follows:

§ 485.70 Personnel qualifications.

* * * * *

(g) A *psychologist* must be certified or licensed by the State in which he or she is practicing, if that State requires certification or licensing, and must hold a masters degree in psychology from and educational institution approved by the State in which the institution is located.

* * * * *

(Catalog of Federal Domestic Assistance, Program No. 13.714, Medical Assistance Program; No 13.773, Medicare—Hospital Insurance; and Program No. 13.774, Medicare—Supplementary Medical Insurance)

Dated: April 25, 1985.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

Approved: June 24, 1985.

Margaret M. Heckler,

Secretary.

[FR Doc. 85-19601 Filed 8-15-85; 8:45 am]

BILLING CODE 4120-01-M

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Bambermycins and Monensin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by American Hoechst Corp., providing for safe and effective use of a complete broiler feed manufactured with separately approved bambermycins and monensin premixes. The feed is used for prevention of coccidiosis and for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: August 16, 1985.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION: American Hoechst Corp., Animal Health Division, Route 202-206 North, Somerville, NJ 08876, filed a supplement to NADA 98-340 providing for use of bambermycins at 1 to 2 grams per ton in combination with monensin 90 to 110 grams per ton in complete broiler feeds. The feeds are used for prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima* and for increased rate of weight gain and improved feed efficiency. The supplemental NADA is approved and the regulations are amended accordingly. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(ii) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

2. In § 558.95 by revising the introductory text of paragraph (e)(1)(vi) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(e) * * *

(1) * * *

(vi) *Amount per ton.* Bambermycins, 1 to 2 grams plus monensin, 90 to 110 grams.

* * * * *

3. In § 558.355 by revising paragraph (f)(1)(vi) to read as follows:

§ 558.355 **Monensin.**

* * * * *

(f) * * *

(1) * * *

(vi) *Amount per ton.* Monensin, 90 to 110 grams plus bambermycins, 1 to 2 grams. See § 558.95(e)(1)(vi).

* * * * *

Dated: August 9, 1985.

Marvin A. Norcross,

Acting Associate Director for Scientific Evaluation.

[FR Doc. 85-19512 Filed 8-15-85; 8:45 am]

BILLING CODE 4160-01-M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2617

Determination of Plan Sufficiency and Termination of Sufficient Plans

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule; correction.

SUMMARY: This document corrects a final rule on determination of plan sufficiency that appeared at page 31167 in the **Federal Register** of Thursday, August 1, 1985 (50 FR 31167). This action is needed to correct typographical and editorial errors in cross references.

FOR FURTHER INFORMATION CONTACT: Mrs. Renae R. Hubbard, Special Counsel, Corporate Policy and Regulations Department, Code 611, Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, D.C. 20006, 202-254-4856 (202-254-8010 for TTY and TDD). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: The following corrections are made in FR Doc. 85-18269 appearing at 31167 in the issue of August 1, 1985:

§ 2617.12 **[Corrected]**

On page 31170, column two, in § 2617.12 (d), "paragraph (b)" is corrected to read "paragraph (a)" and the phrase "or, if applicable, paragraph (c) of this section" is removed.

David M. Walker,

Acting Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 85-19505 Filed 8-15-85; 8:45 am]

BILLING CODE 7708-01-M

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 581

Army Discharge Review Board

AGENCY: Department of the Army, DOD.

ACTION: Final rule.

SUMMARY: On August 26, 1982, the Department of Defense published 32 CFR Part 70 in the **Federal Register**, which provided guidance to the military departments on the procedures and standards for the Discharge Review Boards. The guidelines were intended to ensure that applicants to the DRBs of the Military Services are fully aware of the proper procedures for submitting an application for discharge review and the conduct of the review. The rule being published today is the Army Discharge Review Board's implementing regulations.

EFFECTIVE DATE: August 16, 1985.

FOR FURTHER INFORMATION CONTACT: Mr. John W. Matthews, Deputy Assistant Secretary (DA Review Boards, Personnel Security and Equal Employment Opportunity Compliance and Complaints Review) Room 1E520, Pentagon, Washington, D.C. 20310 Phone: 202-697-9641.

SUPPLEMENTARY INFORMATION:

Background

On August 26, 1982 the Department of the Defense, acting through the Director of the Department of the Army Military Review Boards Agency, published in the **Federal Register** 32 CFR Part 70. This final rule is the Army's implementation of 32 CFR Part 70.

This rule governs the actions and composition of the Army Discharge Review Board (ADRB) under Pub. L. 95-126; Title 10, United States Code (U.S.C.) section 1553; and Department of Defense (DOD) Directive 1332.28. It governs applications and ADRB motions for discharge review, public inspection copying, and distribution of ADRB documents through the Armed Forces Discharge Review/Correction Board Reading Room; preparing decisional documents and index entries; and processing complaints regarding them.

Executive Order 12291

The Department of the Army has determined that this document does not meet the criteria for a "major rule" as specified in section I (8) of E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

Regulatory Flexibility Act

The Department of the Army has determined that Pub. L. 96-354, 5 U.S.C. 601 et seq. does not apply.

Paperwork Reduction Act

The Department of the Army has determined that this document does not contain information collections that require approval by the Office of Management and Budget under 44 U.S.C. 3501 et seq.

List of Subjects in 32 CFR Part 581

Administrative practice and procedure, Archives and records, Disability benefits, Military personnel.

PART 581—[AMENDED]

Accordingly, 32 CFR Part 581 is amended as set forth below:

1. The authority citation for Part 581 is revised to read as set forth below, and any other authority citation appearing under any section in Part 581 is removed.

Authority: 10 U.S.C. 1552, 1553, 1554, 3012; 38 U.S.C. 3103a.

2. Part 581 is amended by revising § 581.2 to read as follows:

§ 581.2 **Army Discharge Review Board.**

(a) *Purpose.*—This regulation implements 10 U.S.C. 1553, Pub. L. 95-126, and DOD Directive 1332.28 (app. A).

(b) *Explanation of terms.*—(1) *Legal consultant of the Army Discharge Review Board (ADRB).* An officer of The Judge Advocate General's Corps assigned to the ADRB to provide opinions and guidance on legal matters relating to ADRB functions.

(2) *Medical consultant of the ADRB.* An officer of the Army Medical Corps assigned to the ADRB to provide opinions and guidance on medical matters relating to ADRB functions.

(3) *Video tape hearing.* A hearing conducted by an ADRB hearing examiner at which an applicant is given the opportuntiy to present his/her appeal to the hearing examiner, with the entire presentation, including cross-examination by the hearing examiner, recorded on video tape. This video tape presentation is later displayed to a full ADRB panel. Video tape hearings will be conducted only with the consent of the applicant and with the concurrence of the President of the ADRB.

(c) *Composition and responsibilities.*—(1) *Authority.* The ADRB is established under Pub. L. 95-126 and 10 U.S.C. 1553 and is responsible for the implementation of the Discharge Review Board (DRB) procedures and standards within DA.